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DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket Number EERE–2012–BT–STD–0027]

RIN 1904–AC81

Energy Conservation Program: Energy Conservation Standards for Dehumidifiers

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

ACTION: Final rule; technical correction.

SUMMARY: The U.S. Department of Energy (DOE) published a final rule in the **Federal Register** on June 13, 2016, adopting more-stringent energy conservation standards for dehumidifiers. This correction addresses an error in the final rule by clarifying in Title 10 of the Code of Federal Regulations (CFR), section 430.32 the energy efficiency metric used to determine compliance with the amended standards. Neither the error nor the correction in this document affect the substance of the energy conservation standards rulemaking or any of the conclusions reached in support of the final rule. In addition, DOE removed 10 CFR 430.32(v)(1) because the requirement is now obsolete.

DATES: This correction is effective August 22, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Bryan Berringer, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–0371. Email: *Bryan.Berringer@ee.doe.gov.*

Ms. Elizabeth Kohl, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–7796. Email: *Elizabeth.Kohl@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On June 13, 2016, DOE published a final rule (the ''June 2016 final rule'') to adopt more-stringent energy conservation standards for dehumidifiers. 81 FR 38337. In the June 2016 final rule, DOE amended 10 CFR 430.32(v) to add paragraph (3) that incorrectly specified the energy efficiency metric for the amended standards. This final rule correction revises 10 CFR 430.32(v)(3) to specify that the metric is ''integrated energy factor'' instead of ''integrated energy efficiency factor'' for dehumidifier energy conservation standards that apply to portable and whole-home dehumidifiers manufactured in, or imported into, the United States on and after June 13, 2019. This energy efficiency metric is consistent with the DOE test procedure final rule to establish a new appendix X1 published on July 31, 2015. 80 FR 45801. DOE also removed 10 CFR 430.32(v)(1) because the requirement is obsolete.

Procedural Issues and Regulatory Review

The regulatory reviews conducted for this rulemaking are those set forth in the June 2016 final rule that originally codified amendments to DOE's energy conservation standards for dehumidifiers. 81 FR 38337. The amendments from that final rule became effective August 12, 2016. *Id.*

Pursuant to the Administrative Procedure Act, 5 U.S.C. 553(b), DOE has determined that notice and prior opportunity for comment on this rule are unnecessary and contrary to the public interest. This final rule correction revises 10 CFR 430.32(v)(3) to specify that the metric is ''integrated energy factor'' instead of ''integrated energy efficiency factor'' for dehumidifier energy conservation standards and removes 10 CFR 430.32(v)(1) because the requirement is obsolete. Neither the errors nor the corrections in this document affect the substance of the rulemaking or any of the conclusions reached in support of the final rule. For these reasons, DOE has also determined that there is good cause to waive the 30-day delay in effective date.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Reporting and recordkeeping requirements, and Small businesses.

Issued in Washington, DC, on August 16, 2016.

Kathleen Hogan,

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

For the reasons set forth in the preamble, part 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations is corrected by making the following correcting amendments:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Section 430.32 is amended by:
■ a. Removing paragraph (v)(1),
■ b. Redesignating paragraph (v)(2) as (v)(1) and paragraph (v)(3) as (v)(2); and
■ c. Revising newly designated paragraph (v)(2) to read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(v) * * *

(2) Dehumidifiers manufactured on or after June 13, 2019, shall have an integrated energy factor that meets or exceeds the following values:

Portable dehumidifier product capacity (pints/day)	Minimum integrated energy factor (liters/kWh)
25.00 or less	1.30
25.01–50.00	1.60
50.01 or more	2.80
Whole-home dehumidifier product case volume (cubic feet)	
8.0 or less	1.77
More than 8.0	2.41

* * * * *

[FR Doc. 2016–19969 Filed 8–19–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2016–4137; Special Conditions No. 25–631–SC]

Special Conditions: Bombardier Aerospace Inc. Model BD–700–2A12 and BD–700–2A13 Airplanes; Automatic Speed Protection for Design Dive Speed

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Bombardier Aerospace Inc. (Bombardier) Model BD–700–2A12 and BD–700–2A13 airplanes. These airplanes will have a novel or unusual feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is associated with a reduced margin between design cruising speed, V_C/M_C, and design diving speed, V_D/M_D, based on the incorporation of a high-speed-protection system that limits nose-down pilot authority at speeds above V_D/M_D. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for these design features. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Bombardier on August 22, 2016. We must receive your comments by October 6, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–4137 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC, 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
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Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mark Freisthler, FAA, Airframe and Cabin Safety Branch, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98057–3356; telephone 425–227–1119; facsimile 425–227–1232.

SUPPLEMENTARY INFORMATION:

Comments Invited

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

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

Background

On May 30, 2012, Bombardier applied for an amendment to type certificate no. T00003NY to include the new Model BD–700–2A12 and BD–700–2A13 airplanes. These airplanes are derivatives of the Model BD–700 series of airplanes currently approved under type certificate no. T00003NY, and are marketed as the Bombardier Global 7000 (Model BD–700–2A12) and Global 8000 (Model BD–700–2A13). These airplanes are ultra-long-range, executive-interior business jets.

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.101, Bombardier must show that the Model BD–700–2A12 and BD–700–2A13 airplanes meet the applicable provisions of the regulations listed in type certificate no. T00003NY, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

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

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

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

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

Novel or Unusual Design Features

The Bombardier Model BD–700–2A12 and BD–700–2A13 airplanes will have a novel or unusual design feature associated with a high-speed-protection system that limits nose-down pilot authority at speeds above V_D/M_D.

Discussion

Bombardier's high-speed-protection system limits nose-down pilot authority at speeds above V_C/M_C, and prevents the airplane from actually performing the maneuver required under § 25.335(b)(1).

Section 25.335(b)(1) is an analytical envelope condition that was originally adopted in Part 4b of the Civil Air Regulations to provide an acceptable speed margin between design cruise

speed and design dive speed. Flutter-clearance design speeds and airframe design loads are impacted by the design dive speed. While the initial condition for the upset specified in the rule is 1g level flight, protection is afforded for other inadvertent overspeed conditions as well. Section 25.335(b)(1) is intended as a conservative enveloping condition for potential overspeed conditions, including non-symmetric ones. To establish that potential overspeed conditions are enveloped, Bombardier must demonstrate that any reduced speed margin, based on the high-speed-protection system, will not be exceeded in inadvertent or gust-induced upsets resulting in initiation of the dive from non-symmetric attitudes; or that the airplane is protected, by the flight-control laws, from getting into non-symmetric upset conditions. Bombardier must conduct a demonstration that includes a comprehensive set of conditions, as described in these special conditions.

These special conditions are necessary to address Bombardier's proposed high-speed-protection system. These special conditions identify various symmetric and non-symmetric maneuvers that will ensure that an appropriate design dive speed is established. Symmetric (pitching) maneuvers are specified in § 25.331, ''Symmetric maneuvering conditions.'' Non-symmetric maneuvers are specified in § 25.349, ''Rolling conditions,'' and in § 25.351, ''Yaw maneuver conditions.''

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

Applicability

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

Conclusion

This action affects only certain novel or unusual design features on two model series of airplanes. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, the FAA has determined that prior public notice and comment are unnecessary, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

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

1. In lieu of compliance with § 25.335(b)(1), if the flight-control system includes functions that act automatically to initiate recovery before the end of the 20-second period specified in § 25.335(b)(1), V_D/M_D must be determined from the greater of the speeds resulting from special conditions 1(a) and 1(b), below. The speed increase occurring in these maneuvers may be calculated if reliable or conservative aerodynamic data are used.

a. From an initial condition of stabilized flight at V_C/M_C, the airplane is upset so as to take up a new flight path 7.5 degrees below the initial path. Control application, up to full authority, is made to try to maintain this new flight path. Twenty seconds after initiating the upset, manual recovery is made at a load factor of 1.5g (0.5 acceleration increment), or such greater load factor that is automatically applied by the system with the pilot's pitch control neutral. Power, as specified in § 25.175(b)(1)(iv), is assumed until recovery is initiated, at which time power reduction and the use of pilot-controlled drag devices may be used.

b. From a speed below V_C/M_C, with power to maintain stabilized level flight at this speed, the airplane is upset so as to accelerate through V_C/M_C at a flight path 15 degrees below the initial path (or at the steepest nose-down attitude that the system will permit with full control authority if less than 15 degrees). The pilot's controls may be in the neutral position after reaching V_C/M_C and before recovery is initiated. Recovery may be initiated three seconds after operation of the high-speed warning system by application of a load of 1.5g (0.5g acceleration increment), or such greater load factor that is automatically applied by the system with the pilot's pitch control neutral. Power may be reduced simultaneously. All other means of decelerating the airplane, the use of which is authorized up to the highest speed reached in the maneuver, may be used. The interval between successive pilot actions must not be less than one second.

2. It must also be demonstrated that the speed margin, established as above, will not be exceeded in inadvertent or gust-induced upsets resulting in initiation of the dive from non-symmetric attitudes, unless the airplane is protected, by the flight-control laws, from getting into non-symmetric upset conditions. The upset maneuvers described in Advisory Circular 25–7C, ''Flight Test Guide for Certification of Transport Category Airplanes,'' section 8, paragraph 32, sub-paragraphs c(3)(a) and (b), may be used to comply with this requirement.

3. The probability of any failure of the high-speed-protection system that would result in an airspeed exceeding those determined by special conditions 1 and 2, above, must be less than 10^{-5} per flight hour.

4. Failures of the system must be annunciated to the pilots. Airplane flight-manual instructions must be provided that reduce the maximum operating speeds, V_{MO}/M_{MO}. With the system failed, the operating speed must be reduced to a value that maintains a speed margin between V_{MO}/M_{MO} and V_D/M_D, and that is consistent with showing compliance with § 25.335(b) without the benefit of the high-speed-protection system.

5. Dispatch of the airplane with the high-speed-protection system inoperative could be allowed under an approved minimum equipment list that would require airplane flight-manual instructions to indicate reduced maximum operating speeds, as described in special condition 4, above. In addition, the flight-deck display of the reduced operating speeds, as well as the overspeed warning for exceeding those speeds, must be equivalent to that of the normal airplane with the high-speed-protection system operative. Also, it must be shown that no additional hazards are introduced with the high-speed-protection system inoperative.

Issued in Renton, Washington, on August 11, 2016.

Paul Bernado,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–19993 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2015–6359; Special Conditions No. 25–633–SC]

Special Conditions: Bombardier Inc. Model BD–700–2A12 and BD–700–2A13 Airplanes; Airplane Electronic-System Security Protection From Authorized Internal Access

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Bombardier Inc. (Bombardier) Model BD–700–2A12 and BD–700–2A13 airplanes. These airplanes will have novel or unusual design features, specifically, digital systems architecture composed of several connected data networks that will have the capability to allow connectivity of the passenger-service computer systems to the airplane critical systems and data networks. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Bombardier on August 22, 2016. We must receive your comments by October 6, 2016.

ADDRESSES: Send comments identified by docket number FAA–2015–6359 using any of the following methods:

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

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

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket, or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Varun Khanna, FAA, Airplane and Flight Crew Interface, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–1298; facsimile 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

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

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

Background

On May 30, 2012, Bombardier applied for an amendment to type certificate no. T00003NY to include the new Model BD–700–2A12 and BD–700–2A13 airplanes. These airplanes are derivatives of the Model BD–700 series of airplanes currently approved under type certificate no. T00003NY, and are marketed as the Bombardier Global 7000 (Model BD–700–2A12) and Global 8000 (Model BD–700–2A13). These airplanes are ultra-long-range, executive-interior business jets.

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.101, Bombardier must show that the Model BD–700–2A12 and BD–700–2A13 airplanes meet the applicable provisions of the regulations listed in type certificate no. T00003NY, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

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

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

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

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

Novel or Unusual Design Features

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

Digital systems architecture composed of several connected data networks. This network architecture and configuration may be used for, or interfaced with, a diverse set of functions, including:

- Flight-safety-related control, communication, and navigation systems (airplane-control domain);

• Operation and administrative support (operator-information-services domain); and

• Passenger information and entertainment systems (passenger-entertainment domain).

In addition, this digital systems architecture will have the capability to allow access to or by external network sources.

Discussion

The Model BD–700–2A12 and BD–700–2A13 airplane digital systems network architecture is different from existing production (and retrofitted) airplanes as it allows new kinds of user access to previously isolated data networks connected to systems that perform functions required for the safe operation of the airplane. This proposed data-network design and integration may result in security vulnerabilities from intentional or unintentional corruption of data and systems critical to the safety and maintenance of the airplane.

The existing regulations and guidance material did not anticipate these types of system architectures or access to airplane systems. Furthermore, 14 CFR regulations, and current system safety-assessment policy and techniques, do not address potential security vulnerabilities that could be caused by unauthorized access to airplane data busses and servers. Therefore, these special conditions are issued to ensure that the security, integrity, and availability of airplane systems are not compromised by certain wired or wireless electronic connections between airplane data busses and networks.

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

Applicability

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

Conclusion

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

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, the FAA has determined that prior public notice and comment are unnecessary, and good cause exists for adopting these special conditions upon publication in the **Federal Register**.

The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

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

1. The applicant must ensure that the design provides isolation from, or airplane electronic system security protection against, access by unauthorized sources internal to the airplane. The design must prevent inadvertent and malicious changes to, and all adverse impacts upon, airplane equipment, systems, networks, or other assets required for safe flight and operations.

2. The applicant must establish appropriate procedures to allow the operator to ensure that continued airworthiness of the airplane is maintained, including all post type certification modifications that may have an impact on the approved electronic system security safeguards.

Issued in Renton, Washington, on August 11, 2016.

Paul Bernado,

Acting Manager, Transport Airplane Directorate Aircraft Certification Service.

[FR Doc. 2016–19994 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2016–8029; Special Conditions No. 25–634–SC]

Special Conditions: Garmin International, Beechcraft Corporation Model 400A Airplanes; Airplane Electronic-System Security Protection From Unauthorized External Access

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Beechcraft Corporation (Beechcraft) Model 400A airplane. This airplane, as modified by Garmin International (Garmin), will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. These airplanes will have a digital-systems network architecture composed of several connected networks that may allow access to or by external computer systems and networks, and may otherwise result in airplane electronic-system security vulnerabilities without appropriate protection. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Garmin on August 22, 2016. We must receive your comments by October 6, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–8029 using any of the following methods:

• *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.

• *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

• *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• *Fax:* Fax comments to Docket Operations at 202–493–2251.

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

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Varun Khanna, FAA, Airplane and Flight Crew Interface, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–1298; facsimile 425–227–1149.

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

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

Comments Invited

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

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

Background

On February 13, 2014, Garmin applied for a supplemental type certificate to allow installation of digital-systems network architecture, composed of several connected networks that may allow access to or by external computer systems and networks, in Beechcraft Model 400A airplanes. The Model 400A airplane is a small, twin-engine, transport-category airplane with a maximum takeoff weight of 16,300 lbs and capable of carrying 7 to 9 passengers, plus 2 crew members.

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.101, Garmin must show that the Beechcraft Model 400A airplane, as changed, continues to meet the applicable provisions of the regulations listed in Type Certificate No. A16SW, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Beechcraft Model 400A airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

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

In addition to the applicable airworthiness regulations and special conditions, the Beechcraft Model 400A airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

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

Novel or Unusual Design Features

The Beechcraft Model 400A airplanes will incorporate the following novel or unusual design features:

The Garmin G5000, installed in the Beechcraft Model 400A airplane, may add wired and wireless access points to the networks of the Aircraft Control Domain and Airline Information Services Domain. This creates a potential for unauthorized persons to access the Aircraft Control Domain and Airline Information Services Domain, and presents security vulnerabilities related to the introduction of computer viruses and worms, user error, and intentional sabotage of airplane electronic assets (networks, systems, and databases) if not appropriately protected.

Discussion

The Garmin G5000 allows connection to airplane electronic systems and networks, and access from airplane external sources (*e.g.,* operator networks, wireless devices, Internet connectivity, service-provider satellite communications, electronic flight bags, etc.) to the previously isolated airplane electronic assets. Airplane electronic assets include electronic equipment and systems, instruments, networks, servers, software and electronic components, field-loadable software and hardware applications, and databases. This proposed design may otherwise result in network security vulnerabilities from intentional or unintentional corruption of data and systems required for the safety, operation, and maintenance of the airplane if not appropriately protected. The existing regulations and guidance material did not anticipate this type of system architecture, or external wired and wireless electronic access to airplane electronic systems. Furthermore, regulations, and current system safety-assessment policy and techniques, do not address potential security vulnerabilities that could be caused by unauthorized access to airplane electronic systems and networks.

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

Applicability

As discussed above, these special conditions are applicable to the Beechcraft Model 400A airplane. Should Garmin apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A16SW to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model of airplane. It is not a rule of general applicability and affects only the

applicant who applied to the FAA for approval of these features on the airplane.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Beechcraft Model 400A airplanes modified by Garmin.

1. The applicant must ensure that the airplane electronic systems are protected from access by unauthorized sources external to the airplane, including those possibly caused by maintenance activity.

2. The applicant must ensure that electronic system-security threats are identified and assessed, and that effective electronic system-security protection strategies are implemented to protect the airplane from all adverse impacts on safety, functionality, and continued airworthiness.

3. The applicant must establish appropriate procedures to allow the operator to ensure that continued airworthiness of the airplane is maintained, including all post-type-certification modifications that may have an impact on the approved electronic system-security safeguards.

Issued in Renton, Washington, on August 11, 2016.

Paul Bernado,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–20000 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 165

[USCBP–2016–0053; CBP Dec. 16–11]

RIN 1515–AE10

Investigation of Claims of Evasion of Antidumping and Countervailing Duties

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

ACTION: Interim regulations; solicitation of comments.

SUMMARY: In accordance with section 421 of the Trade Facilitation and Trade Enforcement Act of 2015, this rule amends the U.S. Customs and Border Protection regulations to set forth procedures for CBP to investigate claims of evasion of antidumping and countervailing duty orders.

DATES: The interim rule is effective August 22, 2016; comments must be received by October 21, 2016.

ADDRESSES: You may submit comments, identified by docket number, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments via docket number USCBP–2016–0053.
- *Mail:* Trade and Commercial Regulations Branch, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Submitted comments may also be inspected during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Trade and Commercial Regulations Branch, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 325–0118.

FOR FURTHER INFORMATION CONTACT: Kevin M. McCann, Chief, Analytical Communications Branch, Office of Trade, U.S. Customs and Border Protection, 202–863–6078.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of the interim rule. U.S. Customs and Border Protection (CBP) also invites comments that relate to the economic, environmental, or federalism effects that might result from this interim rule. Comments that will provide the most assistance to CBP in developing these regulations will reference a specific portion of the interim rule, explain the reason for any recommended change, and include data, information, or authority that support such recommended change. *See* **ADDRESSES** above for information on how to submit comments.

Background

On February 24, 2016, President Obama signed into law the Trade Facilitation and Trade Enforcement Act of 2015 (TFTEA), which contains Title IV-Prevention of Evasion of Antidumping and Countervailing Duty Orders (short title ''Enforce and Protect Act of 2015'' or ''EAPA'') (Pub. L. 114–125, 130 Stat. 122, 155, Feb. 24, 2016) (19 U.S.C. 4301 note). The EAPA establishes a formal process for CBP to investigate allegations of the evasion of AD/CVD orders. Section 421 of the EAPA requires that regulations be prescribed as necessary and within 180 days of TFTEA's enactment to implement the provisions of the EAPA that establish procedures for investigating claims of evasion of AD/CVD orders.

Antidumping and Countervailing Duty Orders

The antidumping (AD) law provides for increased duties on imported

products that the United States International Trade Commission (ITC) has found to have materially injured or threatened with material injury a domestic industry and that the United States Department of Commerce (Commerce) has found to have been sold in the U.S. market at prices below fair market value. The countervailing duty (CVD) law provides for increased duties on imported products that the ITC has found to have materially injured or threatened with material injury a domestic industry and that Commerce has found to have benefitted from a countervailable subsidy from a foreign government or public entity. Statutory authority for AD and CVD investigations derives from Title VII of the Tariff Act of 1930, as amended, 19 U.S.C. 1671 and 1673.

If both Commerce and the ITC issue affirmative final determinations, Commerce issues an AD and/or CVD order that establishes cash deposit rates for the additional duties on entries of imported merchandise subject to the order. Those entries will be liquidated at the cash deposit rate, unless interested parties request an administrative review to establish a revised and final dumping or countervailing duty rate. U.S. Customs and Border Protection is responsible for the collection of cash deposits and final duties on imports of subject merchandise.

Evasion of Antidumping and Countervailing Duty Orders

Evasion refers to entering merchandise into the customs territory of the United States for consumption by an act or omission that is material and false, and which results in antidumping or countervailing duties being reduced or not applied to or collected on such merchandise.

Examples of evasion could include, but are not limited to, the misrepresentation of the merchandise's true country of origin (*e.g.,* through fraudulent country of origin markings on the product itself or false sales), false or incorrect shipping and entry documentation, or misreporting of the merchandise's physical characteristics. CBP is responsible for ensuring that the appropriate duties are collected on imports of merchandise. U.S. Immigration and Customs Enforcement (ICE) is responsible for conducting criminal investigations of the evasion of AD/CVD orders.

Under current customs laws, CBP can take enforcement actions against the evasion of AD/CVD orders, which include the assessment of civil penalties against importers who evade such orders. However, allegations as to evasion submitted by private parties prior to the implementation of the EAPA, did not afford the parties an opportunity to participate in the investigation nor did CBP have an obligation to notify parties that submitted allegations of evasion as to the outcome of CBP's review.

Enforce and Protect Act of 2015

Section 421 of the EAPA amends the Tariff Act of 1930 by creating a new framework for CBP to investigate allegations of evasion of AD/CVD orders, under newly created section 517 (''Procedures for Investigating Claims of Evasion of Antidumping and Countervailing Duty Orders'').

Section 421 of the EAPA requires the Commissioner of U.S. Customs and Border Protection (the Commissioner) to initiate an investigation within 15 business days of receipt of a properly filed allegation from an interested party or referral from another Federal agency (hereinafter referred to as a ''request for an investigation'' from or by another Federal agency) that reasonably suggests that merchandise covered by an AD/CVD order has entered the customs territory of the United States through evasion.

Under the EAPA, when CBP receives properly filed allegations from interested parties that merchandise covered by an AD/CVD order has entered the United States through evasion, or receives requests from Federal agencies for an investigation, the statute requires CBP to take certain actions within specified timeframes. The EAPA requires CBP to determine, not later than 300 calendar days (or 360 calendar days in extraordinarily complicated cases) after the date of initiation of an EAPA investigation, whether there is substantial evidence that merchandise covered by an AD/CVD order was entered into the customs territory of the United States through evasion.

The EAPA authorizes CBP to collect such information as is necessary to make the determination through such methods as CBP considers appropriate. One such method specifically mentioned by the EAPA is the use of questionnaires, which can be used to request information from the interested party making the allegation and the government of the foreign country from which the allegedly covered merchandise was exported, as well as the importer, foreign producer or exporter of the allegedly covered merchandise. The EAPA provides that pursuant to sections 412(b) and 421(a), CBP may make an adverse inference if the importer, foreign producer or exporter of the merchandise under investigation, or the interested party making the allegation, did not act to the best of its ability to provide the information requested by CBP. The EAPA further requires CBP, no later than five business days after making a determination, to communicate the determination to the interested party who made an allegation that initiated the evasion investigation.

If CBP makes an affirmative determination of evasion, CBP will: (1) Suspend the liquidation of unliquidated entries of the covered merchandise that is subject to the determination; (2) extend the period for liquidating the unliquidated entries of covered merchandise that entered before the initiation of the investigation; (3) when necessary, notify Commerce of the determination and request that Commerce determine the appropriate duty rates for such covered merchandise; (4) require importers of covered merchandise to post cash deposits and assess duties on the covered merchandise; and/or (5) take such additional enforcement measures as CBP deems appropriate, including (but not limited to) modifying CBP's procedures for identifying future evasion, reliquidating entries as provided by law, and referring the matter to ICE for a possible civil or criminal investigation.

In order to ensure that appropriate duties can be collected on entries of covered merchandise made during the pendency of an EAPA investigation, the EAPA provides for an interim measures mechanism. Under this mechanism, CBP will determine within 90 calendar days of initiation of an EAPA investigation whether there exists reasonable suspicion that covered merchandise subject to an allegation was entered through evasion. If CBP determines that such reasonable suspicion exists, CBP will: (1) Suspend the liquidation of unliquidated entries of the covered merchandise entered after the date of initiation; (2) extend the period for liquidating the unliquidated entries of covered merchandise that entered before the initiation of the investigation; and (3) take any additional measures necessary to protect the ability to collect appropriate duties, which may include requiring a single transaction bond or posting cash deposits or reliquidating entries as provided by law with respect to entries of the covered merchandise. As provided for in section 517(b)(6) of the Tariff Act of 1930, as amended by the EAPA (19 U.S.C. 1517(b)(6)), if CBP determines during the course of an

EAPA investigation that the merchandise being investigated poses a health or safety risk, CBP will notify the appropriate Federal agencies of that risk and will exercise its administrative powers, as appropriate.

The EAPA provides a period of 30 business days after a determination for the interested party who made the allegation of evasion or the person determined to have entered the covered merchandise subject to the evasion determination to request a de novo administrative review. And not later than 60 business days after such a request for a review of an initial determination is properly filed, CBP must complete the review and issue a final administrative determination.

Section 517(g) of the Tariff Act of 1930, as amended by the EAPA (19 U.S.C. 1517(g)), provides that judicial review of the final administrative determination and the original determination as to evasion will be available to the party alleging evasion or the party found to have entered merchandise subject to the investigation through evasion. A request for such judicial review must be made not later than 30 business days after completion of the final administrative determination. The request for judicial review must be made to the U.S. Court of International Trade (CIT).

In accordance with section 421 of TFTEA requiring that regulations be prescribed as necessary to implement these procedures, CBP is amending title 19 of the Code of Federal Regulations to create new part 165 setting forth procedures for investigating claims of evasion of AD and CVD orders. In these regulations, CBP has endeavored to make the proceedings under the EAPA as transparent as possible and to provide for full participation and engagement by all parties involved in an EAPA proceeding.

New part 165 is drafted with a scope section followed by four subparts: General Provisions; Initiation of Investigations; Investigation Procedures; and Administrative Review of Determinations.

Discussion of New Part 165

Scope

Section 165.0 briefly describes the nature of EAPA investigations and the types of requirements that are set forth in this part. Investigations under the EAPA will be conducted by CBP's Trade Remedy Law Enforcement Directorate (TRLED) which has been established consistent with section 411 of the EAPA. It should be noted that investigations under the EAPA are not the exclusive means, or only statutory authority, by which CBP can investigate allegations by the public or requests by other Federal agencies with respect to the evasion of AD/CVD orders. For example, the public currently has the option to make more general allegations of evasion through CBP's ''e-Allegations'' system, an official online portal for the public to report violations of the trade laws. This current functionality will remain in e-Allegations, but e-Allegations will also have another option for filing allegations of evasion under the EAPA.

Subpart A—General Provisions

Section 165.1 lists definitional terms that are used throughout the new part. It is noted that the definition of ''interested party'' includes not only the importer of the covered merchandise who is alleged to have engaged in evasion, but also importers of the covered merchandise who wish to bring allegations against competing importers. The term ''interested party'' does not include other Federal agencies. CBP also notes that the term ''domestic like product'' is referenced in the definition of ''interested party.'' CBP will rely on the definition of this term, as it is applied by the U.S. International Trade Commission, pursuant to 19 U.S.C. 1677(10).

Section 165.2 specifies that entries that may be the subject of an allegation under § 165.11 or of a request from a Federal agency made under § 165.14 are those entries of allegedly covered merchandise made within one year prior to the receipt of such an allegation or such a request from a Federal agency. CBP is specifying the one-year period for an EAPA investigation in order that the information required for conducting the investigation and rendering a timely determination will be current and readily available. This does not limit CBP's authority, however, to act under any other provision of law with respect to information obtained during an EAPA investigation. For example, CBP has the right to assess penalties pursuant to 19 U.S.C. 1592 in appropriate cases involving the evasion of AD and CVD orders.

Section 165.3 identifies the persons that may make submissions on behalf of interested parties and specifies when power of attorney documentation is required. Agents may act on behalf of an interested party in an EAPA proceeding, including an importer against whom an allegation has been brought. Also, an affiliate of an importer may file documents on the importer's behalf for the EAPA proceedings, but nonetheless must be authorized to act as an agent by means of a power of attorney. A power of attorney is required when an agent who is not an attorney at law is used to make filings under the EAPA.

Section 165.4 addresses how an interested party that makes a submission to CBP in an EAPA proceeding can protect confidential business information. Examples of the kinds of information that may be considered business confidential include: Trade secrets concerning the nature of a product or production process; production costs and other pricing information; and lists of customers, distributors, and suppliers. This section also specifies what information must be provided to CBP as public information in order to facilitate the consolidation of allegations and administration of the proceedings. This section was included in order to protect business confidential information while at the same time ensuring transparency so that an alleged evader will be notified of the allegation and parties to the investigation can participate in the proceeding. Finally, as there is no administrative protective order (APO) process provided for in the EAPA, parties involved in an EAPA proceeding are advised not to submit information to CBP that they obtained exclusively under a protective order from another agency, court, or proceeding unless the scope of that protective order explicitly covers the EAPA investigation or proceeding under consideration. Accordingly, parties are advised to exercise caution when submitting information to CBP in an EAPA proceeding.

Section 165.5 sets forth the scope of and general means by which CBP will obtain information for EAPA proceedings (which must be submitted electronically). CBP requires that only English language or English language translations of written submissions will be accepted. Oral discussions or communications with CBP will not be considered part of the record unless memorialized in written submissions. During CBP's investigation, it is possible that there will be other parties from whom CBP will solicit information and that CBP will put that information on the record. Those parties (who are not parties to the investigation as defined in § 165.1), however, do not have a right to participate in the proceedings. Additionally, CBP may, for good cause, grant requests for extensions of regulatory (but not statutory) deadlines imposed under this part.

Section 165.6 provides that CBP may draw adverse inferences both in an EAPA investigation and in an administrative review of an evasion

determination when the party making the allegation, the alleged evader, a foreign producer or exporter fails to cooperate and comply to the best of its ability with a request for information made by CBP. It also establishes that adverse inferences may be based on the allegation of evasion; other CBP investigations, proceedings or other actions regarding evasion; or any other available information. CBP will not apply an adverse inference against a foreign government if the foreign government does not respond to a request for information.

Section 165.7 obligates interested parties to report to CBP any knowledge or reason to suspect that the covered merchandise may pose a health or safety risk to U.S. consumers. It also requires CBP to report to the appropriate Federal agencies any health or safety risk that the covered merchandise may pose to U.S. consumers.

Subpart B—Initiation of Investigations

Section 165.11 provides the criteria for filing an allegation of evasion pursuant to the EAPA and the specific information that must be contained in an allegation. Each allegation may only concern one importer (because business confidential information may be involved in an EAPA proceeding), although an interested party may file multiple allegations.

Section 165.11 authorizes CBP to provide technical assistance and guidance to small businesses (and to other parties as resources permit) that consider filing an EAPA allegation. It also specifies that technical assistance is available prior to the submission of an allegation to CBP in order to ensure that the filing requirements are satisfied. Any technical assistance and guidance that are provided, however, will not become part of the record, and the fact that assistance or guidance was provided does not guarantee that CBP will proceed to initiate an EAPA investigation. Moreover, such technical assistance and guidance provided by CBP does not include providing research assistance to support an allegation of evasion or to identify potential parties that might be involved in the evasion of AD or CVD orders.

Section 165.12 provides that the date of receipt of a properly filed allegation is the date that CBP determines that the EAPA allegation contains all the information and certifications required in § 165.11 of this part and transmits notice thereof together with a CBP-assigned control number to the party that filed the allegation. CBP will promptly review each allegation as filed for sufficiency. If an allegation is found to be insufficient, the party who filed the allegation will be notified of the insufficiencies and be given the opportunity to remedy them. The CBP-assigned control number should be used to monitor the status of an allegation throughout the pendency of the EAPA proceeding. CBP has 15 business days from the date of receipt to determine whether to initiate an investigation under the EAPA. A party filing an allegation may withdraw the allegation by submitting a request to withdraw the allegation to the designated email address specified by CBP. Decisions regarding whether to initiate an investigation under the EAPA will be effectuated by CBP's TRLED. Such decisions are not subject to administrative or judicial review. In the event that an allegation is withdrawn, CBP may continue to investigate (other than under the EAPA) whether evasion has occurred as originally alleged using but not limited to any information obtained (including from the party who filed the allegation) prior to the date of the request to withdraw the allegation.

Section 165.13 allows for the consolidation of multiple allegations against one or more importers and sets forth criteria for that purpose. It also indicates that the time period to make a decision on whether to investigate is triggered by the first properly filed allegation received by CBP.

As discussed above, requests for an investigation relating to potential evasion of AD/CVD orders may be filed by other Federal agencies with CBP. Section 165.14 sets forth the procedures for such requests for an investigation. Federal agencies are not considered a ''party to the investigation'' as defined in § 165.1. It should be noted, however, that other Federal agencies may continue to use methods other than under the EAPA, as permitted under the law, to inform CBP of possible instances of evasion.

Section 165.15 specifies that CBP will decide if an investigation is warranted based on whether the allegation made under § 165.11 or a request from a Federal agency made under § 165.14 reasonably suggests that evasion has occurred (*i.e.,* the covered merchandise at issue has been entered into the customs territory of the United States through evasion). The deadline to decide whether to initiate an investigation is 15 business days from the date of receipt by CBP of a properly filed allegation or request. If CBP determines that it will initiate an investigation, it will notify all known parties to the investigation no later than 95 calendar days after the initiation of the investigation. CBP will use this 95 calendar-day period in order to investigate the allegation. This timeframe for notification takes into account the dual considerations of transparency and the need to provide adequate time for CBP's investigatory process. Alternatively, if CBP determines that it will not initiate an investigation, it will notify the interested party who filed the allegation within five business days of that determination.

Section 165.16 specifies that CBP may, at its discretion, refer the issue to the Department of Commerce if there is uncertainty as to whether the goods that are the subject of the allegation are within the scope of the applicable AD/CVD order(s). It also directs that the parties to the investigation must be advised of the date of this referral and the time taken by Commerce to decide this issue does not count against any of the deadlines for the EAPA investigation (*i.e.,* the referral to Commerce tolls these deadlines).

Subpart C—Investigation Procedures

As described in § 165.21, CBP will maintain an electronic administrative record for purposes of making a determination as to evasion and conducting an administrative review of the determination as described in subpart D of this part.

Section 165.22 provides that the determination as to whether evasion occurred will be made within 300 calendar days from the date of initiation of the investigation unless, for an extraordinarily complicated case, CBP, at its discretion, extends the deadline by an additional 60 calendar days. This section also sets forth the statutory criteria for extraordinarily complicated cases. Notice of such an extension will be provided to all parties to the investigation. CBP will strive to ensure compliance with these time periods during the course of an investigation. If CBP does not make a determination by the deadline, however, this will not result in a deemed decision with respect to whether or not evasion occurred.

Section 165.23 sets forth the types of and requirements for the submission of factual information. This information will become part of the administrative record. CBP may obtain factual information in a variety of ways. Parties to the investigation may voluntarily submit information to CBP or may provide information in response to requests by CBP (including in response to questionnaires). Interested parties who are not parties to the investigation may provide information only in response to requests by CBP.

Section 165.24 provides that no later than 90 calendar days after the initiation of an investigation, CBP will suspend the liquidation of entries made on or after the date of initiation of the investigation and extend the liquidation for entries made prior to the date of initiation of the investigation if there is reasonable suspicion that evasion has taken place. CBP will give notice to the parties to the investigation of any interim measures it takes within five business days after it takes such measures.

Section 165.25 specifies that, at its discretion, CBP has the authority to conduct verifications of information collected under § 165.23 of this part, in the United States or in foreign countries as is necessary to make its determination. Verifications in foreign countries will be conducted as appropriate and consistent with any agreements or memoranda relating to such activities with the foreign government in whose country the proposed verification is scheduled to occur.

Section 165.26 deals with the ability of parties to the investigation to submit written arguments to CBP in order that they may actively participate in an EAPA proceeding. It provides that the parties to the investigation may submit written arguments to CBP and must serve all other parties to the investigation by an email message or through any other method approved or designated by CBP with a public version of the written arguments. Parties to the investigation receiving a written argument may file a response within 15 calendar days of the filing of the written argument. The party filing a written response must provide it to CBP and serve a public version on all other parties to the investigation via an email message or through any other method approved or designated by CBP.

Section 165.27 provides that upon conclusion of the investigation, CBP will determine whether there is substantial evidence based upon the record that evasion of an AD/CVD order has occurred. Within five business days of CBP's initial determination as to evasion, CBP will issue notice of its determination to the interested party or parties who made the allegation and to the importer alleged to have evaded an AD/CVD order. This section also addresses action by CBP in the event of a negative determination.

Section 165.28 discusses what actions CBP may take if there is an affirmative determination as to evasion.

Subpart D—Administrative Review of Determinations

Subpart D specifies the requirements for requesting an administrative review of an initial determination. Under § 165.41, any party to the investigation has up to 30 business days after the date the initial determination is issued to request an administrative review of that determination by Regulations and Rulings, Office of Trade. Parties seeking review of the initial determination must serve all other parties to the investigation with a public version of the request via an email message or through any other method approved or designated by CBP.

Under § 165.42, parties to the investigation are given an opportunity to submit responses to the request for administrative review.

Section 165.43 provides that any requests for review and responses to requests for review will remain part of the administrative record and cannot be withdrawn.

Section 165.44 provides that Regulations and Rulings may request additional written information from the parties to the investigation at any time during the administrative review process.

Section 165.45 describes that under an administrative review the initial determination will be reviewed de novo. The final administrative determination will be issued within 60 business days from the date of request for review. The review will be based upon the administrative record developed during the initial investigation period and any requests for administrative review and responses to those requests.

Section 165.46 states that Regulations and Rulings will issue a final administrative determination to all parties to the investigation. The final administrative determination is subject to judicial review in accordance with section 421 of the EAPA.

Finally, § 165.47 notifies the public that nothing within this part precludes CBP from taking any action authorized under the law, such as assessing penalties under 19 U.S.C. 1592.

Inapplicability of Notice and Delayed Effective Date Requirements

Under the Administrative Procedure Act (APA) (5 U.S.C. 553), agencies generally are required to publish a notice of proposed rulemaking in the **Federal Register** that solicits public comments on the proposed regulatory amendments and consider public comments in deciding on the content of the final amendments. Section 553(b)(A) of the APA, however, provides that the standard prior notice and comment procedures do not apply to an agency rulemaking to the extent that the rule is a rule of procedure.

The substantive provisions of the EAPA have been established by Congress, and these regulations set forth the procedures for implementing the statute and do not include substantive requirements. Although CBP could issue this as a final rule without prior notice and comment, CBP is soliciting comments in this interim rule and will consider all comments received before issuing a final rule.

Statutory and Regulatory Requirements

Executive Orders 13563 and 12866

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is not a ''significant regulatory action,'' as defined in section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed this regulation.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. Since a general notice of proposed rulemaking is not necessary for this rule, CBP is not required to prepare a regulatory flexibility analysis for this rule.

Paperwork Reduction Act

An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB.

OMB approved collection 1651–0131 will be amended to reflect the additional respondents for e-Allegations and the three new questionnaires for EAPA requirements as described above in accordance with 19 CFR 165.5(a) and 165.23(a). We estimate that this rule will

result in an additional 419 responses annually and an additional 9,386 burden hours. The revision to the information collection includes 44 additional e-Allegations which is in addition to the previously approved 1,600 total e-Allegation submissions annually (for a total of 1,644 e-Allegation submissions). It also establishes new questionnaires for allegers of AD/CVD violations, alleged evaders of AD/CVD orders, and other interested parties, such as the foreign producer or exporter or a foreign government. This revision to this information collection includes 150 new alleger questionnaires annually, 150 new alleged evader questionnaires annually, and 75 new other interested party questionnaires annually. The other interested party could be a foreign producer or exporter or foreign government, or any other interested party. Collection 1651–0131 will be revised to reflect the increased burden hours for each additional e-Allegation submission and EAPA questionnaire added to e-Allegations as follows:

E-Allegations

Estimated number of annual respondents: 44.
Estimated number of annual responses: 44.
Estimated time burden per response: 15 minutes (.25 hours).
Estimated total annual time burden: 11 hours.

Alleger Questionnaire

Estimated number of annual respondents: 150.
Estimated number of annual responses: 150.
Estimated time burden per response: 25 hours.
Estimated total annual time burden: 3,750 hours.

Alleged Evader Questionnaire

Estimated number of annual respondents: 150.
Estimated number of annual responses: 150.
Estimated time burden per response: 25 hours.
Estimated total annual time burden: 3,750 hours.

Other Interested Party Questionnaire

Estimated number of annual respondents: 75.
Estimated number of annual responses: 75.
Estimated time burden per response: 25 hours.
Estimated total annual time burden: 1,875 hours.

Comments concerning the collections of information and the accuracy of the estimated annual burden, and suggestions for reducing that burden, should be directed to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503. A copy should also be sent to the Trade and Commercial Regulations Branch, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

Signing Authority

This document is being issued in accordance with § 0.1(a)(1) of the CBP regulations (19 CFR 0.1(a)(1)) pertaining to the authority of the Secretary of the Treasury (or his or her delegate) to approve regulations related to certain customs revenue functions.

List of Subjects in 19 CFR Part 165

Administrative practice and procedure, Business and industry, Customs duties and inspection.

Amendments to the Regulations

■ For the reasons set forth above, chapter I of title 19, Code of Federal Regulations (19 CFR chapter I), is amended by adding part 165 to read as follows:

PART 165—INVESTIGATION OF CLAIMS OF EVASION OF ANTIDUMPING AND COUNTERVAILING DUTIES

Sec.

Authority: 19 U.S.C. 66, 1481, 1484, 1508, 1517 (as added by Pub. L. 114–125, 130 Stat. 122, 155 (19 U.S.C. 4301 note)), 1623, 1624, 1671, 1673.

§ 165.0 Scope.

This part relates to allegations by the public and requests from Federal agencies for an investigation regarding the evasion of antidumping (AD) and countervailing duty (CVD) orders and the procedures by which CBP investigates such claims consistent with the Trade Facilitation and Trade Enforcement Act of 2015 (TFTEA), which contains Title IV-Prevention of Evasion of Antidumping and Countervailing Duty Orders (short title ''Enforce and Protect Act of 2015'' or ''EAPA'') (Pub. L. 114–125, 130 Stat. 122, 155, Feb. 24, 2016) (19 U.S.C. 4301 note). This part includes the requirements for the filing of allegations and requests for investigations, the investigation procedures, and administrative review of determinations as to evasion of AD/CVD orders under the EAPA. The procedures under this part are not the exclusive manner by which CBP may receive allegations or requests for an investigation from Federal agencies or investigate such allegations or requests with respect to the evasion of AD/CVD orders. An investigation as described in this part, if initiated by CBP, does not preclude CBP or any other government entity from initiating any other investigation or proceeding pursuant to any other provision of law, including proceedings initiated under 19 U.S.C. 1592.

Subpart A—General Provisions

§ 165.1 Definitions.

As used in this part, the following terms will have the meanings indicated unless either the context in which they are used requires a different meaning or a different definition is prescribed for a particular section of this part:

Allegation. The term ''allegation'' refers to a filing with CBP under § 165.11 by an interested party that alleges an act of evasion by an importer of AD/CVD orders.

AD. The term ''AD'' refers to antidumping duty, consistent with section 736, Tariff Act of 1930, as amended (19 U.S.C. 1673e).

AD/CVD. The term ''AD/CVD'' refers to antidumping/countervailing duty, as these terms are defined in this section.

Covered merchandise. The term ''covered merchandise'' means merchandise that is subject to a CVD order issued under section 706, Tariff Act of 1930, as amended (19 U.S.C. 1671e), and/or an AD order issued under section 736, Tariff Act of 1930, as amended (19 U.S.C. 1673e).

CVD. The term ''CVD'' refers to countervailing duty, consistent with section 706, Tariff Act of 1930, as amended (19 U.S.C. 1671e).

Enter or *entry.* The terms ''enter'' and ''entry'' refer to the entry for consumption, or withdrawal from warehouse for consumption, of merchandise in the customs territory of the United States, *see* § 101.1 of this chapter, or to the filing with CBP of the necessary documentation to withdraw merchandise from a duty-deferral program in the United States for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico, *see* §§ 141.0a(f) and 181.53 of this chapter.

Evade or *evasion.* The terms ''evade'' and ''evasion'' refer to the entry of covered merchandise into the customs territory of the United States for consumption by means of any document or electronically transmitted data or information, written or oral statement, or act that is material and false, or any omission that is material and that results in any cash deposit or other security or any amount of applicable antidumping or countervailing duties being reduced or not being applied with respect to the covered merchandise.

Interested party. The term ''interested party'' in this part refers only to the following:

(1) A foreign manufacturer, producer, or exporter, or any importer (not limited to importers of record and including the party against whom the allegation is brought), of covered merchandise or a trade or business association a majority of the members of which are producers, exporters, or importers of such merchandise;

(2) A manufacturer, producer, or wholesaler in the United States of a domestic like product;

(3) A certified union or recognized union or group of workers that is representative of an industry engaged in the manufacture, production, or wholesale in the United States of a domestic like product;

(4) A trade or business association a majority of the members of which manufacture, produce, or wholesale a domestic like product in the United States;

(5) An association a majority of the members of which is composed of interested parties described in paragraphs (2), (3), and (4) of this definition with respect to a domestic like product; or,

(6) If the covered merchandise is a processed agricultural product, as defined in 19 U.S.C. 1677(4)(E), a coalition or trade association that is representative of any of the following: processors; processors and producers; or processors and growers.

Investigation. The term ''investigation'' refers to the CBP administrative process described in subpart C of this part, and is a formal investigation within the meaning of section 592(c)(4), Tariff Act of 1930, as amended (19 U.S.C. 1592(c)(4)).

Parties to the investigation. The phrase ''parties to the investigation'' means the interested party (or interested parties, in the case of consolidation pursuant to § 165.13) who filed the allegation of evasion and the importer (or importers, in the case of consolidation pursuant to § 165.13) who allegedly engaged in evasion. In the case of investigations initiated based upon a request from a Federal agency, parties to the investigation only refers to the importer or importers who allegedly engaged in evasion, and not the Federal agency.

Regulations and Rulings. The term ''Regulations and Rulings'' means the Executive

Director, Regulations and Rulings, Office of Trade, or his or her designee.

TRLED. The term ''TRLED'' refers to the Trade Remedy Law Enforcement Directorate, Office of Trade, that conducts the investigation of alleged evasion under this part, and that was established as required by section 411 of the EAPA.

§ 165.2 Entries subject to this part.

Entries that may be the subject of an allegation made under § 165.11 or a request for an investigation under § 165.14 are those entries of allegedly covered merchandise made within one year before the receipt of an allegation under § 165.11 or of a request for an investigation under § 165.14. In addition, at its discretion, CBP may investigate other entries of such covered merchandise.

§ 165.3 Power of attorney.

(a) *When required.* Any submission made under this part other than by a principal or its employees may be filed by a person acting as agent or attorney in fact for the principal; a power of attorney must specifically authorize such person to make, sign, and file the submission or grant unlimited authority to such person.

(b) *Exception.* No power of attorney is required for an attorney at law to act as agent or attorney for the principal. The signing of a submission as agent or attorney for the principal by the attorney at law will be considered a declaration by the attorney that the attorney is currently an active member in good standing of the highest court of a state, possession, territory, commonwealth, or the District of Columbia, and has been authorized to sign and file the submission for the principal.

(c) *Execution*—(1) *Corporation.* A corporate power of attorney to file the submissions described in paragraph (a) of this section must be signed by a duly authorized officer or employee of the corporation.

(2) *Partnership.* A partnership power of attorney to file the submissions described in paragraph (a) of this section must be signed by at least one member in the name of the partnership or by at least one duly authorized employee of the partnership, provided the power recites the name(s) of all of the members.

(3) *Other persons.* A power of attorney filed by a person other than a corporation or partnership must be signed by that person or an employee of that person who has the legal authority to act on that person's behalf when filing the submissions described in paragraph (a) of this section.

(d) *Revocation.* Any power of attorney will be subject to revocation at any time by written notice given to and received by CBP, Office of Trade.

(e) *Proof.* CBP will require proof of execution of a power of attorney, where applicable, the first time that an agent makes a submission on behalf of any interested party during an investigation or administrative review of a determination as to evasion. CBP may require proof of authority to execute a power of attorney pursuant to paragraph (c) of this section, at any point during the proceedings described in this part.

§ 165.4 Release of information provided by interested parties.

(a) *Claim for business confidential treatment.* Any interested party that makes a submission to CBP in connection with an investigation under this part, including for its initiation and administrative review, may request that CBP treat any part of the submission as

business confidential information except for the information specified in paragraph (c) of this section. Business confidential treatment will be granted if the requirements of this section are satisfied and the information for which protection is sought consists of trade secrets and commercial or financial information obtained from any person, which is privileged or confidential in accordance with 5 U.S.C. 552(b)(4).

(1) *Identification of business confidential information.* An interested party submitting information must identify the information for which business confidential treatment is claimed by enclosing the claimed confidential information within single brackets. The first page of any submission containing business confidential information must clearly state that the submission contains business confidential information. The submitting interested party must also provide with the claimed business confidential information an explanation of why each item of bracketed information is entitled to business confidential treatment.

(2) *Public version.* An interested party filing a submission containing claimed business confidential information must also file a public version of the submission. The public version must be filed on the same date as the business confidential version and contain a summary of the bracketed information in sufficient detail to permit a reasonable understanding of the substance of the information. If the submitting interested party claims that summarization is not possible, the claim must be accompanied by a full explanation of the reasons supporting that claim. The public version must be clearly marked as a public version on the first page.

(b) *Nonconforming submissions.* CBP will reject a submission that includes a request for business confidential treatment but does not meet the requirements of paragraph (a) of this section.

(1) *Notice of rejection.* If CBP determines that the claim of confidentiality is nonconforming, it will treat the relevant portion of the submission as business confidential information until the appropriate corrective action is taken or the submission is rejected.

(2) *Corrective action.* The submitting interested party may take any of the following actions within two business days after receiving CBP's notice of rejection:

(i) Correct the problems and resubmit the information by an email message or through any other method approved or designated by CBP;

(ii) If CBP denies a request for business confidential treatment, agree to have the information in question treated as public information;

(iii) Submit other material concerning the subject matter in lieu of the rejected information.

(3) *Effects of rejection.* If the submitting interested party does not take any of the actions in paragraph (b)(2) of this section, CBP will not consider the rejected submission and, if applicable, adverse inferences may be drawn pursuant to § 165.6.

(c) *Information that will not be protected as confidential.* The following information provided by a party to the investigation in an allegation of evasion will not be protected as business confidential information and will be treated as public pursuant to the certification of informed consent referenced in § 165.11(c):

(1) Name of the party to the investigation providing the information and identification of the agent filing on its behalf, if any, and email address for communication and service purposes;

(2) Specification as to the basis upon which the party making the allegation qualifies as an interested party as defined in § 165.1;

(3) Name and address of importer against whom the allegation is brought;

(4) Description of covered merchandise; and

(5) Applicable AD/CVD orders.

(d) *Certification.* In accordance with paragraph (a)(2) of this section, when providing a public version of their submissions, interested parties must certify that the information they are providing is either their own information (*i.e.*, information from their own business records and not business confidential information of another entity) or information that was publicly obtained or in the public domain.

(e) *Information placed on the record by CBP.* Any information that CBP places on the administrative record, when obtained other than from an interested party subject to the requirements of this section, will include a public summary of the business confidential information as described in paragraph (a)(2) of this section, when applicable.

§ 165.5 Obtaining and submitting information.

(a) *Obtaining of information by CBP.* In obtaining information necessary to carry out its functions and duties under this part, CBP may employ any means authorized by law. In general, CBP will obtain information from its own files, from other agencies of the United States Government, through questionnaires and correspondence, and through field work by its officials.

(b) *Submissions to CBP.* The following requirements pertain to all parties who knowingly make submissions covered in this part:

(1) *Form.* All submissions to CBP must be in writing in the English language or accompanied by an adequate English language translation as they will be part of the record for proceedings and determinations covered in this part. Oral discussions or communications with CBP will not be considered part of the record, unless they are memorialized in a written document that is placed on the record. All submissions must be made electronically to the designated email address specified by CBP for purposes of the investigation or through any other method approved or designated by CBP.

(2) *Certifications.* Every written submission made to CBP by an interested party under this part must be accompanied by the following certifications from the person making the submission:

(i) ''On behalf of the party making this submission, I certify that all statements in this submission (and any attachments) are accurate and true to the best of my knowledge and belief.''

(ii) ''On behalf of the party making this submission, I certify that any information for which I have not requested business confidential treatment pursuant to 19 CFR 165.4(a), may be released for public consumption.''

(iii) ''On behalf of the party making this submission, I certify that I will advise CBP promptly of any knowledge of or reason to suspect that the covered merchandise poses any health or safety risk to U.S. consumers pursuant to 19 CFR 165.7(a).''

(3) *False statement.* Any interested party that provides a material false statement or makes a material omission or otherwise attempts to conceal material facts at any point in the proceedings may be subject to adverse inferences (*see* § 165.6) and prosecution pursuant to 18 U.S.C. 1001.

(c) *Compliance with CBP time limits*—(1) *Requests for extensions.* CBP may, for good cause, extend any regulatory time limit if a party requests an extension in a separate, stand-alone submission and states the reasons for the request. Such requests must be submitted no less than three business days before the time limit expires unless there are extraordinary circumstances. An extraordinary circumstance is an unexpected event that could not have

been prevented even if reasonable measures had been taken. It is within CBP's reasonable discretion to determine what constitutes extraordinary circumstances, what constitutes good cause, and to grant or deny a request for an extension.

(2) *Rejection of untimely submissions.* If a submission is untimely filed, then CBP will not consider or retain it in the administrative record and adverse inferences may be applied, if applicable.

§ 165.6 Adverse inferences.

(a) *In general.* If the party to the investigation that filed an allegation, the importer, or the foreign producer or exporter of the covered merchandise fails to cooperate and comply to the best of its ability with a request for information made by CBP, CBP may apply an inference adverse to the interests of that party in selecting from among the facts otherwise available to make the determination as to evasion pursuant to § 165.27 and subpart D of this part.

(b) *Other adverse inferences.* CBP may also apply an inference adverse to the interests of a party based on a prior determination in another CBP investigation, proceeding, or action that involves evasion with respect to AD/CVD orders, or any other available information.

(c) *Application.* An adverse inference described in this section may be used with respect to the importer of the covered merchandise, or the foreign producer or exporter of the covered merchandise without regard to whether another party involved in the same transaction or transactions under examination has provided the information sought by CBP, such as import or export documentation.

§ 165.7 Protection of public health and safety.

(a) *Notification to CBP.* Any interested party, including an importer, must promptly notify CBP if it has knowledge or reason to suspect that the covered merchandise may pose a health or safety risk to U.S. consumers at any point during the proceedings described in this part.

(b) *Transmission by CBP.* During the course of an investigation or administrative review of a determination as to evasion under this part, CBP will consider whether the covered merchandise may pose a health or safety risk to U.S. consumers and will take into account any notification received under paragraph (a) of this section. CBP will promptly transmit information to the appropriate Federal agencies for purposes of mitigating the risk and will exercise its administrative powers, as appropriate.

Subpart B—Initiation of Investigations

§ 165.11 Allegations by interested parties.

(a) *Filing of allegation.* Any interested party, as defined in § 165.1, may file an allegation that an importer of covered merchandise has evaded AD/CVD orders. An allegation must be filed electronically through the appropriate portal on CBP's online e-Allegations system or through any other method approved or designated by CBP. Each allegation must be limited to one importer, but an interested party may file multiple allegations. An allegation must satisfy the requirements in paragraphs (b) through (d) of this section.

(b) *Contents.* An allegation of evasion must include, but is not limited to, the following information:

(1) Name of the interested party making the allegation and identification of the agent filing on its behalf, if any, and the email address for communication and service purposes;

(2) An explanation as to how the interested party qualifies as an interested party pursuant to § 165.1;

(3) Name and address of importer against whom the allegation is brought;

(4) Description of the covered merchandise;

(5) Applicable AD/CVD orders; and

(6) Information reasonably available to the interested party to support its allegation that the importer with respect to whom the allegation is filed is engaged in evasion.

(c) *Certifications.* An allegation must also be accompanied by the certifications required under § 165.5(b) and the following statement of informed consent from the person making the submission: ''I certify my understanding and consent that the information provided for in § 165.11(b)(1) through (5) may be released for public consumption.''

(d) *Signature.* The person signing the allegation on behalf of the interested party must include his or her name, position in the company or other affiliation, and provide contact information. Electronic submission of this information will be considered ''signed'' for purpose of filing the allegation.

(e) *Technical assistance and guidance*—(1) *Availability.* CBP will provide technical assistance and guidance for the preparation of an allegation of evasion and its submission to CBP, as described in this section.

(i) *Small businesses.* Small businesses are entitled to technical assistance upon request. In general, small businesses are eligible to make such requests if they have neither adequate internal resources nor financial ability to obtain qualified outside assistance in preparing and submitting for CBP's consideration allegations of evasion. Small businesses must satisfy the applicable standards set forth in 15 U.S.C. 632 and implemented in 13 CFR part 121.

(ii) *Other parties.* Other parties may request technical assistance, which CBP may provide if resources are reasonably available.

(2) *Requests.* Requests for technical assistance may be made at any time via the email address designated on CBP's online e-Allegations system or through any other method approved or designated by CBP.

(3) *Limitations.* The act of providing technical assistance is not part of the record for the investigation, nor does it compel a decision by CBP to initiate an investigation pursuant to § 165.15.

§ 165.12 Receipt of allegations.

(a) *Date of receipt.* The ''date of receipt'' of a properly filed allegation is the date on which CBP provides an acknowledgment of receipt of an allegation containing all the information and certifications required in § 165.11, together with a CBP-assigned control number, to the party that filed the allegation. CBP has 15 business days from the date of receipt to determine whether to initiate an investigation under the EAPA.

(b) *Withdrawal.* An allegation may be withdrawn by the party that filed it if that party submits a request to withdraw the allegation to the designated email address specified by CBP.

§ 165.13 Consolidation of allegations.

(a) *In general.* Multiple allegations against one or more importers may be consolidated into a single investigation at CBP's discretion. Consolidations may be made at any point prior to the issuance of a determination as to evasion with respect to a particular importer. If multiple allegations are received and consolidated prior to the initiation of an investigation, then the date of receipt of the first properly filed allegation will start the time period for the deadline to initiate the investigation described in § 165.15 with respect to that allegation.

(b) *Criteria.* CBP may consolidate multiple allegations if warranted based on the consideration of certain factors. The factors that CBP may consider include, but are not limited to, whether the multiple allegations involve:

(1) Relationships between the importers;

(2) Similarity of covered merchandise;
(3) Similarity of AD/CVD orders; and
(4) Overlap in time periods for entries of covered merchandise.

(c) *Notice.* Notice of consolidation will be promptly transmitted to all parties to the investigation if consolidation occurs at a point in the investigation after which they have already been notified of the ongoing investigation. Otherwise, parties will be notified no later than 95 calendar days after the date of initiation of the investigation.

(d) *Service requirements for other parties to the investigation.* Upon notification of consolidation, parties to the consolidated investigation must serve via an email message or through any other method approved or designated by CBP upon the newly added parties to the investigation the public versions of any documents that were previously served upon parties to the unconsolidated investigation. Service must take place within five business days of the notice of consolidation.

§ 165.14 Other Federal agency requests for investigations.

(a) *Requests for investigations.* Any other Federal agency, including the Department of Commerce or the United States International Trade Commission, may request an investigation under this part. CBP will initiate an investigation if the Federal agency has provided information that reasonably suggests that an importer has entered covered merchandise into the customs territory of the United States through evasion, unless the agency submits a request to withdraw to the designated email address specified by CBP.

(b) *Contents of requests.* The following information must be included in the request for an investigation:

(1) Name of importer against whom the allegation is brought;

(2) Description of the covered merchandise;

(3) Applicable AD/CVD orders;

(4) Information that reasonably suggests that an importer has entered covered merchandise into the customs territory of the United States through evasion;

(5) Identification of a point of contact at the agency; and

(6) Notification of any knowledge of or reason to suspect that the covered merchandise poses any health or safety risk to U.S. consumers.

(c) *Receipt of requests.* Requests for an investigation must be filed electronically via CBP's online e-Allegations system or through any other method approved or designated by CBP. The date of receipt is the date that CBP transmits notice of the assigned control number to the Federal agency that filed the request.

(d) *Notice of release of information*—(1) *Public information.* CBP will treat the information required by paragraphs (b)(1) through (3) of this section as public information.

(2) *Business confidential treatment.* CBP will create a public summary of the information required by paragraphs (b)(4) and (6) of this section.

(e) *Access to investigation.* The Federal agency is not a party to the investigation. Therefore, it will neither receive official notice of developments after CBP's receipt of the request for an investigation nor will it receive service of any documents filed by interested parties. Only the parties to the investigation will be entitled to notice and service, as well as the related rights to administrative review and judicial review.

§ 165.15 Initiation of investigations.

(a) *Time for determination.* CBP will make a determination as to whether to initiate an investigation on or before the 15th business day after the date on which a properly filed allegation is received under § 165.12(a) or a request for an investigation is received from a Federal agency under § 165.14.

(b) *Criteria for initiation.* CBP will initiate an investigation under subpart C of this part if the following criteria are satisfied:

(1) *Nature of merchandise.* The covered merchandise described in the allegation or Federal agency request for an investigation is properly within the scope of an AD/CVD order. If CBP lacks sufficient information to make such determination as to the scope of the order, then it will refer the matter to the Department of Commerce pursuant to § 165.16.

(2) *Likelihood of evasion.* The information provided in the allegation or Federal agency request for an investigation reasonably suggests that the covered merchandise has been entered for consumption into the customs territory of the United States through evasion as it is defined in § 165.1.

(c) *Exceptions.* Even if the criteria in paragraph (b) of this section are satisfied, CBP will not initiate an investigation under the following circumstances:

(1) *Clerical error.* A clerical error, as defined in 19 U.S.C. 1517(a)(5)(B), is not evasion, although CBP will take appropriate actions to ensure that AD/CVD duties are assessed and collected.

(2) *Withdrawal.* An allegation or a request for an investigation from another Federal agency may be withdrawn pursuant to the requirements of § 165.12(b) or § 165.14(a), as applicable.

(d) *Notification of the investigation.* If CBP determines that it will not initiate an investigation, it will notify the interested party who filed the allegation within five business days of that determination. Otherwise, the parties to the investigation will be notified consistent with the following time limits:

(1) *In general.* CBP will issue notification of its decision to initiate an investigation to all parties to the investigation no later than 95 calendar days after the decision has been made, and the actual date of initiation will be specified therein. However, notification to all parties to the investigation will occur no later than five business days after interim measures are taken pursuant to § 165.24.

(2) *Consolidated allegations.* If multiple allegations are consolidated, any interested party who filed an allegation after initiation of an investigation will be notified by CBP of the date of the decision to initiate an investigation when that party receives notice of consolidation under § 165.13(c).

(e) *Record of the investigation.* If an investigation is initiated pursuant to subpart B of this part, then the information considered by CBP prior to initiation will be part of the administrative record pursuant to § 165.21.

§ 165.16 Referrals to Department of Commerce.

(a) *When required.* A referral is required if at any point after receipt of an allegation, CBP cannot determine whether the merchandise described in an allegation is properly within the scope of an antidumping or countervailing duty order.

(b) *Referral.* The referral may contain any necessary information available to CBP regarding whether the merchandise described in an allegation is subject to the relevant AD/CVD orders.

(c) *Notice of referral.* TRLED will promptly notify the parties to the investigation of the date of the referral.

(d) *Effect on investigation.* The time period required for any referral and determination by the Department of Commerce will not be counted toward the deadlines for CBP to decide on whether to initiate an investigation under § 165.15 or the deadline to issue a determination as to evasion under § 165.27.

(e) *Notice of decision.* CBP will place the determination by the Department of Commerce on the administrative record of CBP's proceeding and will electronically notify the parties to the investigation.

Subpart C—Investigation Procedures

§ 165.21 Administrative record.

(a) *Administrative record.* CBP will maintain a record for purposes of making a determination as to evasion under § 165.27 and conducting an administrative review under § 165.46. The administrative record will contain all of the following, if applicable, but is not limited to:

(1) Materials obtained and considered by CBP during the course of an investigation under this part;

(2) Factual information submitted pursuant to § 165.23;

(3) Information obtained during and the results of any verification conducted pursuant to § 165.25;

(4) Materials from other agencies provided to CBP pursuant to the investigation;

(5) Written arguments submitted pursuant to § 165.26 and subpart D of this part; and

(6) Summaries of oral discussions with interested parties relevant to the investigation pursuant to § 165.23.

(b) *Maintenance of the record.* CBP will maintain the administrative record of each investigation or review conducted by CBP pursuant to this part. All information properly filed with CBP pursuant to §§ 165.4 and 165.5 will be placed on the administrative record. CBP will not consider in its determinations or include on the administrative record any information that is not properly filed with CBP.

§ 165.22 Time for investigations.

(a) *Time for determination.* Unless CBP has extended the deadline in accordance with paragraph (c) of this section or due to a referral to the Department of Commerce pursuant to § 165.16, CBP will make a determination under § 165.27 not later than 300 calendar days after the date on which CBP initiates an investigation under § 165.15 with respect to whether covered merchandise was entered through evasion.

(b) *Time for determination with consolidated allegations.* If CBP consolidates multiple allegations under § 165.13 into a single investigation under § 165.15, the date on which CBP receives the first of such allegations will be used for the purposes of the requirement under paragraph (a) of this section with respect to the timing of the initiation of the investigation.

(c) *Extension of time for determination.* CBP may extend the time to make a determination under paragraph (a) of this section by not more than 60 calendar days if CBP determines that—

(1) The investigation is extraordinarily complicated because of—

(i) The number and complexity of the transactions to be investigated;

(ii) The novelty of the issues presented; or

(iii) The number of entities to be investigated; and

(2) Additional time is necessary to make the determination under paragraph (a) of this section.

(d) *Notification of extension of time for determination.* CBP will notify all parties to the investigation of an extension not later than 300 calendar days after the date on which CBP initiates an investigation under § 165.15.

§ 165.23 Submission of factual information.

All submissions of factual information to CBP must comply with the requirements specified in §§ 165.4 and 165.5 and this section. The submissions will be placed on the administrative record.

(a) *Request for information by CBP.* In making a determination under § 165.27, CBP may require additional information as is necessary, from, among others:

(1) An interested party that filed an allegation under § 165.11;

(2) An importer who allegedly engaged in evasion;

(3) A person that is a foreign producer or exporter of covered merchandise; and/or

(4) The government of a country from which covered merchandise may have been exported.

(b) *Voluntary submission of factual information.* Any party to the investigation may submit additional information in order to support the allegation of evasion or to negate or clarify the allegation of evasion.

(c) *Time limits and service requirements*—(1) *Responses to CBP requests for factual information.* Factual information requested by CBP pursuant to paragraph (a) of this section must be submitted to CBP within the timeframe set forth by CBP in the request. The public version must also be served via an email message or through any other method approved or designated by CBP on the parties to the investigation. If CBP places new factual information on the administrative record on or after the 200th calendar day after the initiation of the investigation (or if such information is placed on the record at CBP's request), the parties to the investigation will have ten calendar days to provide rebuttal information to the new factual information.

(2) *Voluntary submission of factual information.* Factual information voluntarily submitted to CBP pursuant to paragraph (b) of this section must be submitted no later than 200 calendar days after CBP initiated the investigation under § 165.15. The public version must also be served via an email message or through any other method approved or designated by CBP on the parties to the investigation. Voluntary submissions made after the 200th calendar day after initiation of the investigation will not be considered or placed on the administrative record, except rebuttal information as permitted pursuant to the next sentence herein. Parties to the investigation will have ten calendar days from the date of service of any factual information or from the date of placement of any factual information on the record to provide rebuttal information to that factual information, if the information being rebutted was placed on the administrative record no later than 200 calendar days after CBP initiated the investigation under § 165.15.

(d) *Oral discussions.* Notwithstanding the time limits in paragraph (c) of this section, CBP may request oral discussions either in-person or by teleconference. CBP will memorialize such discussions with a written summary that identifies who participated and the topic of discussion. In the event that confidential business information is included in the written summary, CBP will also place a public version on the administrative record.

§ 165.24 Interim measures.

(a) *Reasonable suspicion.* No later than 90 calendar days after initiating an investigation under § 165.15, CBP will take interim measures if there is a reasonable suspicion that the importer entered covered merchandise into the customs territory of the United States through evasion.

(b) *Measures.* If CBP decides that there is reasonable suspicion under paragraph (a) of this section, then:

(1) For entries that remain unliquidated, CBP will:

(i) Suspend the liquidation of each unliquidated entry of such covered merchandise that entered on or after the date of the initiation of the investigation under § 165.15;

(ii) Extend the period for liquidating each unliquidated entry of such covered merchandise that entered before the date of the initiation of the investigation under § 165.15 pursuant to section

504(b), Tariff Act of 1930, as amended (19 U.S.C. 1504(b)); and

(iii) Take such additional measures as CBP determines necessary to protect the revenue of the United States, including requiring a single transaction bond or additional security or the posting of a cash deposit with respect to such covered merchandise pursuant to section 623, Tariff Act of 1930, as amended (19 U.S.C. 1623).

(2) For entries that are liquidated, CBP may initiate or continue any appropriate measures separate from this proceeding.

(c) *Notice.* If CBP decides that there is reasonable suspicion under paragraph (a) of this section, CBP will issue notification of this decision to the parties to the investigation within five business days after taking interim measures. CBP will also provide parties to the investigation with a public version of the administrative record as of that date.

§ 165.25 Verifications of information.

(a) Prior to making a determination under § 165.27, CBP may in its discretion verify information in the United States or foreign countries collected under § 165.23 as is necessary to make its determination.

(b) CBP will place any relevant information on the administrative record and provide a public summary.

§ 165.26 Written arguments.

All written arguments submitted to CBP pursuant to a proceeding under this part must comply with the requirements specified in §§ 165.4 and 165.5 and this section. The submissions will be placed on the administrative record.

(a) *Written arguments.* Parties to the investigation:

(1) May submit to CBP written arguments that contain all arguments that are relevant to the determination as to evasion and based solely upon facts already on the administrative record in that proceeding. All written arguments must be submitted to the designated email address specified by CBP or through any other method approved or designated by CBP no later than 230 calendar days after the investigation was initiated pursuant to § 165.15; and

(2) Must serve a public version of the written arguments prepared in accordance with § 165.4 on the other parties to the investigation by an email message or through any other method approved or designated by CBP the same day it is filed with CBP.

(b) *Responses to the written arguments.* Parties to the investigation:

(1) May submit to CBP a response to a written argument filed by another party to the investigation. The response must be in writing and submitted to the designated email address specified by CBP or through any other method approved or designated by CBP no later than 15 calendar days after the written argument was filed with CBP. The response must be limited to the issues raised in the written argument; any portion of a response that is outside the scope of the issues raised in the written argument will not be considered; and

(2) Must serve a public version of the response prepared in accordance with § 165.4 on the other parties to the investigation by an email message or through any other method approved or designated by CBP the same day it is filed with CBP.

(c) *Written arguments submitted upon request.* Notwithstanding paragraphs (a) and (b) of this section, CBP may request written arguments on any issue from any party to the investigation at any time during an investigation.

(d) *Form of written argument and response to the written arguments.* The written argument and response to the written argument must be double-spaced, with headings and footnotes single-spaced, margins one inch on all four sides, and font Times New Roman, 12-point font size. The written argument must be no more than 50 pages in length, including exhibits, and the response to the written argument must be no more than 50 pages in length, including exhibits, excluding any pages containing the table of contents and the table of cited authorities. Each written argument and response to the written argument must contain:

(1) The name, address, and email address of the party and of his or her duly authorized agent or attorney at law (if represented by a duly authorized agent or attorney at law);

(2) A summary of the argument or response to the argument, which is a concise summary;

(3) The argument or response to the argument that clearly and accurately presents points of fact and law with applicable citations;

(4) A table of contents and a table of cited authorities; and

(5) A conclusion that states a proposal for CBP's determination as to evasion.

§ 165.27 Determination as to evasion.

(a) *Determination.* Upon conclusion of the investigation, CBP will make a determination based on substantial evidence as to whether covered merchandise was entered into the customs territory of the United States through evasion.

(b) *Notification.* No later than five business days after making a determination under paragraph (a) of this section, CBP will send via an email message or through any other method approved or designated by CBP a summary of the determination limited to publicly available information under paragraph (a) to the parties to the investigation.

(c) *Negative determination.* If CBP makes a determination under paragraph (a) of this section that covered merchandise was not entered into the customs territory of the United States through evasion, then CBP will cease applying any interim measures taken under § 165.24 and liquidate the entries in the normal course.

§ 165.28 Assessments of duties owed; other actions.

(a) *Effect on liquidation.* For entries of covered merchandise that are already liquidated when an affirmative determination is made as to evasion under § 165.27, CBP will initiate or continue any appropriate actions separate from this proceeding. For entries of covered merchandise that are unliquidated:

(1) *Suspension of liquidation.* (i) CBP will suspend the liquidation of unliquidated entries of covered merchandise that is subject to the determination and that entered on or after the date of the initiation of the investigation under § 165.15 with respect to such covered merchandise; or

(ii) If CBP has already suspended the liquidation of such entries pursuant to § 165.24, then CBP will continue to suspend their liquidation.

(2) *Extension of liquidation.* (i) If liquidation is not suspended, then CBP will extend the period for liquidating the unliquidated entries of covered merchandise that is subject to the determination, pursuant to CBP's authority under section 504(b), Tariff Act of 1930, as amended (19 U.S.C. 1504(b)); or

(ii) If CBP has already extended the period for liquidating such entries pursuant to § 165.24, then CBP will continue to extend the period for liquidating such entries.

(b) *Notification to the Department of Commerce.* If CBP makes a determination under § 165.27 that covered merchandise was entered into the customs territory of the United States through evasion, CBP will notify the Department of Commerce of the determination and request, if necessary, that the Department of Commerce:

(1) Identify the applicable antidumping or countervailing duty assessment rates for merchandise covered by the determination; and/or

(2) If no assessment rate is available at the time, identify the applicable cash

deposit rate to be applied, with the applicable antidumping or countervailing duty assessment rate to be provided as soon as that rate becomes available.

(c) *Cash deposits and duty assessment.* CBP will require the posting of cash deposits and assess duties on entries of covered merchandise subject to its affirmative determination of evasion.

Subpart D—Administrative Review of Determinations

§ 165.41 Filing a request for review of the initial determination.

(a) *How to file a request for administrative review.* Requests for administrative review of the initial determination as to evasion pursuant to § 165.27 must be submitted electronically to Regulations and Rulings, in a manner as prescribed by CBP. Requests for review may be filed by any party to the investigation or its attorney at law, or duly authorized agent, and must comply with the requirements specified in § 165.3. Electronic signatures are acceptable.

(b) *Release of information and service.* Requests for review must comply with the requirements for release of information specified in § 165.4.

(c) *Notice to parties to the investigation.* Each party who files a request for review must provide the other parties to the investigation with a public version in accordance with § 165.4.

(d) *When filed.* Requests for review must be filed no later than 30 business days after the issuance of the initial determination as to evasion. Untimely or incomplete requests for review will not be accepted.

(e) *True and accurate information.* All requests must be accompanied by the certifications required pursuant to § 165.5. Any false statements contained in a request for review may subject the party to prosecution under 18 U.S.C. 1001 or other applicable laws.

(f) *Content.* Each request for review must be based solely on the facts already upon the administrative record in the proceeding, in writing, and may not exceed 30 pages. It must be double-spaced with headings and footnotes single spaced, margins one inch on all four sides, and 12-point font Times New Roman. If it exceeds 10 pages, it must include a table of contents and a table of cited authorities. Each request for review must set forth the following:

(1) The allegation control number assigned by CBP with respect to the investigation under consideration;

(2) The name, address and email address of the party seeking review and the name, address and email address of his or her duly authorized agent or attorney at law (if represented by a duly authorized agent or an attorney at law);

(3) A statement of the procedural history and facts as set forth in the administrative record and identified by specific page number or exhibit number and relied upon by the party to prove or establish whether evasion occurred or not;

(4) A concise summary of the argument;

(5) The argument expressing clearly and accurately the points of fact and of law presented and citing the authorities and statutes relied on; and

(6) A conclusion specifying whether the initial determination should be affirmed or reversed.

(7) Each party seeking business confidential treatment must comply with the requirements in § 165.4.

(g) *Assigned case number.* Upon receipt of a timely request for review, the submission will be reviewed to ensure it has been properly filed. If the submission has been properly filed, a case number will be assigned for tracking purposes.

(h) *Consolidation of requests for administrative review.* Multiple requests for review under the same allegation control number assigned by CBP involving the same importer and merchandise may be consolidated into a single administrative review matter.

(i) *Commencement of administrative review.* The 60 business-day review period will commence on the date when CBP accepts the last properly filed request for administrative review and transmits electronically the assigned administrative review case number to all parties to the investigation. All properly filed requests for administrative review must be submitted to CBP no later than 30 business days after the issuance of the initial determination.

§ 165.42 Responses to requests for administrative review.

Any party to the investigation, regardless of whether it submitted a request for administrative review, may submit a written response to the filed request(s) for review. Each written response may not exceed 30 pages in total (including exhibits but not table of contents or table of authorities) and must follow the requirements in § 165.41(f). The written responses to the request(s) for review must be limited to the issues raised in the request(s) for review and must be based solely on the facts already upon the administrative record in that proceeding. The responses must be filed in a manner prescribed by CBP no later than 10 business days from the commencement of the administrative review. All responses must be accompanied by the certifications provided for in § 165.5. Each party seeking business confidential treatment must comply with the requirements in § 165.4. The public version of the response(s) to the request(s) for review must be provided to the other parties to the investigation via an email message or through any other method approved or designated by CBP.

§ 165.43 Withdrawal.

Requests for review and responses to requests for review will remain part of the administrative record and cannot be withdrawn.

§ 165.44 Additional information.

CBP may request additional written information from the parties to the investigation at any time during the review process. The parties who provide the requested additional information must provide a public version to the other parties to the investigation via an email message or through any other method approved or designated by CBP. The submission of additional information requested by CBP must comply with requirements for release of information in § 165.4. CBP may apply an adverse inference as stated in § 165.6 if the additional information requested under this section is not provided.

§ 165.45 Standard for administrative review.

CBP will apply a de novo standard of review and will render a determination appropriate under law according to the specific facts and circumstances on the record. For that purpose, CBP will review the entire administrative record upon which the initial determination was made, the timely and properly filed request(s) for review and responses, and any additional information that was received pursuant to § 165.44. The administrative review will be completed within 60 business days of the commencement of the review.

§ 165.46 Final administrative determination.

(a) *Finality.* The final administrative determination issued by Regulations and Rulings will be in writing and will set forth the conclusion reached on the matter. The conclusion will be transmitted electronically to all parties to the investigation. The final administrative determination is subject to judicial review pursuant to section 421 of the EAPA.

(b) *Effect of the final administrative determination.* If the final

administrative determination affirms the initial determination as to evasion, then no further CBP action is needed. If the final administrative determination reverses the initial determination, then CBP will take appropriate actions consistent with the final administrative determination.

§ 165.47 Potential penalties and other actions.

CBP and other government agencies reserve the right to undertake additional investigations or enforcement actions in cases covered by these provisions. Nothing within this part prevents CBP from assessing penalties of any sort related to such cases or taking action under any other relevant laws.

R. Gil Kerlikowske,

Commissioner, U.S. Customs and Border, Protection.

Approved: August 17, 2016.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 2016–20007 Filed 8–18–16; 4:15 pm]

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2015–0010: T.D. TTB–142; Ref: Notice No. 154]

RIN 1513–AC19

Establishment of the Champlain Valley of New York Viticultural Area

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) establishes the approximately 500-square mile ''Champlain Valley of New York'' viticultural area in Clinton and Essex Counties, New York. The Champlain Valley of New York viticultural area is not located within any other established viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase.

DATES: This final rule is effective September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Kate M. Bresnahan, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; phone 202–453–1039, ext. 151.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01, dated December 10, 2013 (superseding Treasury Order 120–01, dated January 24, 2003), to the TTB Administrator to perform the functions and duties in the administration and enforcement of these laws.

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for the preparation and submission to TTB of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features, as described in part 9 of the regulations, and a name and a delineated boundary, as established in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to the wine's geographic origin. The establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations (27 CFR 4.25(e)(2)) outlines the procedure for proposing an AVA and provides that any interested party may petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions for the establishment or modification of AVAs. Petitions to establish an AVA must include the following:

- Evidence that the area within the proposed AVA boundary is nationally or locally known by the viticultural area name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed AVA;
- A narrative description of the features of the proposed AVA affecting viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed AVA distinctive and distinguish it from adjacent areas outside the proposed AVA boundary;
- The appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed AVA, with the boundary of the proposed AVA clearly drawn thereon; and
- A detailed narrative description of the proposed AVA boundary based on USGS map markings.

Champlain Valley of New York Petition

TTB received a petition from Colin Read, owner of North Star Vineyard, on behalf of the Lake Champlain Grape Growers Association, proposing the establishment of the ''Champlain Valley of New York'' AVA in Clinton and Essex Counties, New York. The proposed Champlain Valley of New York AVA covers approximately 500 square miles and is not located within any other AVA. There are 11 commercial vineyards covering a total of approximately 15.47 acres within the proposed AVA, as well as 6 wineries.

According to the petition, the distinguishing feature of the proposed Champlain Valley of New York AVA is its short growing season, which is conducive to growing cold-hardy North American hybrid grape varieties (such as Frontenac, La Crescent, and Marquette) but not the *Vitis vinifera* grapes that are grown in the surrounding areas. The petition provides information comparing the length of the growing season within the AVA to those of the surrounding areas. In South Hero, Vermont, to the east of the proposed AVA, the growing season is four weeks longer than that in the proposed AVA. In Whitehall, New York,

to the south of the proposed AVA, the growing season is two weeks longer than that in the proposed AVA. The growing season in the Adirondack Mountains, to the west of the proposed AVA, is too short for commercial grape growth. The proposed AVA also has a later last-frost date and an earlier first-frost date than the areas to its east and south. TTB notes that the area directly north of the proposed AVA is in Canada and, therefore, is not eligible to be part of an AVA.

Notice of Proposed Rulemaking and Comments Received

TTB published Notice No. 154 in the **Federal Register** on July 2, 2015 (80 FR 38147), proposing to establish the Champlain Valley of New York AVA. In the notice, TTB summarized the evidence from the petition regarding the name, boundary, and distinguishing features for the proposed AVA. For a detailed description of such evidence, see Notice No. 154. In Notice No. 154, TTB solicited comments on the accuracy of the name, boundary, and other required information submitted in support of the petition. The comment period closed on August 31, 2015. TTB received no comments in response to Notice No. 154.

TTB Determination

After careful review of the petition, TTB finds that the evidence provided by the petitioner supports the establishment of the Champlain Valley of New York AVA. Accordingly, under the authority of the FAA Act, section 1111(d) of the Homeland Security Act of 2002, and parts 4 and 9 of the TTB regulations, TTB establishes the ''Champlain Valley of New York'' AVA in Clinton and Essex Counties, New York, effective 30 days from the publication date of this document.

Boundary Description

See the narrative description of the boundary of the Champlain Valley of New York AVA in the regulatory text published at the end of this final rule.

Maps

The petitioner provided the required maps, and they are listed below in the regulatory text.

Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine's true place of origin. For a wine to be labeled with an AVA name or with a brand name that includes an AVA name, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with an AVA name and that name appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the AVA name appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label. Different rules apply if a wine has a brand name containing an AVA name that was used as a brand name on a label approved before July 7, 1986. See 27 CFR 4.39(i)(2) for details.

With the establishment of this AVA, its name, ''Champlain Valley of New York,'' will be recognized as a name of viticultural significance under § 4.39(i)(3) of the TTB regulations (27 CFR 4.39(i)(3)). The text of the regulation clarifies this point. Consequently, wine bottlers using the name ''Champlain Valley of New York'' in a brand name, including a trademark, or in another label reference as to the origin of the wine, will have to ensure that the product is eligible to use the AVA name as an appellation of origin. TTB is not designating ''Champlain Valley,'' standing alone, as a term of viticultural significance because the term ''Champlain Valley'' also applies to the parts of the valley located in Vermont and Canada. The petitioner proposed the name ''Champlain Valley of New York'' to more accurately describe the location of the AVA. The establishment of the Champlain Valley of New York AVA will not affect any existing AVA. The establishment of the Champlain Valley of New York AVA will allow vintners to use ''Champlain Valley of New York'' as an appellation of origin for wines made primarily from grapes grown within the Champlain Valley of New York AVA if the wines meet the eligibility requirements for the appellation.

Regulatory Flexibility Act

TTB certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of an AVA name would be the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

It has been determined that this final rule is not a significant regulatory action as defined by Executive Order 12866 of September 30, 1993. Therefore, no regulatory assessment is required.

Drafting Information

Kate M. Bresnahan of the Regulations and Rulings Division drafted this final rule.

List of Subjects in 27 CFR Part 9

Wine.

The Regulatory Amendment

For the reasons discussed in the preamble, TTB amends title 27, chapter I, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

■ 2. Subpart C is amended by adding § 9.258 to read as follows:

§ 9.258 Champlain Valley of New York.

(a) *Name.* The name of the viticultural area described in this section is ''Champlain Valley of New York''. For purposes of part 4 of this chapter, ''Champlain Valley of New York'' is a term of viticultural significance.

(b) *Approved maps.* The two United States Geological Survey (USGS) 1:100,000 scale topographic maps used to determine the boundary of the Champlain Valley of New York viticultural area are titled:

(1) Lake Champlain, N.Y.; VT.; N.H.; U.S.; CAN., 1962; revised (U.S. area) 1972; and

(2) Glens Falls, N.Y.; VT.; N.H., 1956; revised 1972.

(c) *Boundary.* The Champlain Valley of New York viticultural area is located in Clinton and Essex Counties, New York. The boundary of the Champlain Valley of New York viticultural area is as described below:

(1) The beginning point is found on the Lake Champlain map at the intersection of the western shore of Lake Champlain and the U.S.-Canada border, just north of the town of Rouses Point.

(2) From the beginning point, proceed south along the western shore of Lake Champlain approximately 109.4 miles, crossing onto the Glens Falls map, to a road marked on the map as State Route 73 (now known as State Route 74) and

known locally as Fort Ti Road, at the Fort Ticonderoga–Larrabees Point Ferry landing; then

(3) Proceed west along State Route 73 (State Route 74/Fort Ti Road) approximately 1.6 miles to State Route 22; then

(4) Proceed north along State Route 22 approximately 21 miles, crossing onto the Lake Champlain map and passing through the town of Port Henry, to an unnamed light-duty road known locally as County Road 44 (Stevenson Road); then

(5) Proceed north along County Road 44 (Stevenson Road) approximately 5.8 miles to a railroad track; then

(6) Proceed northerly along the railroad track approximately 1.6 miles to State Route 9N, west of the town of Westport; then

(7) Proceed westerly along State Route 9N approximately 4.1 miles to Interstate 87; then

(8) Proceed north along Interstate 87 approximately 21 miles to the Ausable River, southwest of the town of Keeseville; then

(9) Proceed west (upstream) along the Ausable River approximately 6 miles to a bridge connecting two unnamed light-duty roads known locally as Burke Road and Lower Road in the town of Clintonville, and proceed north along the bridge to Lower Road; then

(10) Proceed west along Lower Road approximately 0.6 mile to State Route 9N; then

(11) Proceed west along State Route 9N approximately 0.8 mile to an unnamed light-duty road known locally as County Route 39 (Clintonville Road); then

(12) Proceed north along County Route 39 (Clintonville Road) approximately 1.5 miles to the second crossing of the Little Ausable River, west of Cook Mountain; then

(13) Proceed northeast along the Little Ausable River approximately 3.5 miles to the confluence of the river with Furnace Brook, near the town of Harkness; then

(14) Proceed west along Furnace Brook approximately 0.17 mile to an unnamed light-duty road known locally as County Route 40 (Calkins Road); then

(15) Proceed north along County Route 40 (Calkins Road) approximately 5.8 miles to an unnamed light-duty road known locally as County Route 35 (Peasleeville Road), south of an unnamed creek known locally as Arnold Brook; then

(16) Proceed west along County Route 35 (Peasleeville Road) approximately 0.1 mile to an unnamed light-duty road known locally as Connors Road; then

(17) Proceed north along Connors Road approximately 2.1 miles, crossing the Salmon River, to an unnamed light-duty road known locally as County Route 33 (Norrisville Road); then

(18) Proceed west along County Route 33 (Norrisville Road) approximately 1.2 miles to an unnamed light-duty road known locally as Shingle Street; then

(19) Proceed north along Shingle Street approximately 4 miles to an unnamed light-duty road known locally as County Route 31 (Rabideau Street); then

(20) Proceed west along County Route 31 (Rabideau Street) approximately 0.4 mile to an unnamed light-duty road known locally as Goddeau Street; then

(21) Proceed north along Goddeau Street approximately 0.9 mile, crossing the Saranac River, to State Route 3 just east of the town of Cadyville; then

(22) Proceed east along State Route 3 approximately 0.5 mile to an unnamed light-duty road known locally as Akey Road; then

(23) Proceed north on Akey Road approximately 0.2 mile to State Route 374; then

(24) Proceed east along State Route 374 approximately 3.6 miles to State Route 190, also known locally as Military Turnpike; then

(25) Proceed northwest along State Route 190 (Military Turnpike) approximately 15.2 miles to an unnamed light-duty road just east of Park Brook known locally as County Route 12 (Alder Bend Road), northwest of Miner Lake State Park; then

(26) Proceed north along County Route 12 (Alder Bend Road) approximately 3 miles to U.S. Highway 11; then

(27) Proceed west along U.S. Highway 11 approximately 1.7 miles to an unnamed light-duty road known locally as County Route 10 (Cannon Corners Road); then

(28) Proceed north along County Route 10 (Cannon Corners Road) approximately 6 miles to the U.S.-Canada border; then

(29) Proceed east along the U.S.-Canada border approximately 19.8 miles, returning to the beginning point.

Signed: June 27, 2016.

John J. Manfreda,

Administrator.

Approved: August 8, 2016.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

[FR Doc. 2016–19992 Filed 8–19–16; 8:45 am]

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2014–0007: T.D. TTB–141; Ref: Notice No. 145]

RIN 1513–AC10

Expansion of the Sta. Rita Hills Viticultural Area

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) is expanding the approximately 33,380-acre ''Sta. Rita Hills'' viticultural area in Santa Barbara County, California, by approximately 2,296 acres. The established viticultural area and the expansion area are both located entirely within the larger Santa Ynez Valley viticultural area and the multicounty Central Coast viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase.

DATES: This final rule is effective September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; phone 202–453–1039, ext. 175.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01, dated December 10, 2013 (superseding Treasury Order 120–01, dated January

24, 2003), to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for the preparation and submission of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features, as described in part 9 of the regulations, and a name and a delineated boundary, as established in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to the wine's geographic origin. The establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations (27 CFR 4.25(e)(2)) outlines the procedure for proposing an AVA and provides that any interested party may petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions for the establishment or modification of AVAs. Petitions to expand an AVA must include the following:

- Evidence that the area within the proposed expansion area boundary is nationally or locally known by the name of the established AVA;
- An explanation of the basis for defining the boundary of the proposed expansion area;
- A narrative description of the features of the proposed expansion area affecting viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed expansion area similar to the established AVA and distinguish it from adjacent areas outside the established AVA boundary;
- The appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed expansion area, with the boundary of the proposed expansion area clearly drawn thereon; and
- A detailed narrative description of the proposed expansion area boundary based on USGS map markings.

Online Availability of Documents

All documents and comments discussed below in this final rule, including the petition to expand the Sta. Rita Hills AVA and its supporting documents, the notice of proposed rulemaking (Notice No. 145), and the comments and attached supporting documents received in response to that notice, are available for public viewing within Docket No. TTB–2014–0007 on the ''*Regulations.gov*'' Web site at *http://www.regulations.gov.* A direct link to Docket No. TTB–2014–0007 is available under Notice No. 145 on the TTB Web site at *https://www.ttb.gov/wine/wine-rulemaking.shtml.*

Petition To Expand the Sta. Rita Hills AVA

TTB received a petition from Patrick L. Shabram, on behalf of John Sebastiano Vineyards and Pence Ranch Vineyards, proposing to expand the established Sta. Rita Hills AVA. The Sta. Rita Hills AVA (27 CFR 9.162) was established by T.D. ATF–454, published in the **Federal Register** on May 31, 2001 (66 FR 29476).[1]

The Sta. Rita Hills AVA, which covers approximately 33,380 acres, is located in Santa Barbara County, California, between the towns of Lompoc, which lies to the west, and Buellton, which lies to the east. The Sta. Rita Hills AVA and the proposed expansion area are located within the Santa Ynez Valley AVA (27 CFR 9.54), which is entirely within Santa Barbara County. The Santa Ynez Valley AVA is within the larger multicounty Central Coast AVA (27 CFR 9.75). The Sta. Rita Hills AVA and the proposed expansion area do not overlap any other established or proposed AVA.

The proposed expansion area is located along the existing eastern boundary of the Sta. Rita Hills AVA. The proposed expansion area contains approximately 2,296 acres and three commercial vineyards, two of which are currently divided by the existing eastern boundary of the AVA. Pinot Noir and Chardonnay are among the varietals of grapes grown in the proposed expansion area. The proposed expansion would move a portion of the AVA's existing eastern boundary approximately one-half mile farther to the east. The new boundary would then be defined by a road within a north-south canyon named ''Cañada de los Palos Blancos,'' which is located west of the city of Buellton. According to the expansion petition, the new boundary would still be within the Santa Rita Hills because a 1906 decision card issued by the U.S. Board on Geographic Names [2] states that the hills extend as far east as the mouth of the canyon.

According to the petition, the climate, topography, soils, and native vegetation of the proposed expansion area are similar to those of the established AVA. The climate of both the proposed expansion area and established AVA is influenced by cool winds and fog that move inland from the Pacific Ocean, providing a climate that is suitable for growing cool-climate wine grapes such as Pinot Noir and Chardonnay. The proposed expansion area and the established AVA contain oak-studded rolling hills of similar elevations. Finally, both the established AVA and the proposed expansion area have soils that contain loam, sand, silt, and clay.

Although the proposed expansion area is more similar to the established Sta. Rita Hills AVA than the surrounding regions, the petition states that the proposed expansion area still shares some of the features of the surrounding Santa Ynez Valley AVA and Central Coast AVA. For instance, the proposed expansion area has elevations and rolling hills similar to those found in portions of the larger Santa Ynez Valley AVA. However, the proposed expansion area lacks the diversity of topography found within the larger Santa Ynez Valley, such as maze-like canyons and broad alluvial plains. The proposed expansion area also shares a marine-influenced climate with the Central Coast AVA and the western portions of the Santa Ynez Valley AVA. However, the proposed expansion area receives less marine-cooled air and fog than the portions of

[1] The Sta. Rita Hills AVA was originally established under the name ''Santa Rita Hills.'' The AVA name was later abbreviated to ''Sta. Rita Hills'' in order to prevent potential confusion between wines bearing the Santa Rita Hills appellation and the Santa Rita brand name used by a Chilean winery. For details, see T.D. TTB–37, published in the **Federal Register** on December 7, 2005 (70 FR 72710).

[2] The United States Board on Geographic Names is a Federal body created in 1890 and established in its present form by Federal law in 1947 to maintain uniform geographic name usage throughout the Federal Government. Sharing its responsibilities with the Secretary of the Interior, the Board promulgates official geographic feature names with locative attributes as well as principles, policies, and procedures governing the use of domestic names, foreign names, Antarctic names, and undersea feature names. See *http://geonames.usgs.gov/* for more information.

the Central Coast AVA closer to the Pacific Ocean and more marine influence than the eastern regions of the Santa Ynez Valley AVA.

Publication of Notice of Proposed Rulemaking (Notice No. 145)

TTB published Notice No. 145 in the **Federal Register** on August 7, 2014 (79 FR 46204), proposing to expand the Sta. Rita Hills AVA. In the notice, TTB summarized the evidence from the petition regarding the name, boundary, and distinguishing features for the proposed expansion area. For a detailed description of the evidence relating to the name, boundary, and distinguishing features of the proposed expansion area, and for a comparison of the distinguishing features of the proposed expansion area to the surrounding areas, see Notice No. 145.

In Notice No. 145, TTB solicited comments on the accuracy of the name, boundary, and other required information submitted in support of the petition. The comment period for Notice No. 145 was originally scheduled to close on October 6, 2014. On August 18, 2014, TTB received a letter from the chairman of the Sta. Rita Hills Winegrowers Alliance (comment 20) requesting a 90-day extension of the comment period in order to allow more time for industry members to submit comments. The letter stated that local grape growers and winemakers were in the process of bottling previous vintages and preparing for harvest and thus did not have time to prepare and submit comments before the close of the comment period.

TTB determined that good cause existed to extend the comment period. Accordingly, TTB published Notice No. 145A in the **Federal Register** on September 3, 2014 (79 FR 52273), which extended the comment period for an additional 60 days. TTB did not extend the comment period for the requested 90 days because the bureau believed that neither Notice No. 145 nor the petition and supporting materials were voluminous or unusually complex, and that a 60-day extension would extend the comment period well past the peak of a typical harvest period. As a result, the comment period for Notice No. 145 closed on December 5, 2014.

Comments Received

In response to Notice No. 145, TTB received a total of 121 comments. Of these, TTB posted 117 comments for public viewing within *Regulations.gov* docket number TTB–2014–0007 (see *http://www.regulations.gov/).* TTB did not post three anonymous comments and one duplicate comment. As noted in Notice No. 145, TTB has a policy of not accepting anonymous comments.

Of the 117 comments TTB posted to the docket, 91 comments oppose the proposed expansion, and 19 comments support the proposed expansion. TTB also received five comments from the petitioner in defense of his analyses and credentials (comments 17, 29, 47, 102, and 113). In addition, TTB posted one comment requesting an extension of the comment period (comment 20). Finally, TTB posted one comment (comment 91) that responds to claims made in an earlier comment (comment 83), but does not specifically express support for or opposition to the proposed expansion.

Supporting Comments Received

TTB received 19 comments supporting the proposed expansion of the Sta. Rita Hills AVA. Most of these comments assert that the petitioner's evidence demonstrates that the proposed expansion area is similar enough to the Sta. Rita Hills AVA that it should be considered part of the established AVA. These commenters include local vineyard owners and winemakers, a food and wine writer, sommeliers, a soil and plant nutrition consultant, and wine consumers. Of the 19 supporting comments, 18 provide anecdotal evidence, and 1 offers non-anecdotal evidence in the form of a chemical analysis of grapes grown within the AVA and grapes grown on the commenter's property within the proposed expansion area.

Opposing Comments Received

TTB received 91 comments from 88 individual commenters who oppose the expansion of the Sta. Rita Hills AVA. The commenters include local residents, local vineyard and winery owners, food and wine writers and bloggers, vineyard managers and consultants, the president of the Lompoc Valley Chamber of Commerce and Visitors Bureau, sommeliers, and the Sta. Rita Hills Winegrowers Alliance. Three of the 88 commenters submitted 2 comments each, including the Sta. Rita Hills Winegrowers Alliance (SRHWA), which sent in a link to a video presentation as well as a large package of documents that contains statements and reports from several experts. TTB considers the package submission from the SRHWA to be a single comment, even though it contains statements and reports from multiple persons writing on behalf of the alliance.

The two most common reasons provided for opposing the proposed expansion of the Sta. Rita Hills AVA are that the proposed expansion area is not known to be part of the area known as Santa Rita Hills and that the proposed expansion area has a different climate. Some of the opposing comments also question the accuracy of the petitioner's data collection methods and analysis.

Discussion of Comments

In the following sections, TTB will provide a detailed discussion of the comments received in response to Notice No. 145 and the bureau's response to the comments.

Name Evidence

Opposing Comments

Forty-one of the opposing comments address the name evidence in the proposed expansion petition. All of these comments state that the proposed expansion area is not a part of the Santa Rita Hills and is instead on an entirely different landmass. Some of the comments describe this landmass as part of the Purisima Hills. The majority, however, state that the proposed expansion area is located within a landmass known as the ''Buellton Flats,'' ''Buell Flats,'' or ''Buell Flat.'' Of the opposing comments that address the name evidence included in the expansion petition, two provide non-anecdotal evidence to support their claims (comments 97 and 116).

The SRHWA submitted comment 97, a detailed comment which addresses, among other things, the name evidence provided in the expansion petition. The comment claims although the expansion petition's name evidence is largely based on a 1906 U.S. Board on Geographic Names decision card that defined the boundaries of the Santa Rita Hills, the decision card was essentially revoked by a 1907 USGS bulletin on oil resources in Santa Barbara County. One of the two authors of the bulletin was Ralph Arnold, the paleontologist listed on the 1906 decision card as the ''authority'' who submitted the request to the U.S. Board on Geographic Names. The bulletin describes the Santa Rita Hills as extending as far east as ''nearly to the edge of the Santa Rosa [land] grant.'' The comment asserts that by this definition, the Santa Rita Hills would not extend as far east as the proposed expansion area and would, instead, end within the current boundaries of the Sta. Rita Hills AVA.

Comment 97 also states that USGS Geographic Names Information System, which provides a link to the 1906 decision card, provides three sets of latitude and longitude coordinates relating to the Santa Rita Hills. The comment claims that when mapped, these coordinates ''place the easternmost point of the Santa Rita Hills

just west of Mail Road,'' which is within the current AVA boundaries and approximately 2.5 miles west of the proposed expansion area. The comment asserts that this is further evidence that the proposed expansion area cannot be known as ''Sta. Rita Hills'' because the Santa Rita Hills do not extend into the proposed expansion area.

Comment 97 also includes several historical newspaper articles from the Lompoc Record and asserts that these articles demonstrate that the proposed expansion area is located in a region called the ''Buellton Flats'' or ''Buell Flat(s).'' According to the comment, these two terms are used to describe all of the lands historically owned by the Buell family, including ''the entire Rancho de San Carlos de Jonata, [and] the Canada [sic] de los Palos Blancos . . . .'' The comment concludes that, by this description, the proposed expansion area is located in an area that was historically known as ''Buell Flat'' because the proposed expansion area is within the San Carlos de Jonata land grant, and the Cañada de los Palos Blancos forms the eastern edge of the proposed expansion area.

Another comment (comment 116) also challenges the expansion petitioner's interpretation of the 1906 decision card issued by the U.S. Board on Geographic Names. Although the decision card states that the Santa Rita Hills extend to the ''mouth of the Cañada de los Palos Blancos,'' the commenter asserts that the term ''mouth'' does not refer to the mouth of the canyon, which is located just north of State Highway 246. Instead, the commenter believes that ''mouth'' refers to the point where the seasonal creek that runs through the canyon enters the Santa Ynez River. The creek curves to the west as it exits the canyon and joins with the river south of State Highway 246, outside both the proposed expansion area and the current AVA boundary. The commenter also states that the geological feature known as the Santa Rita Syncline ''separates the Santa Rita Hills from the Purisima Hills'' and follows the path of State Highway 246. The commenter states that, by his interpretation of the 1906 decision card, the Santa Rita Hills do not extend as far east as the actual canyon known as the Cañada de los Palos Blancos, which forms the eastern boundary of the proposed expansion area, nor do the hills extend north of the geological feature known as the Santa Rita Syncline.

The commenter also concludes that, using his definition of the boundaries of the actual Santa Rita Hills, none of the three vineyards located either entirely or partially within the expansion area are planted on the geological feature known as the Santa Rita Hills. The commenter asserts that the two vineyards planted north of State Highway 246 are planted on a ridge that ''buttresses the Purisima Hills,'' and the third vineyard, which is located south of both State Highway 246 and the junction of the creek and the Santa Ynez River, is planted in the Santa Rosa Hills. Because none of the three vineyards within the proposed expansion area are planted on the geological feature known as the Santa Rita Hills, the commenter claims that the expansion petition does not meet the name evidence requirements to say that the proposed expansion area is known as the ''Sta. Rita Hills.''

Finally, comment 97 includes a report by an expert in land titles which examines the historical land records of a man named Charles Lewis. The report shows that in 1910, Mr. Lewis obtained a parcel of land consisting of 550.89 acres cut from the Santa Rosa land grant. The parcel includes the present-day Pence Ranch vineyard, which is located within the proposed expansion area. Mr. Lewis' ranch house still stands on the Pence Ranch property and is shown on the USGS Solvang quadrangle map and on a 1919 map (included in comment 97) just north of present-day State Highway 246. The title expert's report then references a September 1913 article from the Lompoc Record that describes Mr. Lewis travelling from ''his Buell Flat ranch'' to Lompoc. The report concludes that because Mr. Lewis' property included a large portion of the proposed expansion area, the term ''Buell Flat'' applies to the proposed expansion area.

Supporting Comments

One of the 19 comments submitted in support of the proposed AVA expansion addresses the question of name evidence (comment 115). The commenter states that although many of the opposing comments claim the proposed expansion area is known as either ''Buell Flats'' or ''Buellton Flats,'' the only reference to those terms of which she is aware is a reference to an area east of Buellton, several miles beyond the proposed expansion area. TTB notes that the commenter did not provide any evidence to support her claim of the location of a region known as ''Buell Flats'' or ''Buellton Flats.''

In response to the comments challenging the name evidence in the expansion petition, the petitioner, Patrick Shabram, submitted two additional comments (comments 102 and 113). In comment 102, Mr. Shabram addresses the claims in comment 76 that the proposed expansion area extends into an area called the ''Buell Flat.'' Mr. Shabram provided anecdotal evidence that the proposed expansion area is not known as ''Buell Flat'' in the form of a statement by the current owner of Buell Ranch, who indicated the ''Buell Flat'' was never considered to extend west of Buellton. Instead, the ranch owner described ''Buell Flat'' as being ''on either side of [State Highway] 246 from Ballard Canyon to about Neilson Supply,'' which is a building supply store in Solvang.

Finally, in comment 113, Mr. Shabram provides additional evidence to demonstrate that the proposed expansion area is associated with the name ''Sta. Rita Hills.'' A 2013 article from the Santa Barbara Independent newspaper describes a wine tasting festival in Solvang, which included wine from Pence Ranch, one of the vineyards within the proposed expansion area. The article describes the vineyard as being located ''on the eastern edge of the Sta. Rita Hills [sic].'' An advertisement for the 2013 PinotFest in Pasadena features ''the Best of Pinot Noir from Sta. Rita Hills'' and lists Pence Ranch as one of the featured wineries. Finally, a brochure from Dragonette Cellars describing their 2011 Sta. Rita Hills-labeled Pinot Noir notes that 12 percent of the grapes used to make the wine are from Pence Ranch, and that all the grapes used in the wine were selected for their ''ability to add unique but complementary characteristics to the final blend.'' According to Mr. Shabram, the article and the festival advertisement both demonstrate that the Pence Ranch is currently associated with the Sta. Rita Hills AVA, even though it is not within the AVA. Furthermore, Mr. Shabram believes the brochure from Dragonette Cellars shows that the quality and characteristics of the Pinot Noir grapes grown within the proposed expansion area are similar enough to Pinot Noir grapes grown within the AVA that they may be blended with AVA-grown fruit.

TTB Analysis

TTB has carefully reviewed all of the comments that address the issue of name evidence. TTB has also reviewed the regulatory history of the Sta. Rita Hills AVA to ensure that its determination regarding the name evidence for the proposed expansion area is consistent with the previous rulemaking, namely T.D. ATF–454.

TTB notes that the majority of the opposing comments solely provided anecdotal evidence to support their claims that the proposed expansion area is located in a region known as the

''Buellton Flats,'' ''Buell Flat,'' or ''Buell Flats.'' Although the expansion petitioner includes a statement from the current owner of Buell Ranch in the expansion petition and his two additional comments, stating that the ranch owner considers the ''Buell Flat'' to be located between the cities of Buellton and Solvang, this is also anecdotal evidence. Section 9.12(a)(1)(ii) of the TTB regulations (27 CFR 9.12(a)(1)(ii)) states that ''anecdotal information by itself is not sufficient'' to demonstrate name usage, and that evidence from sources independent of the petitioner, such as newspaper or magazine articles, books, or maps, must also be provided. Therefore, TTB cannot determine the exact location of a region historically or currently known as the ''Buellton Flats,'' or ''Buell Flat(s),'' or if the region contains the proposed expansion area, based solely on the anecdotal evidence provided by the commenters.

With regard to the articles referencing ''Buell Flat(s)'' which were included in comment 97, TTB notes that the articles all date to 1920 or earlier. Section 9.12(a)(1) requires evidence to show that the name is ''currently and directly'' associated with the area of the AVA. Nevertheless, TTB has examined the historical articles and has determined that their descriptions of the location of ''Buell Flat(s)'' are too vague or broad to state conclusively that the proposed expansion area was located within the area known by that name. For these reasons, TTB has determined that the historical articles do not conclusively demonstrate that the proposed expansion area is in an area currently or historically known as ''Buell Flat(s).''

TTB has also carefully considered the land title expert's analysis of the property records of Charles Lewis, which was included in comment 97. TTB agrees with the title expert's findings that the present-day Pence Ranch was once owned by Mr. Lewis, who was referred to in the 1913 newspaper article as living on a ''Buell Flat ranch.'' However, the 1910 survey map included with the title expert's analysis does not include any reference to ''Buell Flat'' and refers to various portions of the parcel of land owned by Mr. Lewis as ''Hill Land,'' ''Palos Blancos Flat,'' and ''Bottom Land.'' Therefore, TTB believes that the region of the proposed expansion area has been referred to by various names over time and was not known exclusively as ''Buell Flat,'' even at the time the land was owned by Mr. Lewis. Finally, TTB notes that the analysis does not provide evidence that the proposed expansion area is currently known as ''Buell Flat,'' as required by § 9.12(a)(1) of the TTB regulations.

TTB disagrees with the assertion in comment 97 that the 1906 U.S. Board on Geographic Names decision card was revoked the following year by the 1907 USGS bulletin. Although the 1907 bulletin does not describe the eastern edge of the Santa Rita Hills in the same manner as the 1906 decision card, the bulletin does not affect the decision card. If the description of the Santa Rita Hills in the bulletin had been intended to officially replace the description in the 1906 decision card, then the Board would have issued a second card noting the new decision. However, no such card was provided to TTB during the comment period, so TTB does not consider the 1907 bulletin to have officially revoked or amended the 1906 decision card. Because TTB finds no evidence that the decision card was officially revoked or amended, TTB considers the card's definition of the Santa Rita Hills to be current, even though the decision was made in 1906.

TTB also disagrees with the interpretation of the three sets of coordinates attributed to the Santa Rita Hills in the USGS Geographic Names Information System (GNIS). TTB does not believe that these coordinates are intended to demarcate the edges of the Santa Rita Hills. Instead, TTB believes these coordinates are intended to help map users locate the hills on each of the three USGS quadrangle maps on which they appear. On the GNIS Web site, each of the sets of coordinates is specifically linked to one of these three USGS quadrangle maps. When plotted on its specific map, each set of coordinates corresponds to a point within the hills, usually a point roughly in the middle of the printed words ''Santa Rita Hills.'' TTB agrees that the easternmost set of these coordinates, which is a point on the Santa Rosa Hills quadrangle map, corresponds to a point within the current AVA boundary that is west of Drum Canyon. However, TTB does not agree that this set of coordinates is intended to show the easternmost edge of the Santa Rita Hills, because the printed words ''Santa Rita Hills'' clearly continue east of Drum Canyon and onto the landmass that includes both the AVA's current eastern boundary and the proposed expansion area.

TTB also finds no conclusive evidence to support the claim in comment 116 that the ''mouth'' mentioned in the 1906 decision card refers to the junction of the Santa Ynez River and the intermittent creek that runs through the Cañada de los Palos Blancos. Even if TTB was to use this interpretation, a portion of the Santa Rita Hills would still be within the proposed expansion area. Under the definition of ''mouth'' offered in comment 116, the landmass that includes both the current eastern boundary of the Sta. Rita Hills AVA and the proposed expansion area would contain portions of two separate ranges: the portion of the landmass that is north of the Santa Rita Syncline (which follows the path of State Highway 246) would be in the Purisima Hills, and the portion south of the syncline would be in the Santa Rita Hills. TTB notes that the portion of the landmass that is south of the syncline extends into the proposed expansion area. Therefore, even if TTB were to use the definition of the ''mouth'' of the canyon used in comment 116, a portion of the Santa Rita Hills would still be within the proposed expansion area.

Additionally, comment 116 places the Santa Rita Syncline within the proposed expansion area, following the path of State Highway 246. TTB notes that the Santa Rita Syncline also runs through the Sta. Rita Hills AVA and was used in the original AVA petition as evidence to support the name ''Santa Rita Hills'' (later ''Sta. Rita Hills''). Therefore, the existence of the syncline within the proposed expansion area further supports the expansion petition's claim that the proposed expansion area is associated with the AVA name.

TTB also disagrees with the assertion in comment 116 that all three vineyards within the proposed expansion area must be planted on the actual Santa Rita Hills in order for the proposed expansion area to qualify to use the name. Section 9.12(a)(1) of the TTB regulations only requires that the name be ''currently and directly associated with an area in which viticulture exists.'' TTB does not require vineyards to be planted on the geographical feature that gives its name to the region. For example, no vineyards are planted in any of the creeks and rivers that give their names to numerous AVAs. Furthermore, TTB notes that many of the vineyards already within the Sta. Rita Hills AVA are not planted on the geographical feature known as the Santa Rita Hills and are, instead, planted in the Santa Rita Valley, along the floodplains along the Santa Ynez River, or on the foothills of the Purisima and Santa Rosa Hills.

TTB has determined that evidence provided by Mr. Shabram in comment 113 provides additional support for the claim that the proposed expansion area is known as the ''Sta. Rita Hills.'' TTB believes that the article from the Santa Barbara Independent that describes Pence Ranch as being located on the

''edge of the Sta. Rita Hills'' demonstrates that wine critics associate the vineyards and wineries within the proposed expansion area more with the Sta. Rita Hills AVA than with the larger, surrounding Santa Ynez Valley AVA. The advertisement for the Pasadena PinotFest includes Pence Ranch in its list of Sta. Rita Hills AVA wineries, even though Pence Ranch is not located within the AVA's boundaries and its wines are not labeled with the appellation. Pence Ranch's inclusion in the festival strongly suggests wine community members and consumers associate the proposed expansion area with the AVA.

However, TTB does not believe that the brochure from Dragonette Cellars provides additional name evidence, even though grapes from Pence Ranch are specifically included in the Sta. Rita Hills-labeled wine, because TTB regulations allow up to 15 percent of the grapes from an AVA-labeled wine to come from outside the AVA. The brochure does not claim that 100 percent of the grapes in the wine are from within the Sta. Rita Hills AVA, and only 12 percent of the grapes in the wine are specifically attributed to Pence Ranch.

Finally, TTB notes that the presence within the proposed expansion area of geographical features with names other than ''Santa Rita Hills,'' such as the Purisima Hills or the Buellton/Buell Flat(s), does not preclude the proposed expansion area from also being known as the ''Sta. Rita Hills.'' TTB notes that the Sta. Rita Hills AVA currently includes several geographical features known by other names, including the Santa Rita Valley, the Santa Ynez River, Drum Canyon, and the foothills of both the Purisima Hills and the Santa Rosa Hills.

In conclusion, TTB has determined that the evidence included in the opposing comments does not sufficiently demonstrate that the proposed expansion area does not contain a portion of the geographical feature known as the Santa Rita Hills. Additionally, TTB has determined that the evidence included in any of the opposing comments does not conclusively show that the region of the proposed expansion area is not known at the ''Sta. Rita Hills'' or is currently referred to solely as the ''Buellton Flats'' or ''Buell Flat(s).'' Therefore, taking into account the name evidence described in both the original AVA petition and T.D. ATF–454, TTB concludes that the name evidence provided in the expansion petition and supplemented by the evidence provided in comment 113 is sufficient to demonstrate that the proposed expansion area is known by the name ''Sta. Rita Hills.''

Topography and Native Vegetation

Opposing Comments

TTB received 23 comments that argue that the topography of the proposed expansion area is markedly different from the established Sta. Rita Hills AVA. Several of the comments state that the current eastern boundary of the AVA was placed at the point where the hills change orientation from east-west (within the AVA) to north-south (within the proposed expansion area). For example, comment 97 includes a letter stating that the proposed expansion area was excluded from the AVA because ''it deviates from the orientation of the existing AVA into the unique Santa Rita Hills and its surrounding valleys.'' The letter asserts that the proposed expansion area is oriented towards the city of Buellton and is therefore ''fundamentally and uniquely different'' from the AVA. Other comments state that the proposed expansion area contains significant expanses of flat land that are different from the terrain within the AVA. For instance, comment 45 states that the AVA contains ''tight valleys,'' whereas the proposed expansion area is in the ''vast open plain'' beyond the eastern AVA boundary. Additionally, comment 89 claims that the proposed expansion area ''is actually in the flat lands east of the Santa Rita Hills.''

Two opposing comments include non-anecdotal evidence (comments 76 and 111) to support the claims that the topography of the proposed expansion area differs from that of the Sta. Rita Hills AVA. Comment 76 includes a link to a video created by the SRHWA that compares the topography of the Sta. Rita Hills AVA to that of the proposed expansion area and the region farther east. The video describes the AVA as a ''transverse valley'' marked by parallel hills that run east-west, while the region east of the AVA has hills that are aligned north-south. The video states that the current eastern boundary of the AVA follows a high ridgeline ''over 1,000 feet high'' that is ''close to 800 feet above the Buell Flats valley floor'' and marks the point where the orientation of the hills changes. The video also asserts that, ''It is important to note that the watershed east of the ridgeline [outside of the Sta. Rita Hills AVA] drains into the Buell Flats.'' Comment 111 includes a wide-angle aerial photograph looking west into the Sta. Rita Hills AVA. The current Sta. Rita Hills eastern boundary and a portion of the proposed expansion area are marked on the photo. The commenter asserts that one can tell from the photo that the Sta. Rita Hills AVA and the proposed expansion area are ''two different landmasses, two different drainages, and exposures.''

Three comments also oppose the proposed expansion based on the native vegetation of the proposed expansion area. Comment 103 describes the proposed expansion area as ''windswept grasslands,'' whereas the Sta. Rita Hills is covered with ''majestic oaks.'' Comment 97 and comment 111 both include copies of a report from an environmental services company. The report is described as a ''peer review'' of the expansion petition and focuses on the petition's description of the climate and native vegetation of the proposed expansion area. The report states that the expansion petition significantly undercounted the number of valley oaks in the region between U.S. Highway 101 and the eastern boundary of the AVA, including those valley oaks located within the proposed expansion area. The environmental services company conducted its own survey of oak trees in the eastern portion of the AVA, between Drum Canyon/Mail Road and the eastern boundary. The report claims that at three locations within in the survey area, valley oaks comprised less than one percent of the oaks present at each location. However, at the fourth location, which was ''at or near the AVA's eastern boundary,'' valley oaks comprised approximately 50 percent of the oaks present, suggesting ''an abrupt change'' at the ridgeline that forms the boundary between the AVA and the proposed expansion area ''to a climate that is significantly more favorable to valley oak'' than to live oak.

Supporting Comments

TTB received three comments in support of the proposed expansion area that specifically mentioned its topography. According to the three comments, the proposed expansion area and the AVA both contain similar topography. Comment 23 asserts that ''the mesa part of the vineyard [within the proposed expansion area] is not dissimilar to other vineyards on flat ground'' within the Sta. Rita Hills AVA. Comment 33 argues that the proposed expansion area is not on a separate landmass from the AVA because it is on the same hillside as the current AVA's eastern boundary. Finally, comment 109 claims that the proposed expansion area is not flat and low-lying, as many opposing comments claim, but is ''of a higher elevation and with steeper slopes than much of the existing AVA terrain.''

The expansion petitioner, Mr. Shabram, submitted three comments

further describing the topography of the proposed expansion area (comments 17, 29, and 102). Comment 17, submitted in response to several opposing comments that claim the proposed expansion would extend the AVA significantly to the east and beyond the influence of the marine air, includes a map showing the location of the Sta. Rita Hills AVA and the proposed expansion area, as well as the distance to the ocean from both regions. Mr. Shabram asserts that the map shows the proposed expansion area would not extend the AVA substantially farther from the ocean. Comment 29, submitted in response to comments claiming that the proposed expansion area is flatter than the AVA, contains a map showing the slope angles of both the proposed expansion area and the AVA, which Mr. Shabram asserts are similar.

In comment 102, Mr. Shabram responds to the video included in comment 76. Mr. Shabram first notes that although the video states that the Sta. Rita Hills AVA is a transverse valley, the satellite images in the video show that the transverse valley is not limited to the AVA but in fact extends from the Pacific Ocean through the AVA and the proposed expansion area and ends at a point ''well east'' of the city of Buellton. Mr. Shabram then disputes the video's claim that the AVA's eastern boundary is formed by a ridgeline with elevations over 1,000 feet. Mr. Shabram asserts that the boundary is not a true ridgeline but ''the eastern edge of the Santa Rita Valley or a narrowing of the gap between the Purisma [sic] Hills and the Santa Rita/Santa Rosa Hills.'' Mr. Shabram further states that the highest point along the eastern AVA boundary is an ''unnamed hill of 1,063 feet upon which John Sebastiano Vineyards sit. Some of the vineyards on this hill are in the Sta. Rita Hills AVA, some are outside.'' Although this hill's elevation is over 1,000 feet, Mr. Shabram observes that the highest point along State Highway 246 is only 557 feet, as shown on the USGS maps. The highway connects the AVA and the proposed expansion area and follows a natural wind gap in the mountains. Because the diurnal inversion layers in Santa Barbara County typically reach as high as 900 feet, Mr. Shabram concludes that this wind gap, which is approximately 160 feet above the valley floor adjacent to the west, is not so high as to block marine air and fog from entering the proposed expansion area. Finally, Mr. Shabram states that although the video claims that it is important that the region east of the current AVA, including the proposed expansion area, drains into the ''Buell Flats,'' both the AVA and the proposed expansion area are part of the larger Santa Ynez River watershed.

TTB Analysis

TTB has carefully reviewed all of the comments that address the issue of topography and native vegetation. TTB has also reviewed the regulatory history of the Sta. Rita Hills AVA to ensure that its determination regarding the topographical and native vegetation evidence for the proposed expansion area is consistent with the previous rulemaking.

T.D. ATF–454 describes the topography of the AVA as ''an oak studded, hill-laden maritime throat that runs east to west, a few miles east of Lompoc to a few miles west of the Buellton Flats'' and is ''isolated geographically'' by the Santa Rosa Hills to the south and the Purisima Hills to the north. These two east-west oriented ranges ''frame the interior of the Santa Rita Hills [sic] AVA.'' TTB notes that the importance of the AVA's orientation was that it allows marine-influenced air to enter the AVA and moderate the climate.

TTB has determined that the opposing comments do not provide sufficient evidence to demonstrate that the topography of the proposed expansion area is different from that of the existing Sta. Rita Hills AVA. The topographical maps provided with the expansion petition, as well as the slope angle map submitted by Mr. Shabram in comment 17, demonstrate that the proposed expansion area is a region of hillsides similar to those found in the Sta. Rita Hills AVA.

TTB disagrees that the aerial photograph included in comment 111 shows that the terrain of the proposed expansion area is different. The AVA's current eastern boundary is marked on the photo, and State Highway 246 is visible, which makes it possible to identify the proposed expansion area. TTB notes that the hilly terrain of the proposed expansion area, located to the right of the highway in the photo, resembles the hillsides within the AVA. The flat floodplain of the Santa Ynez River, which is prominent in the foreground of the photo, is not within the proposed expansion area. Furthermore, nothing in T.D. ATF–454 excludes valleys, floodplains, or other flat lands from the AVA. In fact, TTB notes that T.D. ATF–454 states that ''viticultural viability'' within the AVA was determined by, among other factors, the presence of both ''hillside and alluvial basin plantings.''

With regard to the comments that claim the proposed expansion area should be excluded from the Sta. Rita Hills AVA because it is not part of the east-west maritime throat that defines the AVA, TTB believes that the proposed expansion area is part of the east-west oriented ranges described in the original petition as ''framing'' the AVA. The proposed expansion area sits on the eastern side of the same landmass that forms the AVA's current eastern boundary, meaning that the western slopes of this landmass are already within the AVA. TTB does not believe that any of the comments contain sufficient evidence to demonstrate that the eastern slopes of this landmass are topographically different from the western slopes, which are within the AVA.

TTB does agree that the eastern slopes of the landmass do face away from the interior of the AVA and the Santa Rita Hills. However, TTB notes that T.D. ATF–454 does not exclude all slopes that face away from the interior of the AVA. Currently, there are slopes along the canyons and creek valleys within the AVA that face east or west and not north or south into the interior of the AVA. Therefore, TTB does not believe that slope orientation should prevent the proposed expansion area from being included in the Sta. Rita Hills AVA.

After reviewing the video included in comment 76, TTB does not believe that the video demonstrates any significant topographical difference between the proposed expansion area and the Sta. Rita Hills AVA. TTB does agree that the topography of the vineyards near Buellton and Solvang, which are shown in the video, appears different from the AVA. However, none of these vineyards are within the proposed expansion area. TTB also notes that, while the region east of the current AVA boundary may drain away from the Santa Rita Hills, all the creeks within the AVA and the proposed expansion area eventually drain into the Santa Ynez River. Although T.D. ATF–454 mentions that the AVA has a different drainage than the Lompoc basin, to the west, there is no discussion of any differences in drainage between the AVA and the region to the east, where the proposed expansion area is located. In fact, T.D. ATF–454 states that the ''Santa Rita Upland Basin,'' located within the AVA, is in ''hydrologic continuity'' with the ''Buellton Upland Basin.'' TTB notes that a map included in the original Sta. Rita Hills petition as Exhibit 3 shows that the ''Buellton Upland Basin'' covers an area that includes both the eastern portion of the AVA and the proposed expansion area. Therefore, TTB does not

consider hydrologic features to distinguish the AVA from the region to the east, including the proposed expansion area.

With regard to the comments on the native vegetation within the proposed expansion area, TTB believes that the report from the environmental services company contained in comments 97 and 111 suggests the description of the native vegetation in the expansion petition may be inaccurate. The report asserts that valley oaks are more common within the proposed expansion area than the expansion petition claims. However, both the report and the expansion area concur that oak trees, in general, do grow in both the AVA and the proposed expansion area. TTB also notes that T.D. ATF–454 states that the AVA is ''oak studded'' but does not distinguish between valley oaks and coastal live oaks. Therefore, although TTB agrees that the expansion petition's estimate of the number of valley oaks versus live oaks found within the proposed expansion area may not be accurate, the presence or absence of a specific species of oak is not a distinguishing feature of the AVA. TTB has also determined that the expansion petition contains enough other evidence to demonstrate the similarity between the proposed expansion area and the AVA to allow the expansion petition's native vegetation evidence to be excluded from consideration.

Climate

Opposing Comments

TTB received 45 comments opposing the proposed expansion based on climate. The majority of these opposing comments state that the proposed expansion area is warmer than the AVA because the ridgeline that forms the current eastern boundary of the AVA prevents most, if not all, of the cool marine air and fog from travelling farther east. For example, many of the opposing comments claim that as one travels east along State Highway 246, the temperature becomes noticeably warmer after crossing the eastern boundary of the AVA. Some of the comments claim that it is evident that the proposed expansion area has a warmer climate than the AVA because different vegetables and berries are grown in the proposed expansion area (comment 53) or because bud break and harvest occur earlier in the proposed expansion area (comments 81, 87, and 105). Another comment, comment 116 claims, ''An average daily high temperature of less than 80 degrees and an abundance of sunshine is the factor that distinguishes the Sta. Rita Hills AVA from all others,'' and that the proposed expansion area's daily highs are warmer than 80 degrees. Other comments question the petitioner's data collection methods, claiming that the petitioner ''cherry-picked'' temperature data to make it appear as though the proposed expansion area's climate is similar to the AVA (comment 44), and that the petitioner should have used an eastern comparison point closer to the proposed expansion area than Ballard Canyon (comments 86 and 97).

Three of these opposing comments provide non-anecdotal evidence (comments 76, 97, and 111). For example, the video in comment 76 includes footage of fog covering the AVA, while the vineyards in the proposed expansion area are fog-free. The video states that the absence of fog over the proposed expansion area demonstrates that the ridgeline forming the AVA's eastern boundary prevents marine-influenced fog and air from moving farther east. Comment 97 also refers to this video as evidence that marine air does not enter the proposed expansion area.

Additionally, comment 97 asserts that the climate data in the expansion petition ''cannot be considered adequate or credible evidence to establish that the original petitioners were incorrect or incomplete in their analysis of the distinctive climate of the AVA . . . .'' The comment asserts that it is inappropriate for the expansion petition to use a weather station in the Ballard Canyon AVA to demonstrate that the proposed expansion area's climate is more similar to the Sta. Rita Hills AVA than the region east of the proposed expansion area because Ballard Canyon is ''over 6 miles away and separated by a mountain range . . . .'' Furthermore, the comment asserts that the expansion petition should not have used comparison data from a region that is already within an established AVA because, ''[w]hen TTB established the Ballard Canyon AVA, the agency recognized the area as viticultural [sic] distinct from the surrounding areas. The petitioners have simply stated the obvious truth of what TTB determined–the areas outside Ballard Canyon AVA are not like Ballard Canyon AVA.''

Comment 97 also states that the Web site from Pence Ranch, which is a vineyard within the proposed expansion area, provides additional evidence that the climate of the proposed expansion area is different from that of the Sta. Rita Hills AVA. The Pence Ranch Web site notes that the vineyard is contemplating, in the words of the commenter, ''graft[ing] an acre of Pinot Noir vines to Gamay (not one of the Burgundian varietals that the AVA is known to grow so successfully) . . . .'' The Web site also includes a photo showing a neighboring vineyard within the AVA ''nestled in fog,'' while the Pence Ranch vineyard is sunny. The letter suggests that the absence of fog in the photo of the Pence Ranch vineyard along with the vineyard owner's plans to graft Pinot Noir vines onto a varietal not currently grown in the Sta. Rita Hills AVA demonstrate that the proposed expansion area has a different climate.

Comment 97 also includes a report from Dr. Deborah Elliott-Fisk, Professor Emeritus of Geography, Ecology, and Wildlife, Fish and Conservation Biology at the University of California, Davis. In her report, Dr. Fisk critiques the climate data provided in the expansion petition. Dr. Fisk commissioned Mark Battany, the University of California Cooperative Extension Viticulture Farm Advisor for Santa Barbara and San Luis Obispo counties, to provide an analysis of data from weather stations placed in vineyards throughout Santa Barbara County. These weather stations include stations that Dr. Fisk asserts correspond to stations used in the expansion petition, as well as several stations she describes as being ''just outside'' of the Sta. Rita Hills AVA. Dr. Fisk states that Mr. Battany's climate analysis used two different methods to calculate growing degree days (GDDs), and the results were converted into isotherm maps that show the climate patterns in the county. According to Dr. Fisk, the results of the analysis demonstrate that the proposed expansion area is consistently warmer than the AVA, and the isotherm maps show that the transition to warmer temperatures occurs at the current eastern boundary of the AVA. Dr. Fisk also claims that when comparing Mr. Battany's GDD data to the GDD data in the expansion petition, ''none of the numbers match . . . .'' As a result, Dr. Fisk concludes that the climate data in the expansion petition is inaccurate and that the petitioner's data collection methods and analysis methods were faulty.

Finally, comment 97 and comment 111 both also include the same report from the environmental services company that was previously discussed in the ''Topography and Native Vegetation'' section of this document. The report critiques a map included in the expansion petition that illustrates the flow of wind through the AVA and into the proposed expansion area. The report asserts that the map provides an inaccurate description of the wind patterns, and that the winds move at different speeds as they are constricted

at the bend in the Santa Ynez River near the current eastern boundary. The report states that ''given the lack of empirical evidence, these conclusions [should] be considered as an untested hypothesis.'' The report also critiques the climate data provided in the expansion petition, claiming that the data is insufficient because it was collected for too short of a time period. Furthermore, the report asserts that the expansion petition did not provide any information as to the model of the weather stations used to gather the data, how they were calibrated, or where they were placed with respect to ''slope, aspect, orientation, land-cover, vegetation, and nearby structures.''

The environmental services company's report provides its own wind and temperature models to support the assertion that the proposed expansion area has a different climate than the AVA. The report's wind models were derived from a ''48-hour hindcast of a sea breeze circulation over Santa Barbara County on July 4th, 2009, using the Weather Research Forecasting Model (WRF) from the National Center for Atmospheric Research.'' The temperature models show day and night cloud cover and land surface temperatures for the period between April and October from 2003 to 2013. The report states that these models demonstrate that the wind patterns shown on the map in the expansion petition are inaccurate, and that the ''region of the proposed AVA expansion . . . is several degrees warmer, on average,'' than the Sta. Rita Hills AVA.

Supporting Comments

Eleven comments supporting the proposed expansion specifically mention climate. These comments all essentially state that the proposed expansion area's climate is similar to that of the Sta. Rita Hills AVA, with cooling marine breezes and fog. Two of these comments also claim that bud break and harvest within the proposed expansion area occur at approximately the same time as in the AVA (comments 23 and 110). TTB notes that none of these supporting comments provide non-anecdotal evidence to support their claims.

In response to comments questioning the climate data in the expansion petition, Mr. Shabram submitted two comments (comments 102 and 113). In comment 102, Mr. Shabram responds to the video included in comment 76. First, Mr. Shabram states that, contrary to the claim made in the video, marine air flows inland much farther than the current eastern boundary of the Sta. Rita Hills AVA and extends at least to the Ballard Canyon AVA. Mr. Shabram states that the ridgeline that forms the current eastern boundary of the AVA is not too high to prevent the marine air and fog from entering, particularly since the rise along State Highway 246 has an elevation of 557 feet, which is only approximately 160 feet above the floor of the adjacent valley within the AVA. Mr. Shabram also states that the narrowing of the mountains at the point of this rise actually increases the speed of the wind into the proposed expansion area, instead of slowing or stopping it. Finally, Mr. Shabram states that the footage showing fog over the AVA but not over the proposed expansion area is inconclusive, as the video provides no information about the time of day when the footage was shot, and one ''momentary shot is by no means telling of an entire growing season.'' Furthermore, Mr. Shabram speculates that the fog shown in the video is not marine fog but radiation fog, which is the result of cool air draining into the Santa Ynez River valley.

In comment 113, Mr. Shabram responds to critiques of the climate data he provided in the expansion petition. Mr. Shabram again asserts that the current eastern boundary of the AVA does not block marine air from travelling farther east but instead acts as a funnel to increase the speed of marine breezes, propelling them into the proposed expansion area. As evidence, Mr. Shabram provides wind speed data from Pence Ranch vineyards, within the proposed expansion area, and compares the data to wind speed data collected in the city of Lompoc, which is approximately two miles west of the Sta. Rita Hills AVA and receives unobstructed winds from the Pacific Ocean. The data shows that the maximum wind speeds in the proposed expansion area are significantly higher than those in Lompoc, even though the proposed expansion area is farther from the ocean and on the eastern side of the ridgeline. As additional evidence that fog can enter the proposed expansion area, Mr. Shabram included a link to a recent video of workers harvesting grapes at Pence Ranch, which shows fog shrouding the vineyard.

Mr. Shabram then addresses the report from Dr. Fisk in comment 97 by providing more information on the models of weather stations he used to collect his climate data, along with photographs of the stations. He states that he used the Ballard Canyon AVA as a comparison point because he was unable to find a weather station closer to the proposed expansion area that had complete data sets. Mr. Shabram notes that while several of the stations used in Dr. Fisk's report are near the stations used in the expansion petition, only one of the weather stations is actually the same station used in the expansion petition: Station 26, located in the southeastern corner of the AVA, is the same station referred to as Station E in the expansion petition. None of the stations used in Dr. Fisk's report are located within the proposed expansion area. Mr. Shabram also states that the weather stations that Dr. Fisk described as being ''just outside'' the Sta. Rita Hills AVA are in fact several miles away, with the closest (Station 23) located along U.S. Highway 101 in Buellton and the next closest station appearing to be within the Ballard Canyon AVA.

Finally, Mr. Shabram clarified the method he used to calculate GDDs, which is different from the two methods used in Dr. Fisk's report. One of the methods in the report used an average of only the daily maximum and daily minimum temperatures, while the second method used a daily average temperature that was calculated using temperatures gathered every 15 minutes. Both of these methods set the minimum for the temperatures used to calculate the daily average at zero, and the temperatures were measured in degrees Celsius. By contrast, Mr. Shabram's GDD calculation method used the average of the daily maximum high and daily minimum low temperatures measured in degrees Fahrenheit. Furthermore, if the daily minimum low temperature was below 50 degrees Fahrenheit, the minimum temperature needed for grapevine growth and fruit development, Mr. Shabram's method substituted 50 degrees for the minimum temperature. Mr. Shabram states that the differences in the methods used to calculate GDDs would naturally cause differences in the results, and both of the methods used in Dr. Fisk's report would always produce smaller GDD totals than Mr. Shabram's method. Furthermore, using degrees Celsius would also naturally result in smaller GDD totals than using degrees Fahrenheit, regardless of the GDD calculation method used.

TTB Analysis

TTB has carefully reviewed all of the comments that address the issue of climate. TTB has also reviewed the regulatory history of the Sta. Rita Hills AVA to ensure that its determination regarding the climatic evidence for the proposed expansion area is consistent with the previous rulemaking.

TTB notes that T.D. ATF–454 describes the climate of the AVA as being moderated by cooling breezes and

fog from the Pacific Ocean. T.D. ATF–454 also states that the Sta. Rita Hills AVA is cooler than the region ''east of Highway 101'' and is cool enough to grow cool-climate grapes, specifically Pinot Noir and Chardonnay, which are not typically grown farther east. The original Sta. Rita Hills AVA petition included climate data from Lompoc, adjacent to the western boundary of the AVA, and Lake Cachuma, approximately 17 miles east of the eastern boundary of the AVA, but provided no climate data from within the AVA or the region that is now the proposed expansion area.

TTB has determined that the opposing comments do not provide sufficient evidence to demonstrate that the climate of the proposed expansion area is different from that of the existing Sta. Rita Hills AVA, as defined in T.D. ATF–454. Although many of the opposing comments state that the proposed expansion area is warmer, receives less fog, and has an earlier harvest date than the Sta. Rita Hills AVA, the majority of these comments provide only anecdotal evidence. Therefore, TTB is unable to determine the accuracy of these statements.

Finally, with regard to the comments stating that different vegetable and berry crops are grown in the proposed expansion area, TTB notes that AVAs are established based on factors that affect viticulture. Different crops have different growing requirements and may be more susceptible to slight variations in growing conditions than wine grapes. Therefore, TTB does not consider the presence or absence of crops other than wine grapes to be a relevant feature of the Sta. Rita Hills AVA.

With regard to the video submitted in comment 76, TTB has also determined that the video does not provide sufficient evidence to contradict the climate evidence provided in the expansion petition. The footage of sunny conditions in the proposed expansion area while fog covers a neighboring vineyard within the AVA captures only one moment of one day and does not conclusively demonstrate that fog never reaches the expansion area. TTB notes that both the photograph of fog in the Pence Ranch that was included in the expansion petition and the video of fog submitted by Mr. Shabram in comment 113 show that fog can reach the proposed expansion area at some point during the growing season. TTB notes that the presence of marine fog is a distinguishing feature of the Sta. Rita Hills AVA, but T.D. ATF–454 does not set a minimum number of days when fog must be present or a certain time of day by which fog must be present. Therefore, TTB believes that the evidence provided in the expansion petition is sufficient to demonstrate that fog occurs within the proposed expansion area.

TTB also does not believe that comment 97 contains sufficient evidence to demonstrate that the petitioner's methods were seriously flawed. The TTB regulations in § 9.12 do not prohibit use of comparison data from within an established AVA. The Ballard Canyon AVA is east of both the proposed expansion area and the Sta. Rita Hills AVA and, therefore, may be used to distinguish the proposed expansion area from the region to the east. TTB also notes that the Ballard Canyon AVA station is closer to both the Sta. Rita Hills AVA and the proposed expansion area than the station at Lake Cachuma, which was used as a comparison station in T.D. ATF–454. When the Sta. Rita Hills AVA was originally proposed, TTB did not receive any negative public comments regarding the use of the Lake Cachuma weather station, which is significantly east of the proposed AVA. Therefore, TTB believes that the expansion petition's use of temperature data from a station in the Ballard Canyon AVA is appropriate.

Additionally, TTB does not believe that the plan by the owner of the Pence Ranch to graft Pinot Noir vines to Gamay vines, as described in comment 97, is sufficient to demonstrate that the proposed expansion area has a different climate from the Sta. Rita Hills AVA. T.D. ATF–454 states that the Sta. Rita Hills AVA boundaries were drawn, in part, to include areas cool enough to grow Pinot Noir and Chardonnay, but TTB regulations do not require that only certain varietals of grapes can be planted or used for grafting within a given AVA. Furthermore, TTB notes that all three vineyards located either entirely or partially within the proposed expansion area do currently grow both Pinot Noir and Chardonnay. Therefore, TTB does not believe that the Pence Ranch owner's decision to experiment with additional grape varietals or grafting techniques on one acre of his property is evidence that the proposed expansion area's climate is different from that of the Sta. Rita Hills AVA.

TTB has also carefully reviewed the report from Dr. Fisk included in comment 97 and has determined that the temperature analysis Dr. Fisk commissioned from Mr. Battany does not conclusively demonstrate that the temperature of the proposed expansion area is warmer than that of the AVA. TTB does agree that the data indicates that the southeastern corner of the AVA is not always warmer than the rest of the AVA, as the expansion petition suggests. The data from 2008 and 2011 shows that, for those two years, the southeastern portion of the AVA was actually cooler than the northeastern portion, when the ''daily maximum-minimum'' method of GDD calculation was used. However, given that the report used different weather stations and different GGD calculation methods from the expansion petition, TTB cannot say that the report's findings from these two years conclusively negate any or all of the temperature data in the expansion petition.

TTB also notes that Mr. Battany clearly states in his analysis that his isotherm maps ''are intended to be aids for the viewer to observe broad regional trends,'' and that they ''should not be used for assigning values to non-measured locations . . . .'' TTB notes that the proposed expansion area is not identified on the isotherm maps, nor was a weather station from within the proposed expansion area used to develop the maps. However, based on the satellite photo included in the report to show the locations of his weather stations, TTB estimates that the proposed expansion area is almost due north of Station 26 and slightly east of Station 17, which places both stations within the current boundaries of the Sta. Rita Hills AVA. Based on this estimation, TTB believes that the isotherm maps show the proposed expansion area to be in the same isotherm as either Station 17 or Station 26 in some years, and to be in the same isotherm as both stations in other years. Station 23, in Buellton, is the closest station to the proposed expansion area and is consistently in a warmer isotherm than both the proposed expansion area and the AVA. Therefore, TTB does not believe that the isotherm maps conclusively demonstrate that the temperature of the proposed expansion area is either greater than the range of temperatures found in the AVA or is more similar to the temperatures of the region east of the AVA.

Furthermore, TTB notes that although T.D. ATF–454 states that a cool climate conducive for growing Pinot Noir and Chardonnay grapes is a distinguishing feature of the AVA, it does not set a maximum or minimum GDD total or a specific range of temperatures as a distinguishing feature of the AVA. T.D. ATF–454 describes climate data from Lompoc and Lake Cachuma and essentially states that the AVA is warmer than Lompoc and cooler than Lake Cachuma. The isotherm maps in comment 97 consistently show that the

warmest station is Station 25, which is near Lake Cachuma. None of the isotherm maps show Station 25 in an isotherm that extends west of Buellton, which means that the proposed expansion area is always cooler than the station closest to the comparison location used in T.D. ATF–454. Therefore, TTB believes the isotherm maps do not provide sufficient evidence to show that the proposed expansion area does not meet the temperature parameters for the Sta. Rita Hills AVA as set forth in T.D. ATF–454.

TTB has also determined that the differences in Mr. Battany's and Mr. Shabram's GDD totals can be explained by their use of different GDD calculation methods and different scales for measuring temperature. When comparing the 2008–2011 GDD totals for the only station used by both Mr. Shabram and Mr. Battany (Station 26/Station E), TTB does agree with the statement in comment 97 that the totals appear vastly different at first glance. For instance, Mr. Battany reports a GDD total of 1,694 for Station 26/Station E for 2008, using the ''daily maximum-minimum'' calculation method, while Mr. Shabram reports a GDD total of 3,363 using a similar but slightly different calculation method. However, when one converts Mr. Battany's GDD total for Station 26/Station E from degrees Celsius to degrees Fahrenheit by multiplying by 1.8, the GDD total becomes 3,049.2, which is much closer to Mr. Shabram's total.[3] TTB believes that the remaining difference of 314 GDDs may be explained by the fact that Mr. Shabram's calculation method does not allow for daily minimum temperatures below 50 degrees, which naturally results in higher totals than either of Mr. Battany's calculation methods, which use any minimum temperature above 0. Therefore, TTB does not agree with Dr. Fisk's assertion that Mr. Battany's GDD totals prove that the temperature data included in the expansion petition is inaccurate and that Mr. Shabram's methods were faulty.

TTB notes that wind speed was not mentioned in T.D. ATF–454 and is not considered to be a distinguishing feature of the Sta. Rita Hills AVA. Nevertheless, TTB reviewed the report from the environmental services company that was included in comments 97 and 111. With regard to the report's critique of the wind map provided in the expansion petition, TTB notes that the intent of the map was to show the direction of airflow through the Sta. Rita Hills AVA and the paths the marine air takes to enter the proposed expansion area. The map was not intended to show how strongly the wind moves through the AVA or the force with which it exits the AVA and enters the proposed expansion area. TTB notes that the scale of the wind maps created by the environmental services company and included in the report is small and difficult to read, and that the AVA and proposed expansion area are only vaguely marked. However, TTB notes that the maps do appear to show that air is able to enter the proposed expansion area from the west, which is not contrary to what the expansion petition claims.

TTB believes that the temperature maps compiled by the environmental services company are also of too small a scale to read easily. The AVA and proposed expansion area are vaguely marked on these maps, as well. Therefore, TTB cannot agree with the environmental services company's claim that their temperature maps show that the proposed expansion area is ''several degrees warmer, on average,'' than the Sta. Rita Hills AVA.

With regard to the report's critique of the temperature collection methods used in the expansion petition, TTB first notes that § 9.12 does not set forth a minimum number of years that climate data must be collected. Section 9.12(a) only requires that a petition include ''sufficient information, data, and evidence such that no independent verification or research is required by TTB.'' However, petitioners are encouraged to submit data from as long a period as possible in order to provide the most complete picture of a region's climate. TTB notes that the expansion petition originally included only 2 years' worth of temperature data from within the proposed expansion area. Later, Mr. Shabram provided a third year of data, which came from a different weather station within the proposed expansion area because the original weather station was no longer in service. TTB was satisfied that the new station was in close enough proximity to the location of the original station and allowed the data to be used in the petition.

TTB also notes that § 9.12 does not require petitioners to provide detailed information on the model of the weather stations they used, how the stations were calibrated, or where the stations were placed with respect to ''slope, aspect, orientation, land-cover, vegetation, and nearby structures.'' TTB believes it is sufficient for a petitioner to provide the years during which the weather data was collected and the general locations of the stations. The expansion petition states the length of time data was collected at each station and provides a general description of where the station was placed (*i.e.,* inside the AVA, inside the proposed expansion area, within the Ballard Canyon AVA), as well as a map showing the location of each weather station. Furthermore, the expansion petition includes the latitude and longitude of each weather station, although TTB does not require such detailed information. Finally, in response to comments questioning his data collection methods, Mr. Shabram submitted comment 113 to provide more detailed information on the weather station models he used, as well as photographs of the several of the stations, neither of which was required by TTB. Therefore, TTB believes the expansion petitioner has provided more information on the weather stations used in the expansion petition than TTB regulations require.

In summary, TTB has determined that the expansion petition provides sufficient evidence to demonstrate that the climate of the proposed expansion area meets the climate parameters for the Sta. Rita Hills AVA as set forth in T.D. ATF–454: temperatures that are moderated by marine air and fog, are cool enough for growing cool-climate grape varietals (specifically, Pinot Noir and Chardonnay), and are warmer than temperatures in Lompoc and cooler than temperatures in the eastern portion of the Santa Ynez Valley AVA (specifically, the region near Lake Cachuma). TTB has also determined that none of the opposing comments provide sufficient evidence to show conclusively that the climate of the proposed expansion area does not meet these parameters. Finally, TTB believes that the petitioner has provided a sufficient explanation of the methods he used to collect and analyze the climate data for the proposed expansion area, and that TTB is able to determine that his methods are sound.

Comments Regarding Issues Outside the Scope of Part 9

Numerous comments include various reasons for opposition to the proposed expansion of the Sta. Rita Hills AVA that do not relate to the regulatory criteria set forth in § 9.12 for AVA petitions. The points made by these comments include the following:

1. *Grapes and wines from the proposed expansion area have different characteristics/flavors from grapes and wines from the Sta. Rita Hills AVA.* Many comments state that consumers have come to expect a certain taste or

[3] Celsius-to-Fahrenheit conversion method from the National Weather Service's Climate Prediction Center Web page (*http://www.cpc.noaa.gov/products/wesley/cfsr/GDD.html*).

style from wines of the Sta. Rita Hills AVA. These comments assert that the grapes and wines from the proposed expansion area taste so different that consumers will be confused if the grapes and wines are marketed as coming from the Sta. Rita Hills AVA.

TTB notes that the purpose of AVAs is to allow vintners to describe more accurately the origin of their wines to consumers and to help consumers identify wines they may purchase. The establishment of an AVA is neither an approval nor an endorsement by TTB of the wine or grapes produced in that area, including a determination of wine or grape taste or quality. Therefore, discussions of wine and grape taste and quality are not relevant in determining whether or not to expand the Sta. Rita Hills AVA.

2. *Approval of the proposed expansion will tarnish the reputation of the Sta. Rita Hills AVA.* Numerous commenters claim that including the proposed expansion area in the Sta. Rita Hills AVA will cause the AVA to lose its defining characteristics. Some commenters state that expanding the AVA will cause it to lose its ''purity and distinctiveness'' (comment 27), and the expansion would negate the ''countless hours and resources [spent] educating and indoctrinating millions of consumers about the AVA'' (comment 45). Other commenters assert that the petitioners' motives for proposing the expansion are purely financial and have nothing to do with maintaining or enhancing the character of the AVA.

TTB's regulations in part 9 set forth the requirements for petitions proposing the establishment or modification of an AVA. TTB has determined that the expansion petition meets the requirements of part 9 and demonstrates that the proposed expansion area is within the parameters of the distinguishing features set forth in T.D. ATF–454. Therefore, TTB does not believe that expanding the Sta. Rita Hills AVA to include the proposed expansion area would be arbitrary or contrary to either the TTB regulations as set forth in part 9 or the parameters for the Sta. Rita Hills AVA as set forth in T.D. ATF–454.

TTB also notes that vineyard owners and vintners within an AVA will frequently form an association dedicated to promoting grapes and wines of the AVA and the business interests of its members. Therefore, the hope of financial benefits is likely not an uncommon motive for petitioning to establish or expand an AVA. However, any benefit derived from the use of an AVA name is the result of a proprietor's efforts and consumer acceptance of wines from that area, and hypothetical financial gains or losses that may result from the establishment or expansion of an AVA are not considered by TTB in determining the merits of a petition.

3. *Expansion of the Sta. Rita Hills AVA will lead to further expansions of the Sta. Rita Hills AVA as well as other AVAs.*

Several comments argue that approving the proposed expansion will lead to more petitions to expand the Sta. Rita Hills AVA and/or other established AVAs. The comments generally state that approving the proposed expansion will set a precedent for expansion that will make it more difficult for TTB to reject future expansions to the Sta. Rita Hills AVA because the integrity of the original boundaries will have been impacted. As a result, the comments predict that TTB will see a large increase expansion petitions submittals, many of which will lack merit.

The modification of AVA boundaries is specifically allowed under § 9.12 of the TTB regulations, which also sets forth the requirements for such petitions. The merits of expansion petitions are evaluated based on these requirements, as well as on the regulatory history of the AVA, meaning that the expansion petitions must provide adequate name evidence and demonstrate that the proposed expansion area has the same distinguishing features as described in the Treasury Decision that established the AVA. TTB's decision regarding whether to approve a proposed expansion is not based on the potential for further expansion or other modification of the boundaries of the affected AVA or any other established AVA, nor would TTB's decision affect the likelihood of the approval of any such proposals in the future.

TTB Determination

After careful review of the petition and the comments received in response to Notice No. 145, TTB finds that the evidence provided by the petitioner supports the expansion of the Sta. Rita Hills AVA, based on the requirements of § 9.12 and the distinguishing features of the Sta. Rita Hills AVA as defined in T.D. ATF–454. TTB has also determined that the comments received in response to Notice No. 145 did not provide sufficient evidence to refute the evidence provided in the expansion petition. Accordingly, under the authority of the FAA Act, section 1111(d) of the Homeland Security Act of 2002, and parts 4 and 9 of the TTB regulations, TTB expands the Sta. Rita Hills AVA in Santa Barbara County, California, by approximately 2,296 acres, effective 30 days from the publication date of this document.

Boundary Description

See the narrative description of the boundary of the expanded Sta. Rita Hills AVA in the regulatory text published at the end of this final rule.

Maps

The petitioner provided the required maps, and they are listed below in the regulatory text.

Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine's true place of origin. For a wine to be labeled with an AVA name or with a brand name that includes an AVA name, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with an AVA name and that name appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the AVA name appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label. Different rules apply if a wine has a brand name containing an AVA name that was used as a brand name on a label approved before July 7, 1986. See 27 CFR 4.39(i)(2) for details.

Bottlers currently using ''Central Coast,'' ''Santa Ynez Valley,'' or ''Sta. Rita Hills'' as an appellation of origin or in a brand name for wines made from grapes grown within the Central Coast, Santa Ynez Valley, or Sta. Rita Hills AVAs will not be affected by the expansion of the Sta. Rita Hills AVA. The expansion of the Sta. Rita Hills AVA will allow vintners to use ''Sta. Rita Hills,'' ''Santa Ynez Valley,'' and ''Central Coast'' as appellations of origin for wines made primarily from grapes grown within the expansion area if the wines meet the eligibility requirements for the appellation.

Regulatory Flexibility Act

TTB certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of an AVA name would be the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no

regulatory flexibility analysis is required.

Executive Order 12866

It has been determined that this final rule is not a significant regulatory action as defined by Executive Order 12866 of September 30, 1993. Therefore, no regulatory assessment is required.

Drafting Information

Karen A. Thornton of the Regulations and Rulings Division drafted this final rule.

List of Subjects in 27 CFR Part 9

Wine.

The Regulatory Amendment

For the reasons discussed in the preamble, TTB amends title 27, chapter I, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

■ 2. Section 9.162 is amended by adding paragraph (b)(6), revising paragraphs (c)(3) through (6), redesignating paragraphs (c)(7) through (19) as paragraphs (c)(8) through (20), and adding a new paragraph (c)(7).

The additions and revisions read as follows:

§ 9.162 Sta. Rita Hills.

* * * * *

(b) * * *

(6) ''Zaca Creek, Calif.,'' edition of 1959.

(c) * * *

(3) Proceed west-northwest in a straight line 0.5 mile to the intersection of Santa Rosa Road and an unnamed, unimproved road that runs just north of a marked gaging station.

(4) Proceed west along the unnamed, unimproved road approximately 0.4 mile to a ''T'' intersection with an unnamed, unimproved road and the 320-foot elevation contour, Santa Rosa Land Grant, T. 6N, R. 32W.

(5) Proceed northwest along the 320-foot elevation contour, crossing onto the Santa Rosa Hills, Calif., Quadrangle U.S.G.S. map, then continue northwest, north, and northeast along the meandering 320-foot elevation contour for approximately 1.2 miles, crossing onto the Solvang, Calif., Quadrangle U.S.G.S. map, and continue east then north along the 320-foot elevation contour approximately 0.5 miles, crossing onto the Zaca Creek, Calif., Quadrangle U.S.G.S. map, to the intersection of the 320-foot elevation contour with an unnamed, unimproved north-south road that follows the length of the Cañada de los Palos Blancos, San Carlos de Jonata Land Grant, T. 6N, R. 32W.

(6) Proceed north-northwest along the unnamed, unimproved road 1.2 miles, crossing onto the Los Alamos, Calif., Quadrangle U.S.G.S. map, and continue along the road 1.3 miles to the marked 635-foot elevation point at the intersection of the road and a 4-wheel drive trail, San Carlos de Jonata Land Grant, T. 7N, R. 32W.

(7) Proceed northwest in a straight line approximately 1.3 miles to an unnamed hilltop, elevation 1443 feet. Section 20, T. 7N, R. 32W.

* * * * *

Signed: July 27, 2016.

John J. Manfreda,

Administrator.

Approved: August 3, 2016.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

[FR Doc. 2016–19998 Filed 8–19–16; 8:45 am]

BILLING CODE 4310–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0774]

Drawbridge Operation Regulation; Victoria Barge Canal, Bloomington, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulations.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Victoria Barge Canal Railroad Bridge across Victoria Barge Canal, mile 29.4, at Bloomington, Victoria County, Texas. The deviation is necessary to conduct maintenance on the bridge. This deviation allows the bridge to remain temporarily closed-to-navigation for 12 hours.

DATES: This deviation is effective from 8 a.m. to 8 p.m. on September 1, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0774] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Donna Gagliano, Bridge Administration Branch, Coast Guard; telephone 504–671–2128, email *Donna.Gagliano@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Victoria County Navigation District/Port of Victoria in conjunction with the Union Pacific Railroad (UPRR), requested a temporary deviation from the operating schedule of the Victoria Barge Canal Railroad Lift Bridge across Victoria Barge Canal, mile 29.4, at Bloomington, Victoria County, Texas. This deviation was requested to allow the bridge owner to replace old wire cables utilized in the raising and lowering of the bridge deck. This bridge is governed by 33 CFR 117.991.

This deviation allows the vertical lift bridge to remain closed-to-navigation from 8 a.m. to 8 p.m. on Thursday, September 1, 2016. The bridge has a vertical clearance of 22 feet above high water in the closed-to-navigation position and 50 feet above high water in the open-to-navigation position. Navigation on the waterway consists of commercial traffic,-which is primarily vessels and tows providing services to the Port of Victoria.

For the duration of the replacement of cables, vessels will not be allowed to pass through the bridge. Vessels traffic coordination will be scheduled to avoid unnecessary delays. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

David M. Frank,

Bridge Administrator, Eighth Coast Guard District.

[FR Doc. 2016–19933 Filed 8–19–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0802]

Drawbridge Operation Regulation; Lake Washington Ship Canal, Seattle, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Montlake Bridge across the Lake Washington Ship Canal, mile 5.2, at Seattle, WA. The deviation is necessary to accommodate vehicular traffic attending football games at Husky Stadium at the University of Washington, Seattle, WA. This deviation allows the bridge to remain in the closed-to-navigation position two and a half hours before and two and a half hours after each game. The game times for three of the seven games scheduled for Husky Stadium have not yet been determined due to NCAA television scheduling.

DATES: This deviation is effective from 8:30 a.m. on September 3, 2016 to 11 p.m. on November 19, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0802] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Washington State Department of Transportation, on behalf of the University of Washington Police Department, has requested that the Montlake Bridge bascule span remain in the closed-to-navigation position, and need not open to vessel traffic to facilitate timely movement of pre-game and post game football traffic at Husky Stadium at the University of Washington, Seattle, WA. The Montlake Bridge crosses the Lake Washington Ship Canal at mile 5.2; and while in the closed-to-navigation position provides 30 feet of vertical clearance throughout the navigation channel and 46 feet of vertical clearance throughout the center 60-feet of the bridge. These vertical clearances are made in reference to the Mean Water Level of Lake Washington. The normal operating schedule for Montlake Bridge operates in accordance with 33 CFR 117.1051(e).

The deviation period will cover the following dates: from 8:30 a.m. to 11 a.m., and from 2:30 p.m. to 5 p.m. on September 3, 2016; from 11:30 a.m. to 2 p.m. and from 5:30 p.m. to 8 p.m. on September 10, 2016; from 2:30 p.m. to 5 p.m. and from 8:30 p.m. to 11 p.m. on September 17, 2016; from 3:30 p.m. to 6 p.m. and from 8:30 p.m. to 11 p.m. on September 30, 2016. The times for the closures on October 22, 2016, November 12, 2016, and November 19, 2016 will be determined, and announced in the Coast Guard's Local Notice to Mariners and Broadcast Notice to Mariners as they become available. Due to NCAA television scheduling, the times for the games are not currently available. The bridge shall operate in accordance to 33 CFR 117.1051(e) at all other times. Waterway usage on the Lake Washington Ship Canal ranges from commercial tug and barge to small pleasure craft. Vessels able to pass through the bridge in the closed-to-navigation position may do so at anytime. The bridge will be able to open for emergencies and there is no immediate alternate route for vessels to pass.

In accordance with 33 CFR 117.35(e), the drawbridges must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: August 15, 2016.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2016–19930 Filed 8–19–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0729]

Drawbridge Operation Regulation; Sacramento River, Sacramento, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Tower Drawbridge across the Sacramento River, mile 59.0, at Sacramento, CA. The deviation is necessary to allow the community to participate in the FroYo Run event. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period.

DATES: This deviation is effective from 7:30 a.m. to 10 a.m. on August 20, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0729] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, email *David.H.Sulouff@uscg.mil.*

SUPPLEMENTARY INFORMATION: California Department of Transportation has requested a temporary change to the operation of the Tower Drawbridge, mile 59.0, over Sacramento River, at Sacramento, CA. The vertical lift bridge navigation span provides a vertical clearance of 30 feet above Mean High Water in the closed-to-navigation position. The draw operates as required by 33 CFR 117.189(a). Navigation on the waterway is commercial and recreational.

The drawspan will be secured in the closed-to-navigation position from 7:30 a.m. to 10 a.m. on August 20, 2016, to allow the community to participate in the FroYo Run event. This temporary deviation has been coordinated with the waterway users. No objections to the proposed temporary deviation were raised.

Vessels able to pass through the bridge in the closed position may do so at any time. The bridge will be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: Aug 17, 2016.

D.H. Sulouff,

District Bridge Chief, Eleventh Coast Guard District.

[FR Doc. 2016–20019 Filed 8–19–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0725]

RIN 1625–AA00

Safety Zone; Lake Superior Dragon Boat Festival Fireworks Display; Superior Bay, Superior, WI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone in Superior Bay near Barkers Island in Superior, WI. This safety zone is intended to restrict vessels from specified waters in the Superior Bay during the Dragon Boat Festival Fireworks Display. This safety zone is necessary to protect spectators from the hazards associated with the fireworks display.

DATES: This rule is effective from 8:30 p.m. through 10:30 p.m. on August 26, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0725 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade John Mack, Waterways management, MSU Duluth, Coast Guard; telephone 218–725–3818, email *John.V.Mack@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. Because the event is scheduled for August 26, 2016, there is insufficient time to accommodate the comment period. Thus, delaying the effective date of this rule to wait for the comment period to run would be both impracticable and contrary to public interest because it would inhibit the Coast Guard's ability to protect spectators and vessels from the hazards associated with the event.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest as it would inhibit the Coast Guard's ability to protect spectator and vessels from the hazards associated with the event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Duluth (COTP) has determined that potential hazards associated with fireworks displays starting at 9:00 p.m. on August 26, 2016 will be a safety concern for anyone within a 350-foot radius of the launch site. The likely combination of recreational vessels, darkness punctuated by bright flashes of light, and fireworks debris falling into the water presents risks of collisions which could result in serious injuries or fatalities. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display.

IV. Discussion of the Rule

This rule establishes a safety zone from 8:30 p.m. through 10:30 p.m. August 26, 2016. The safety zone will cover all navigable waters within an area bounded by a circle with a 350-foot radius of the fireworks display launching site located in Superior, WI at coordinates 46°43′28″ N, 092°03′47″ W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive order related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-year of the safety zone. Vessel traffic will be able to safely transit around this safety zone which will impact a small designated area of Superior Bay in Superior, WI for 2 hours and during a time of year when commercial vessel traffic is normally low. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175 because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting no more than 2 hours that will prohibit entry within a 350-foot radius from where a fireworks display will be conducted. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T09–0725 to read as follows:

§ 165.T09–0725 Safety zone; Lake Superior Dragon Boat Festival Fireworks Display, Superior Bay, Superior, WI.

(a) *Location.* All waters of Superior Bay within an area bounded by a circle with a 350-foot radius at position 46°43′28″ N., 092°03′47″ W.

(b) *Effective period.* This safety zone is effective from 8:30 p.m. through 10:30 p.m. on August 26, 2016.

(c) *Regulations.* (1) In accordance with the general regulations in section 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Duluth, or his designated on-scene representative.

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

(3) The ''on-scene representative'' of the Captain of the Port is any Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port to act on his behalf. The on-scene representative of the Captain of the Port will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Duluth or his on-scene representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Duluth or his on-scene representative.

Dated: August 16, 2016.

E.E. Williams,

Commander, U.S. Coast Guard, Captain of the Port Duluth.

[FR Doc. 2016–19943 Filed 8–19–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2015–0642; FRL–9950–91–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Minor New Source Review Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the Commonwealth of Virginia state implementation plan (SIP). These revisions pertain to preconstruction permitting requirements under Virginia's minor New Source Review (NSR) program. EPA is approving these revisions to the Virginia SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: This rule is effective on October 21, 2016 without further notice, unless EPA receives adverse written comment by September 21, 2016. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2015–0642 at *http://www.regulations.gov,* or via email to *campbell.dave@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: David Talley, (215) 814–2117, or by email at *talley.david@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 15, 2013, the Commonwealth of Virginia submitted a formal revision to its SIP. The SIP revision consists of amendments to the Virginia Department of Environmental Quality's (VADEQ) minor New Source Review (NSR) program, as well as a complete recodification of those regulations.

On July 24, 1996, EPA took final action to approve in part and disapprove in part a revision to the Virginia SIP relating to minor NSR permitting requirements. *See* 61 FR 38388. EPA disapproved revisions to the public participation requirements which were, at the time, codified at Virginia Regulations (VR) section 120–08–1. Specifically, EPA disapproved sections 120–08–01G.1 and .01G.4.b because they purported to exempt major modifications of less than 100 tons per year (tpy) from the prescribed public participation procedures, contrary to the requirements of 40 CFR 51.161. This left the previously approved SIP requirements of VR section 120–08–01C.4 in place to govern public participation. EPA approved the remainder of the submittal into Virginia's SIP.

Subsequently, on April 21, 2000, EPA took final action to approve a revision to the Virginia SIP which did not revise any of the substantive requirements, but included in the SIP Virginia's reorganized and recodified regulations from the VR–120–08–01 format to match the Virginia Administrative Code (VAC) format (*e.g.*, 9VAC5–80–10). *See* 78 FR 21315.

II. Summary of SIP Revision and EPA Analysis

Virginia's July 15, 2013 submittal encompasses a number of revisions to Virginia's regulations that were completed at the Commonwealth level, but not submitted to and approved by EPA as revisions to the Virginia SIP. VADEQ compiled the various revisions and submitted them so that EPA could review the program as a whole. A thorough discussion of the details of the regulatory changes made by Virginia as well as EPA's analysis of those changes to the regulations and the Virginia SIP are located in the technical support document (TSD) in the docket for this action, available at *www.regulations.gov,* and will not be restated here.

Among those revisions was the evolution and recodification of VADEQ's minor NSR program from 9VAC5 Chapter 80 sections 10 and 11 to Article 6 of Part II of 9VAC5 Chapter 80. Sections 10 and 11 of 9VAC5–80 are being removed from the SIP and replaced as part of this action. Additionally, the submittal includes revisions to 9VAC5–50, sections 240, 250, and 260. The submittal also includes revisions to the requirements for public participation under Article 6 which correct the deficiencies which were the reason for EPA's previously-mentioned July 24, 1996 disapproval action.

9VAC5–50–240 has been revised to maintain consistency with revisions in the new Article 6; to clarify which emissions units are subject to the minor NSR regulations; and to appropriately exempt hazardous air pollutants (HAPs) regulated under 9VAC5–60, consistent with 40 CFR 51.166.

Additionally, a number of revisions have been made to the best available control technology (BACT) requirements under Virginia's minor NSR program. The definition of BACT under 9VAC5–50–250 has been revised to provide for the consideration of additional factors in determining BACT (*e.g.*, nature and amount of emissions, control efficiencies across industry source types, etc.). 9VAC5–50–260 has been revised to require BACT determinations for all emissions units subject to the minor NSR program, and to require that, for phased construction projects, BACT must be reviewed within 18 months of construction of each individual phase. 9VAC5–50–260 has also been revised to require BACT for all emissions units which are subject to the minor NSR program. These changes to 9VAC5–50 have been made in order to simplify the minor NSR program, and are appropriate and meet the federal requirements of 40 CFR 51.160 and 51.161, and CAA section 110(a)(2)(C). Additionally, the revisions are in accordance with section 110(l) of the CAA because they will not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable CAA requirement.

Generally, the new Article 6 regulations represent a recodification of the minor NSR program from section 10 and 11 of 9VAC5–80. Sections 10 and 11 are being deleted from the SIP because they are largely duplicative with the new provisions. In addition, the deficiency related to the public participation requirements identified in

EPA's 1996 disapproval action has been corrected. Therefore, the previously approved public participation requirements under VR 120–08–01 are being removed from the SIP as well. Additionally, as discussed in more detail below, the revisions include new regulations designed to confer federal enforceability upon Virginia's program for regulating HAPs (consistent with 40 CFR parts 61 and 63) and the removal of provisions which were inadvertently included in the SIP by EPA's 1996 approval, and which inappropriately conferred federal enforceability upon Virginia's state-only enforceable provisions for regulating toxic air pollutants. Virginia's definition of ''toxic air pollutant'' is more broad than the federal ''hazardous air pollutant,'' and by inadvertently applying the minor NSR program to the former, Virginia's SIP went beyond what VADEQ intended. Specifically, the requirements of sections 1100I, 1105F, and 1170A are being added, and paragraph 1200B is being deleted from the SIP. These revisions are appropriate and meet the federal requirements of 40 CFR 51.160 and 51.161, and CAA section 110(a)(2)(C). Additionally, the revisions (and in particular the deletions) are in accordance with section 110(l) of the CAA because they will not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable CAA requirement.

The unit reconstruction requirements of 9VAC5–80–1100 have been revised to evaluate applicability for the reconstruction of an emissions unit via the replacement of some of its components in the same manner as any other modification. Additionally, provisions have been added to allow sources to opt into permit review, and to clarify applicability of fugitive emissions. Provisions have been added to sections 80–1100M, 1105C and D, and 1100C to regulate fine particulate matter with an aerodynamic diameter less than 2.5 micrometers ($PM_{2.5}$) in a manner consistent with federal requirements, particularly related to the condensable fraction of $PM_{2.5}$.

9VAC5–80–1105 contains the exemptions formerly codified at section 80–11. Many of the revisions to these exemptions are administrative or clarifying in nature. However, there are some additions and deletions as well. New exemptions include, but are not limited to, those for mulch recycling operations, replacement units where the potential to emit (PTE) does not increase, engines and turbines which do not exceed 500 hours per year of operation, and exhaust flares at natural gas and coal bed methane extraction wells. Additionally, the emission-rate based exemption for VOC coating operations, and the provisions which prohibit the exemption of certain New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) sources have been deleted. Exemption thresholds for $PM_{2.5}$ have been added, below which minor NSR will not apply.

The new (and existing) exemptions exist because VADEQ considers the associated emissions to be de minimis, and not worth the administrative effort required to issue permits for de minimis emissions. As a safeguard, however, provisions have been added to state that any exemption from the minor NSR requirements does not create an exemption from major NSR. All such sources would be considered emissions sources for purposes of determining major source status under Virginia's SIP approved major NSR program.

The definitions under 9VAC5–80–1110 have been revised to make the minor NSR program more compatible with the major NSR program. Additional revisions of note include: The addition of provisions for ensuring that permit terms relating to emissions caps are practically enforceable (9VAC5–80–1180B, C, and D); criteria relating to invalidation of permits due to delays in construction (9VAC5–80–1210B); criteria for issuance of general permits (9VAC5–80–1250); provisions relating to permit modifications (9VAC5–80–1260 through 1300); as well as several non-substantive, clarifying revisions.

All of the new and revised provisions of 9VAC5–80 Article 6 meet the federal requirements of 40 CFR 51.160 and 51.161, and CAA section 110(a)(2)(C). Additionally, the revisions (and in particular the deletions) are in accordance with section 110(l) of the CAA because they will not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable CAA requirement as EPA finds Virginia's conclusions regarding de minimis emissions reasonable.

Additional details regarding Virginia's amended regulations for its minor NSR program and EPA's detailed analysis of those regulations for the Virginia SIP are located in the TSD in the docket for this action, available at *www.regulations.gov,* and will not be restated here.

III. Final Action

EPA is approving Virginia's July 15, 2013 submittal as a revision to the Virginia SIP because it meets the federal requirements of 40 CFR 51.160 and 51.161, and CAA section 110(a)(2)(C). Additionally, the revisions (and in particular the deletions) are in accordance with section 110(l) of the CAA because they will not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable CAA requirement given de minimus emissions impacts and removal of duplicative measures. EPA is publishing this rule without prior proposal because EPA views this as a noncontroversial amendment and anticipates no adverse comment. However, in the ''Proposed Rules'' section of this **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on October 21, 2016 without further notice unless EPA receives adverse comment by September 21, 2016. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

IV. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) ''privilege'' for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information that: (1) Are generated or developed before the commencement of a

voluntary environmental assessment; (2) are prepared independently of the assessment process; (3) demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege Law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information ''required by law,'' including documents and information ''required by federal law to maintain program delegation, authorization or approval,'' since Virginia must ''enforce federally authorized environmental programs in a manner that is no less stringent than their federal counterparts . . . .'' The opinion concludes that ''[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by federal law to maintain program delegation, authorization or approval.'' Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that ''[t]o the extent consistent with requirements imposed by federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with federal law, which is one of the criteria for immunity.''

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its NSR program consistent with the federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

V. Incorporation by Reference

In this rulemaking action, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the Virginia regulations as described in the amendments to 40 CFR part 52 set forth below. Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update of the SIP compilation.[1] The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or may be viewed at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

A. General Requirements

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

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

The SIP is not approved to apply on any Indian reservation land as defined in 18 U.S.C. 1151 or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 21, 2016. Filing a petition for reconsideration by the

[1] 62 FR 27968 (May 22, 1997).

Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of this **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking action. This action pertaining to Virginia's minor NSR program may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: August 9, 2016.

Shawn M. Garvin,

Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart VV—Virginia

■ 2. In § 52.2420, the table in paragraph (c) is amended by:
■ a. Removing the section entitled ''9VAC5, Chapter 80 Permits for Stationary Sources [Part VIII]'' including the entries for Sections 5–80–10, 10A through 10P, VR120–08–01C.4.b and .01C.4.c, and 5–80–11;
■ b. Revising the entries for Sections 5–50–240, 5–50–250, and 5–50–260;
■ c. Adding the heading ''Article 6—Permits for New and Modified Stationary Sources'' and entries for Sections 5–80–1100 through 5–80–1300 immediately following the entry for 5–80–1040.

The revisions and additions read as follows:

§ 52.2420 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES

State citation	Title/Subject	State effective date	EPA Approval date	Explanation [former SIP citation]
*	*	*	*	* * *
9 VAC 5, Chapter 50 New and Modified Stationary Sources [Part V]				
*	*	*	*	* * *
Article 4 Standards of Performance for Stationary Sources (Rule 5–4)				
5–50–240	Applicability and designation of affected facility.	11/7/12	8/22/16 [Insert **Federal Register** Citation].	Paragraphs A and C are revised.
5–50–250	Definitions	11/7/12	8/22/16 [Insert **Federal Register** Citation].	Paragraphs A–C are revised.
5–50–260	Standards for stationary sources.	11/7/12	8/22/16 [Insert **Federal Register** Citation].	Paragraphs A–D are revised.
*	*	*	*	* * *
9 VAC 5, Chapter 80 Permits for Stationary Sources [Part VIII]				
*	*	*	*	* * *
Article 6—Permits for New and Modified Stationary Sources				
5–80–1100	Applicability	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1105	Permit Exemptions	11/7/12	8/22/16 [Insert **Federal Register** Citation].	Paragraph E is excluded.
5–80–1110	Definitions	11/7/12	8/22/16 [Insert **Federal Register** Citation].	The definition at paragraph 5 under ''Regulated air pollutant,'' and the definition of ''Toxic pollutant'' are excluded.
5–80–1120	General	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1130	Reserved			Excluded from SIP.
5–80–1140	Applications	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1150	Application information required.	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1160	Action on permit application	11/7/12	8/22/16 [Insert **Federal Register** Citation].	The latter portion of paragraph D (beginning with ''. . . direct consideration by the board . . .'') is excluded.
5–80–1170	Public participation	11/7/12	8/22/16 [Insert **Federal Register** Citation].	Paragraphs F and G are excluded. *See* § 52.2423(o).

EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES—Continued

State citation	Title/Subject	State effective date	EPA Approval date	Explanation [former SIP citation]
5–80–1180	Standards and conditions for granting permits.	11/7/12	8/22/16 [Insert **Federal Register** Citation].	The portion of paragraph A.1 pertaining to hazardous air pollutant sources as proscribed under 9VAC5–60 is excluded.
5–80–1190	Application review and analysis.	11/7/12	8/22/16 [Insert **Federal Register** Citation].	Paragraph 2 is excluded.
5–80–1200	Compliance determination and verification by performance testing.	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1210	Permit invalidation, suspension, revocation and enforcement.	11/7/12	8/22/16 [Insert **Federal Register** Citation].	Paragraph B is excluded.
5–80–1220	Existence of permit no defense	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1230	Compliance with local zoning ..	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1240	Transfer of permits	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1250	General permits	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1260	Action to combine permit terms and conditions.	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1270	Actions to change permits	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1280	Administrative permit amendments.	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1290	Minor permit amendments	11/7/12	8/22/16 [Insert **Federal Register** Citation].	
5–80–1300	Significant amendment procedures.	11/7/12	8/22/16 [Insert **Federal Register** Citation].	

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[FR Doc. 2016–19770 Filed 8–19–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2016–0247; FRL–9950–82–Region 4]

Air Plan Approval; South Carolina; Prong 4–2008 Ozone, 2010 NO_2, SO_2, and 2012 $PM_{2.5}$

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is conditionally approving the portions of revisions to the South Carolina State Implementation Plan (SIP), submitted by the South Carolina Department of Health and Environmental Control (SC DHEC), addressing the Clean Air Act (CAA or Act) visibility transport (prong 4) infrastructure SIP requirements for the 2008 8-hour Ozone, 2010 1-hour Nitrogen Dioxide (NO_2), 2010 1-hour Sulfur Dioxide (SO_2), and 2012 annual Fine Particulate Matter ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA, commonly referred to as an ''infrastructure SIP.'' Specifically, EPA is conditionally approving the prong 4 portions of South Carolina's July 17, 2008, 8-hour Ozone infrastructure SIP submission; April 30, 2014, 2010 1-hour NO_2 infrastructure SIP submission; May 8, 2014, 2010 1-hour SO_2 infrastructure SIP submission; and December 18, 2015, 2012 annual $PM_{2.5}$ infrastructure SIP submission. All other applicable infrastructure requirements for these SIP submissions have been or will be addressed in separate rulemakings.

DATES: This rule will be effective September 21, 2016.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2016–0247. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, *i.e.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Sean Lakeman of the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW.,

Atlanta, Georgia 30303–8960. Mr. Lakeman can be reached by telephone at (404) 562–9043 or via electronic mail at *lakeman.sean@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

By statute, SIPs meeting the requirements of sections 110(a)(1) and (2) of the CAA are to be submitted by states within three years after promulgation of a new or revised NAAQS to provide for the implementation, maintenance, and enforcement of the new or revised NAAQS. EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of sections 110(a)(1) and 110(a)(2) as ''infrastructure SIP'' submissions. Sections 110(a)(1) and (2) require states to address basic SIP elements such as the requirements for monitoring, basic program requirements, and legal authority that are designed to assure attainment and maintenance of the newly established or revised NAAQS. More specifically, section 110(a)(1) provides the procedural and timing requirements for infrastructure SIPs. Section 110(a)(2) lists specific elements that states must meet for the infrastructure SIP requirements related to a newly established or revised NAAQS. The contents of an infrastructure SIP submission may vary depending upon the data and analytical tools available to the state, as well as the provisions already contained in the state's implementation plan at the time in which the state develops and submits the submission for a new or revised NAAQS.

Section 110(a)(2)(D) has two components: 110(a)(2)(D)(i) and 110(a)(2)(D)(ii). Section 110(a)(2)(D)(i) includes four distinct components, commonly referred to as ''prongs,'' that must be addressed in infrastructure SIP submissions. The first two prongs, which are codified in section 110(a)(2)(D)(i)(I), are provisions that prohibit any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state (prong 1) and from interfering with maintenance of the NAAQS in another state (prong 2). The third and fourth prongs, which are codified in section 110(a)(2)(D)(i)(II), are provisions that prohibit emissions activity in one state from interfering with measures required to prevent significant deterioration of air quality in another state (prong 3) or from interfering with measures to protect visibility in another state (prong 4). Section 110(a)(2)(D)(ii) requires SIPs to include provisions ensuring compliance with sections 115 and 126 of the Act, relating to interstate and international pollution abatement.

The prong 4 portions of South Carolina's infrastructure SIP submissions for the 2008 8-hour Ozone, 2010 1-hour NO_2, 2010 1-hour SO_2, and 2012 annual $PM_{2.5}$ NAAQS cite to the State's regional haze SIP as satisfying prong 4 requirements.[1] However, the State may not currently rely on its regional haze SIP to satisfy these requirements because EPA has not yet fully approved South Carolina's regional haze SIP as it relies on the Clean Air Interstate Rule (CAIR) to satisfy the nitrogen oxides (NO_X) and SO_2 Best Available Retrofit Technology (BART) requirements for the CAIR-subject electric generating units (EGUs) in the State and the requirement for a long-term strategy sufficient to achieve the state-adopted reasonable progress goals.[2] Therefore, on April 19, 2016, South Carolina submitted a commitment letter to EPA requesting conditional approval of the prong 4 portions of the aforementioned infrastructure SIP revisions.

In its commitment letter, South Carolina commits to satisfy the prong 4 requirements for the 2008 8-hour ozone NAAQS, 2010 1-hour NO_2 NAAQS, 2010 1-hour SO_2 NAAQS, and 2012 $PM_{2.5}$ NAAQS by providing a SIP revision within one year of EPA's final conditional approval of the prong 4 portions of the infrastructure SIP revisions and provides an anticipated schedule for these revisions. Specifically, South Carolina commits ''to provide to the EPA a SIP revision that adopts provisions for participation in the Cross-State Air Pollution Rule (''CSAPR'') annual NOx and annual SO_2 trading programs, including annual NO_X and annual SO_2 budgets. Any adopted budgets would be at least as stringent as the budgets codified for South Carolina at 40 CFR 97.710(a) (annual SO_2 group 2 trading budgets) and 40 CFR 97.410(a) (annual NO_X trading budgets), as promulgated in the **Federal Register** notice of June 12, 2012 (77 FR 34,830). We will rely on this SIP revision adopting such budgets to submit a concurrent SIP revision that will satisfy the visibility requirements of section 110(a)(2)(D)(i)(II) and EPA's corresponding guidance on those requirements. We commit to provide this concurrent SIP revision within the one-year period described above. This concurrent SIP revision will rely on either an analysis provided therein showing that emissions from sources in South Carolina will not interfere with the attainment of the reasonable progress goals of other states or on a fully approved regional haze SIP relying on CSAPR. If the concurrent SIP revision relies on a fully approvable regional haze SIP, we commit to provide this regional haze SIP to EPA within the one year period described above.''

If South Carolina meets its commitment within one year of final conditional approval, the prong 4 portions of the conditionally-approved infrastructure SIP submissions will remain a part of the SIP until EPA takes final action approving or disapproving the new SIP revision(s). However, if the State fails to submit these revisions within the one-year timeframe, the conditional approval will automatically become a disapproval one year from EPA's final conditional approval and EPA will issue a finding of disapproval. EPA is not required to propose the finding of disapproval. If the conditional approval is converted to a disapproval, the final disapproval triggers the federal implementation plan requirement under CAA section 110(c).

In a notice of proposed rulemaking (NPRM) published on June 8, 2016 (81 FR 36842), EPA proposed to conditionally approve the prong 4 portions of the aforementioned infrastructure SIP submissions. The NPRM provides additional detail regarding the rationale for EPA's action, including further discussion of the Prong 4 requirements and the basis for South Carolina's commitment letter. Comments on the proposed rulemaking were due on or before July 8, 2016. EPA received no adverse comments on the proposed action.

II. Final Action

EPA is conditionally approving the prong 4 portions of South Carolina's July 17, 2008, 8-hour Ozone infrastructure SIP submission; April 30, 2014, 2010 1-hour NO_2 infrastructure SIP submission; May 8, 2014, 2010 1-hour SO_2 infrastructure SIP submission; and December 18, 2015, 2012 annual $PM_{2.5}$ infrastructure SIP submission. All other applicable infrastructure requirements for these SIP submissions

[1] The April 30, 2014, 2010 1-hour NO_2 submission; May 8, 2014, 2010 1-hour SO_2 submission; and December 18, 2015 also cite to the State's December 2012 regional haze progress report.

[2] CAIR, promulgated in 2005, required 27 states and the District of Columbia to reduce emissions of NO_X and SO_2 that significantly contribute to, or interfere with maintenance of, the 1997 NAAQS for fine particulates and/or ozone in any downwind state. CAIR imposed specified emissions reduction requirements on each affected State, and established several EPA-administered cap and trade programs for EGUs that States could join as a means to meet these requirements.

have been or will be addressed in separate rulemakings.

III. Statutory and Executive Order Reviews

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

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

In addition, this action does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). The Catawba Indian Nation Reservation is located within the State of South Carolina. Pursuant to the Catawba Indian Claims Settlement Act, South Carolina statute 27–16–120, ''all state and local environmental laws and regulations apply to the [Catawba Indian Nation] and Reservation and are fully enforceable by all relevant state and local agencies and authorities.'' However, EPA has determined that because this rule does not have substantial direct effects on an Indian Tribe because, as noted above, this action is not approving any specific rule, but rather conditionally approving South Carolina's already approved SIP meets certain CAA requirements. EPA notes this action will not impose substantial direct costs on Tribal governments or preempt Tribal law.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 21, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

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

Dated: August 8, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart PP—South Carolina

■ 2. Section 52.2127 is added to read as follows:

§ 52.2127 Conditional approval.

South Carolina submitted a letter to EPA on April 19, 2016, with a commitment to address the State Implementation Plan deficiencies regarding requirements of Clean Air Act section 110(a)(2)(D)(i)(II) related to interference with measures to protect visibility in another state (prong 4) for the 2008 8-hour Ozone, 2010 1-hour NO_2, 2010 1-hour SO_2, and 2012 annual $PM_{2.5}$ NAAQS. EPA conditionally approved the prong 4 portions of South Carolina's July 17, 2008, 8-hour Ozone infrastructure SIP submission; April 30, 2014, 2010 1-hour NO_2 infrastructure SIP submission; May 8, 2014, 2010 1-hour SO_2 infrastructure SIP submission; and December 18, 2015, 2012 annual $PM_{2.5}$ infrastructure SIP submission in an action published in the **Federal Register** on August 22, 2016. If South Carolina fails to meet its commitment by August 22, 2017, the conditional approval will automatically become a disapproval on that date and EPA will issue a finding of disapproval.

[FR Doc. 2016–19537 Filed 8–19–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Parts 10, 60, 78, 79, 80, 206, and 209

[Docket ID FEMA–2016–0018]

RIN 1660–AA87

Removal of Environmental Considerations Regulations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: The Federal Emergency Management Agency (FEMA), a component of the Department of Homeland Security (DHS), is removing its environmental considerations regulations and replacing the regulations with a new Directive and

Instruction on environmental planning and historical preservation requirements. DHS instituted procedures for environmental considerations that apply Department-wide (including FEMA) in a new Directive and Instruction. FEMA is issuing supplemental procedures to the new DHS Directive and Instruction; a Notice of Availability for these supplemental procedures appears in the Notice section of today's edition of the **Federal Register**.

DATES: This final rule is effective August 22, 2016.

FOR FURTHER INFORMATION CONTACT: Katherine Zeringue, Environmental Officer, Federal Emergency Management Agency, 400 C Street SW., Suite 313, Washington, DC 20472–3020; 202–212–2282, or *Katherine.Zeringue@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The National Environmental Policy Act (NEPA) [1] declares a national policy to promote efforts that will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man, and to enrich the understanding of the ecological systems and natural resources important to the Nation.[2] NEPA establishes a Council on Environmental Quality (CEQ) within the Executive Office of the President, composed of members who are appointed by the President with the advice and consent of the Senate, to analyze and interpret environmental trends and information of all kinds, to appraise programs and activities of the Federal government in light of NEPA's purpose, to be conscious of and responsive to the scientific, economic, social, esthetic, and cultural needs and interests of the Nation, and to formulate and recommend national policies to promote the improvement of the quality of the environment.[3]

CEQ has promulgated regulations at 40 CFR parts 1500 to 1518. The CEQ regulations set out specific procedures that Federal agencies must follow to comply with NEPA.[4] The CEQ regulations require each agency to ''adopt procedures'' to supplement the CEQ regulations.[5]

FEMA established its Environmental Considerations regulations via a final rule on June 18, 1980, which established part 10 of 44 CFR.[6] Prior to publishing a final rule, FEMA published a proposed rule on December 6, 1979, seeking public comment on the new regulations.[7] FEMA received two public comments on the proposed rule. FEMA has not substantively revised 44 CFR part 10 since promulgating a final rule in 1980.

II. Discussion of Removal of Part 10

FEMA was an independent agency when it promulgated part 10 in 1980. In 2003, FEMA became a component of the Department of Homeland Security (DHS).[8] DHS initially issued Management Directive 5100.1 to ensure DHS components complied with the requirements of NEPA. On April 19, 2006, DHS promulgated a comprehensive Directive 023–01 to establish the policies and procedures for assuring compliance with NEPA. DHS components were required to comply with the DHS Directive unless a pre-existing regulation required an action conflicting with the Directive. On November 26, 2014, DHS issued revised NEPA implementing procedures, applicable to all DHS components, via a Directive and Instruction, which went into effect on March 26, 2015.[9] The DHS Directive and Instruction are included in the docket for this rulemaking at *www.regulations.gov.*

Prior to the issuance of the 2006 DHS Directive and Instruction, DHS did not have Department-wide NEPA procedures, but rather, each component of DHS followed its own implementing procedures. FEMA's implementing procedures, as already noted, are at 44 CFR part 10.

As a component of DHS, FEMA is required to follow DHS Directives and Instructions that apply to the whole Department. As such, FEMA is removing 44 CFR part 10, so that it may follow completely the new DHS Directive and Instruction. Accordingly, FEMA is also removing references to Part 10 throughout the regulations at 44 CFR and, where appropriate, replacing them with references to applicable environmental and historic preservation laws, regulations, Executive Orders, and agency policy. The DHS Directive and Instruction allow each DHS component to issue supplemental procedures. FEMA is issuing supplemental procedures in the form of a Directive and Instruction, a Notice of Availability for which appears in the Notice section of today's edition of the **Federal Register**. The similarities and differences between 44 CFR part 10 and the new supplemental procedures (the DHS Directive and Instruction and the FEMA Directive and Instruction) are described in the following section-by-section analysis. The changes to references to 44 CFR part 10 are also discussed below.

III. Section-by-Section Analysis

A. 44 CFR 10.1 Background and Purpose

Paragraph (a) of § 10.1 describes the purpose of 44 CFR part 10: to implement the CEQ regulations and to provide policy and procedures to enable FEMA officials to be informed of and take into account environmental considerations when authorizing or approving major FEMA actions that significantly affect the environment of the United States. The new supplemental procedures have a broader scope than Part 10. Part 10 focuses solely on NEPA implementation; the new supplemental procedures will address all environmental and historic preservation compliance (commonly referred to as ''EHP'' compliance). EHP compliance includes NEPA compliance but is broader to include other legal requirements for environmental and historic preservation. For example, the new supplemental procedures address compliance with the National Historic Preservation Act,[10] the Endangered Species Act,[11] Executive Order 11988 ''Floodplain Management,'' and Executive Order 12148 ''Protection of Wetlands,'' in addition to NEPA compliance.[12] The introductory paragraphs of the FEMA Directive and FEMA Instruction reflect this broader scope.[13]

[1] 42 U.S.C. 4321, 4331–4335, 4344, 4365.

[2] See 42 U.S.C. 4321.

[3] See 42 U.S.C. 4342; see also 42 U.S.C. 4344.

[4] See 40 CFR 1507.1.

[5] See 40 CFR 1507.3(a).

[6] See 45 FR 41141.

[7] See 44 FR 70197.

[8] Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135 (Nov. 25, 2002). See also 6 U.S.C. 313 (''There is in the Department [of Homeland Security] the Federal Emergency Management Agency.'')

[9] See 79 FR 70538 (Nov. 26, 2014). DHS published a draft Directive and Instruction for public comment on June 5, 2014. See 79 FR 32563.

[10] 16 U.S.C. 470h–2(c).

[11] 16 U.S.C. 1531.

[12] The FEMA Directive and Instruction do not supersede 44 CFR part 9, FEMA's implementing regulations for EO 11988 and EO 11990 (the precursor to EO 12148). Rather, these documents provide guidance for FEMA's implementing regulations of that EO.

[13] The Introduction to the FEMA Directive and Section 1.5.A of the FEMA Instruction state the following: ''Environmental stewardship, preservation of historic and cultural resources, and sustainability are complementary goals to the emergency management mission and activities of FEMA. FEMA promotes these goals to support development of resilient communities in light of disasters, sea level rise, climate change, and other impacts that threaten the human environment. Environmental, historic, and cultural resources are important considerations when preparing for, responding to, recovering from, and mitigating hazards to the United States. Protection and

Continued

Paragraphs (b) and (c) of § 10.1 restate the CEQ requirements directing all Federal agencies to adopt procedures to supplement the CEQ regulations, and that the provisions of Part 10 must be read together with the CEQ regulations and NEPA as a whole when applying the NEPA process. As stated above, the new DHS Directive and Instruction, as well as the FEMA Directive and Instruction, fulfill the CEQ requirement to adopt procedures to supplement the CEQ regulations.[14]

B. 44 CFR 10.2 Applicability and Scope

Section 10.2 states that Part 10 applies to FEMA, including any office or administration of FEMA, and the FEMA regional offices. The applicability is unchanged under the new procedures, which apply to all components of FEMA.[15]

C. 44 CFR 10.3 Definitions

Paragraph (a) of § 10.3 defines ''Regional Administrator'' as ''the Regional Administrator of the Federal Emergency Management Agency for the region in which FEMA is acting.'' The Regional Administrator positions have not changed since FEMA promulgated Part 10 in 1980 but the Homeland Security Act sets forth the responsibilities of the Regional Administrators.[16] The FEMA Directive and Instruction do not further define ''Regional Administrator'' per se, but the FEMA Directive does describe the Regional Administrator's duties in detail at Section VI.C.

Paragraph (c) of § 10.3 defines ''Environmental Officer'' as the ''Director, Office of Environmental Planning and Historic Preservation, Mitigation Directorate, or his or her designee.'' The title of this position is relatively unchanged: The ''Director of the Office of Environmental Planning and Historic Preservation (OEHP).'' The FEMA Directive, which describes the duties of this position in section VI.E, states that this position is designated by the FEMA Administrator and has the authority and responsibility to administer the OEHP and ensure its functional integration into FEMA missions. The FEMA Directive and Instruction do refer to an ''Environmental Officer,'' but it is no longer the Director of OEHP. Now, the Environmental Officer has duties distinct from the Director of OEHP, and is designated by and reports directly to the Director of OEHP. The FEMA Directive describes the duties of the Environmental Officer in Section VI.G.

Paragraph (b) of § 10.3 states that the other terms used in Part 10 are defined in the CEQ regulations at 40 CFR part 1508. The DHS Directive includes all CEQ definitions that FEMA uses in its Directive and Instruction. These include definitions for ''categorical exclusion (CATEX),'' [17] ''environmental assessment (EA),'' [18] ''environmental impact statement (EIS),'' [19] ''finding of no significant impact,'' [20] ''human environment,'' [21] and ''record of decision''.[22]

D. 44 CFR 10.4 Policy

Section 10.4(a) sets forth FEMA's goals to ensure that FEMA's actions, including disaster planning, response and recovery, and hazard mitigation and flood insurance are carried out in a manner consistent with NEPA, and that all practical means and measures are used to protect, restore, and enhance the quality of the environment, and to avoid or minimize adverse environmental consequences. The introduction to the FEMA Directive generally includes these goals, and FEMA Instruction section 1.5 also generally sets forth the policies included in 44 CFR 10.4. For example, paragraph 10.4(a)(1), regarding achieving the use of the environment without degradation, and paragraph 10.4(a)(3), regarding achieving a balance between resource use and development within the sustained carrying capacity of the ecosystem involved, are now included in the introduction of the FEMA Directive and Section 1.5.A of the Instruction, which state that ''FEMA promotes antidegradation and balances resource use and development with sustainability and use of renewable resources to manage these natural and cultural resources.'' Paragraph (a)(2) of § 10.4, addressing the preservation of historic, cultural and natural aspects of national heritage, is addressed in sections 1.5.A and B of the FEMA Instruction. Sections 1.5.B.3.a and b state that FEMA will conduct NEPA and other EHP reviews early in the decision making process and before making a decision ''that adversely affects natural or cultural resources,'' and will tailor the NEPA process so as to spend minimal time and resources on decisions ''that do not have potential to adversely affect natural and cultural resources.''

E. 44 CFR 10.5 Responsibilities

Section 10.5 sets out the responsibilities of the FEMA Regional Administrators, the Environmental Officer, the Heads of the Offices, Directorates, and Administrations of FEMA, and the Office of Chief Counsel.

The responsibilities of the FEMA Regional Administrators, which are in paragraph (a) of § 10.5, appear in section VI.C of the FEMA Directive. Note that many of the responsibilities of the FEMA Regional Administrators that appear in paragraph (a) of § 10.5 now fall under or are shared with other positions as outlined in the FEMA Directive, to reflect current FEMA practice. Paragraphs (a)(1) and (2) of § 10.5 require the Regional Administrators to prepare a finding of no significant impact, an EA (to be sent to the Environmental Officer and the Office of Chief Counsel), or EIS for each action not categorically excluded from Part 10 and falling within their respective jurisdictions. These duties appear generally under section VI.C, and more specifically under section VI.C.2.viii, of the FEMA Directive.

Paragraph (a)(3) of § 10.5 requires Regional Administrators to coordinate and provide information regarding environmental review with applicants for FEMA assistance. This duty appears in section VI.C.1.vii of the FEMA Directive, which states that Regional Administrators shall support early, proactive, and comprehensive outreach processes for EHP in their Regions with resource/regulatory agencies, applicants, and the public.

Paragraph (a)(4) of § 10.5 requires Regional Administrators to prepare and maintain an administrative record for each proposal that is determined to be categorically excluded from Part 10. Similarly, section VI.C.2.viii of the FEMA Directive states that Regional Administrators must ensure appropriate documentation of records of

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stewardship of the Nation's natural resources including floodplains and wetlands, coastal barriers, forests and fauna, biodiversity, endangered species, habitats, and other natural landscapes provide increased protection to communities throughout the Nation and support resiliency. Consistent with the goals of environmental and historic preservation laws and the policies of DHS, FEMA promotes antidegradation and balances resource use and development with sustainability and use of renewable resources to manage these natural and cultural resources.''

[14] See DHS Directive 023–01, Section I, ''This Directive and the Instruction Manual adopt and supplement the CEQ regulations and are to be used in conjunction with those regulations.''

[15] Section II of the FEMA Directive states that ''Policies in this EHP Directive apply to all FEMA headquarters, regional and field offices, programs, and directorates inclusive of all associated operations and facilities and including Joint Field Offices (JFO).''

[16] 6 U.S.C. 317. To view the organizational structure of FEMA and FEMA regions, go to this link: *http://www.fema.gov/about-agency.*

[17] 40 CFR 1508.4; DHS Instruction section II.

[18] 40 CFR 1508.9; DHS Instruction section II.

[19] 40 CFR 1508.11; DHS Instruction section II.

[20] 40 CFR 1508.13; DHS Instruction section II.

[21] 40 CFR 1508.14; DHS Instruction section II.

[22] 40 CFR 1505.2; DHS Instruction section II.

environmental consideration for CATEXs.

Paragraph (a)(5) of § 10.5 requires Regional Administrators to involve environmental agencies, applicants, and the public to the extent practicable in preparing EAs. The FEMA Directive describes this duty more generally as public outreach, falling under the positions of the Administrator (section VI.A.2.iv), the Heads of FEMA Offices, Programs, and Directorates (section VI.B.2.vi), the Regional Administrators (section VI.C.1.vii), the Director of the Office of Environmental Planning and Historic Preservation (section VI.E.1.iv), the Regional Environmental Officers (section VI.H.1.iii), and the EHP Program Coordinator (section VI.L.1.iv).

Paragraph (a)(6) requires the Regional Administrator to prepare, as required, a supplement to either the draft or final EIS. This duty falls under general NEPA compliance duties in the FEMA Directive. Section VI.B.2.vii of the FEMA Directive requires the Heads of Offices, Programs, and Directorates in FEMA to ensure the completion of appropriate EHP documentation for actions within their responsibility. Section VI.C.2.viii includes the same requirement for the Regional Administrators, and section VI.D.1.vi includes the same requirement for Federal Coordinating Officers. Section VI.E.4.ii.a requires the Director of the Office of Environmental Planning and Historic Preservation to oversee and ensure these duties are fulfilled. Section VI.H.4.iii.a requires the Regional Environmental Officers to ensure completion of appropriate NEPA documentation as well.

Paragraph (a)(7) requires the Regional Administrator to circulate draft and final EISs. This duty is no longer necessary and the FEMA Directive and Instruction do not include this specific provision. The appropriate FEMA personnel (such as the Environmental Officer) handle internal agency circulation of any environmental documentation falling under their responsibility as part of normal business practice.

Paragraph (a)(8) requires Regional Administrators to ensure that decisions are made in accordance with the policies and procedures of NEPA and Part 10, and to prepare a concise public record of such decisions. The FEMA Directive includes these duties generally for the Administrator (section VI.A), the Heads of Offices, Programs, and Directorates in FEMA (section VI.B.2.i: ''Ensure that all policies, programs, activities, and operations in their respective offices, programs, or directorates comply with all applicable EHP requirements'' and section VI.B.2.vii: ''Ensure completion of appropriate EHP documentation for actions within their responsibility. This responsibility includes ensuring that the action or project record includes adequate EHP documentation.''), the Regional Administrators (section VI.C.2.i: ''Ensure that all policies, programs, activities, and operations in their regions comply with all applicable EHP requirements'', section VI.C.2.ii: ''Consider the effects of their decisions on environmental, historic, and cultural resources in accordance with NEPA, CEQ regulations, the DHS Instruction 023–01, the EHP Instruction, and this EHP Directive'', and section VI.C.2.viii: ''Ensure appropriate documentation of EHP compliance for actions within their responsibility, such as Records of Environmental Consideration (RECs) for CATEXs, . . . This includes ensuring that the administrative record incorporates EHP documentation and a public record of decisions made in accordance with the policies and procedures of NEPA and other EHP requirements.''), the Federal Coordinating Officer (section VI.D.1.ii: ''Perform oversight and monitoring of the EHP review process'' and section VI.D.1.vi: ''Ensure appropriate documentation of the EHP review process for actions within their responsibility''), the Director of OEHP (section VI.E.2.i: ''Provide the quality assurance and quality control function for OEHP''), and the Regional Environmental Officers (section VI.H.2: ''Support EHP compliance within their Regions'' and section VI.H.4.iii.a: ''Support completion of the appropriate EHP review process, including the analyses and documentation for EHP requirements'').

Paragraph (a)(9) requires Regional Administrators to consider mitigating measures to avoid or minimize environmental harm, and, in particular, harm to and within floodplains and wetlands. The FEMA Directive includes this Regional Administrator responsibility in section VI.C.2.iv. The FEMA Directive also requires the Administrator to ensure FEMA Offices, Programs, and Directorates recommend EHP mitigation for FEMA's direct actions and grant decisions when appropriate (section VI.A.1.vi), requires the Federal Coordinating Officer to incorporate EHP mitigation measures as appropriate and practicable (section VI.D.1.vii), and requires the Environmental Officer to promote EHP mitigation as part of applicant projects and support enforcement of associated monitoring and EHP mitigation measures (section VI.G.3.i).

Paragraph (a)(9) requires the Regional Administrators to review and comment upon, as appropriate, EAs and impact statements of other Federal agencies and of State and local entities within their respective regions. The FEMA Directive includes this as a responsibility of the Environmental Officer, stating in section VI.G.2.vii that the Environmental Officer shall ''Review and comment upon, as appropriate and following notification to and approval by DHS SEP, EAs and EISs prepared by other Federal agencies or State and local entities that affect FEMA programs.''

The responsibilities of the Environmental Officer appear in paragraph (b) of § 10.5. The FEMA Directive includes these duties under two separate positions, the Director of OEHP (section VI.E) and the Environmental Officer (section VI.G). The Director of OEHP oversees the position of the Environmental Officer.

Paragraph (b)(1) states that the Environmental Officer shall determine, on the basis of the EA, whether an EIS is required, or whether a finding of no significant impact shall be prepared. The FEMA Directive does not specifically address this particular task, but it does require the Environmental Officer to oversee the EHP review process (section VI.G.2.i), and the Office of Chief Counsel provides legal sufficiency reviews, when appropriate, for EHP analyses and documents (section VI.K.2.iv), and as such these entities assist in making the determination of whether an action requires an EIS.

Paragraph (b)(2) requires the Environmental Officer to review all proposed changes or additions to the list of CATEXs. This responsibility appears in section VI.G.1.i of the FEMA Directive, under the duties of the Environmental Officer.

Paragraph (b)(3) requires the Environmental Officer to review all findings of no significant impact. This responsibility falls generally under the duties of the Environmental Officer in section VI.G.2.v of the FEMA Directive, which states that the Environmental Officer shall review draft and final environmental documentation and analyses prepared by OEHP or other headquarters offices when EHP Approval Authority has not been delegated to those offices. If authority is delegated, this task may fall to the Regional Environmental Officer (section VI.H.2.v) or the EHP Program Coordinator (section VI.L.1.ix) as oversight and review of environmental

documentation and analyses is included in EHP Approval Authority.

Paragraph (b)(4) requires the Environmental Officer to review all proposed draft and final environmental statements. As with the review of findings of no significant impact, this responsibility falls generally under the duties of the Environmental Officer in section VI.G.2.v of the FEMA Directive, which states that the Environmental Officer shall review draft and final environmental documentation and analyses prepared by OEHP or other headquarters offices when EHP Approval Authority has not been delegated to those offices. If authority is delegated, this task may fall to the Regional Environmental Officer (section VI.H.2.v) or the EHP Program Coordinator (section VI.L.1.ix).

Paragraph (b)(5) requires the Environmental Officer to publish the required notices in the **Federal Register**. While not mentioned specifically in the FEMA Directive, this duty would fall under the Environmental Officer's general duties of overseeing the EHP review process for FEMA (section VI.G.2.i).

Paragraph (b)(6) requires the Environmental Officer to provide assistance in the preparation of EAs and impact statements and assign lead agency responsibility when more than one FEMA office or administration is involved. In the FEMA Directive, this duty falls under the Environmental Officer in section VI.G.3.ii, which states that the Environmental Officer shall determine which FEMA program will lead the EHP review process for a project that crosses multiple FEMA programs when the FEMA programs involved in the project cannot agree upon who will serve as the lead, and in section VI.G.2.iv, which states that the Environmental Officer will provide assistance in the preparation of environmental documentation in the Regions and Programs as appropriate and assign lead agency responsibility when more than one FEMA office or administration is involved.

Paragraph (b)(7) requires the Environmental Officer to direct the preparation of environmental documents for specific actions when required. While not mentioned specifically in the FEMA Directive, this duty would fall under the Environmental Officer's general duties of overseeing the EHP review process for FEMA (section VI.G.2.i).

Paragraph (b)(8) requires the Environmental Officer to comply with the requirements of Part 10 when the FEMA Administrator promulgates regulations, procedures, or other issuances making or amending Agency policy. The Director of OEHP retains this duty generally to follow the requirements of the Agency's NEPA procedures for any Agency-wide action. The FEMA Directive states that it is the policy of FEMA to comply with all EHP Requirements, including all applicable laws, regulations, and executive orders, and it is the responsibility of the Heads of Offices, Programs, and Directorates with support from the Director of OEHP to comply with the Agency's policy (section VI.B.2.i and VI.E.2).

Paragraph (b)(9) requires the Environmental Officer to provide, when appropriate, consolidated FEMA comments on draft and final impact statements prepared for the issuance of regulations and procedures of other agencies. The FEMA Directive includes this requirement under the responsibilities of the Environmental Officer at section VI.G.2.vii, which states that the Environmental Officer shall review and comment upon, as appropriate, EAs and EISs of other Federal agencies.

Paragraph (b)(10) requires the Environmental Officer to review FEMA issuances that have environmental implications. While not mentioned specifically in the FEMA Directive, this duty would fall under the Environmental Officer's general duties of overseeing the EHP review process for FEMA (section VI.G.2.i).

Paragraph (b)(11) states that the Environmental Officer shall maintain liaison with CEQ, the Environmental Protection Agency, the Office of Management and Budget (OMB), other Federal agencies, and State and local groups, with respect to environmental analysis for FEMA actions affecting the environment. Under the DHS Directive section IV.B.2, the DHS Director of Sustainability and Environmental Programs (SEP) serves, unless otherwise delegated, as the single point of contact for DHS on NEPA and NEPA related-matters in interactions with CEQ, the OMB, the Advisory Council on Historic Preservation, and other Federal agency headquarters. Under the FEMA Directive section VI.G.2.iii, the Environmental Officer serves as the liaison with other Federal, State, and local agencies regarding environmental analyses for FEMA actions.

The responsibilities of the Heads of the Offices, Directorates, and Administrations of FEMA, which are listed in paragraph (c) of § 10.5, appear in section VI.B of the FEMA Directive.

Paragraph (c)(1) requires the Heads of the Offices, Directorates, and Administrations of FEMA to assess environmental consequences of proposed and ongoing programs within their respective organizational units. Section VI.B.2.ii of the FEMA Directive requires these entities to assess EHP requirements of proposed, new, and ongoing programs, policies, plans and projects within their organizational units before they make decisions or take action. Section VI.B.1.ii requires these entities to incorporate EHP review processes into development of regulations, procedures, and other policies for compliance with EHP requirements.

Paragraph (c)(2) requires the Heads of the Offices, Directorates, and Administrations of FEMA to prepare and process EAs and EISs for all regulations, procedures and other issuances making or amending program policy related to actions which do not qualify for CATEXs. Under the FEMA Directive, this responsibility falls under the Regional Administrators to prepare an EA (to be sent to the Environmental Officer and the Office of Chief Counsel), or EIS for each action not categorically excluded from Part 10 and falling within their respective jurisdictions. These duties appear generally under section VI.C, and more specifically under section VI.C.2.viii, of the FEMA Directive.

Paragraph (c)(3) requires the Heads of the Offices, Directorates, and Administrations of FEMA to integrate environmental considerations into their decision making process. This responsibility appears in section VI.B.1.i of the FEMA Directive, which mirrors the language of paragraph (c)(3) and adds the requirement that the integration occur *early* in the decision making process.

Paragraph (c)(4) requires the Heads of the Offices, Directorates, and Administrations of FEMA to ensure that regulations, procedures and other issuances making or amending program policy are reviewed for consistency with the requirements of Part 10. As stated above, section VI.B.1.ii of the FEMA Directive requires these entities to incorporate EHP review processes into development of regulations, procedures, and other policies for compliance with EHP requirements.

Paragraph (c)(5) requires the Heads of the Offices, Directorates, and Administrations of FEMA to designate a single point of contact for matters pertaining to this part. The FEMA Directive, in section VI.L, designates this single point of contact as the EHP Program Coordinator, who serves as a technical EHP resource for a specific program office.

Paragraph (c)(6) requires the Heads of the Offices, Directorates, and

Administrations of FEMA to provide applicants for FEMA assistance with technical assistance regarding FEMA's environmental review process. The FEMA Directive captures this duty in section VI.B.4.iv.d which stipulates that the Offices, Programs, and Directorates of FEMA must assist applicants or eligible entities in identifying the EHP requirements triggered by their proposed projects and the potential EHP mitigation measures that may affect project design. The FEMA Directive also lists this as a duty of the Regional Environmental Officer in section VI.H.4.iii.e, which states that the Regional Environmental Officer shall provide technical assistance and guidance to applicants regarding EHP review processes.

The responsibilities of the Office of Chief Counsel, which are in listed paragraph (d) of § 10.5, appear in section VI.K of the FEMA Directive. Paragraph (d)(1) states that the Office of Chief Counsel shall provide advice and assistance concerning the requirements of Part 10. The list of specific duties in section VI.K of the FEMA Directive all fall under this requirement to provide advice and assistance regarding compliance with NEPA. Specifically, section VI.K.2.v requires the Office of Chief Counsel to provide guidance to the Director of OEHP, FPO, EO, EHP Program Coordinators, the Heads of Offices, Programs, and Directorates, and others as appropriate to assist FEMA in maintaining EHP compliance.

Paragraph (d)(2) requires the Office of Chief Counsel to review all proposed changes or additions to the list of CATEXs. The FEMA Directive includes this as a primary responsibility of the Environmental Officer with support from the Office of Chief Counsel (section VI.G.1.i and VI.K.1.iv).

Paragraph (d)(3) requires the Office of Chief Counsel to review all findings of no significant impact, and paragraph (d)(4) requires the Office of Chief Counsel to review all proposed draft and final EISs. These duties fall under section VI.K.2.iv of the FEMA Directive, which requires the Office of Chief Counsel to provide legal sufficiency reviews on EHP analyses and documents. These analyses and documents can include findings of no significant impact and proposed draft and final EISs.

F. 44 CFR 10.6 Making or Amending Policy

Section 10.6 states that for all regulations, procedures, or other issuances making or amending policy, the head of the FEMA office or administration establishing such policy shall be responsible for application of Part 10 to that action. This responsibility continues to be that of the Heads of Offices, Programs, and Directorates under the FEMA Directive (section VI.B.2.i). As noted above, § 10.5(b)(8) requires the Environmental Officer to comply with the requirements of Part 10 when the FEMA Administrator promulgates regulations, procedures or other issuances making or amending Agency policy. Under the FEMA Directive, the Director of OEHP retains this duty generally to follow the requirements of the Agency's NEPA procedures for any Agency-wide action. The FEMA Directive states that it is the policy of FEMA to comply with all EHP Requirements, including all applicable laws, regulations, and executive orders, and it is the responsibility of the Heads of Offices, Programs, and Directorates with support from the Director of OEHP to comply with the Agency's policy (section VI.B.2.i and VI.E.2).

G. 44 CFR 10.7 Planning

Early Planning

Paragraph (a) of § 10.7 states that the Regional Administrator shall integrate the NEPA process with other planning at the earliest possible time to ensure that planning decisions reflect environmental values, to avoid delays later in the process, and to head off potential conflicts. The FEMA Directive mirrors this language in its list of Regional Administrator responsibilities in section VI.C.1.i. More generally, the FEMA Instruction in section 1.5.B.3.a states that it is the policy of FEMA to conduct NEPA and other EHP reviews early in the decision making process and before making a decision that adversely affects natural or cultural resources or limits the choices of alternatives to satisfy an Agency objective. Other requirements to integrate EHP review early in the process appear throughout the FEMA Directive and Instruction; for example, section 1.5.B.3.f of the Instruction states that it is the policy of FEMA to clearly convey EHP requirements, expectations, timelines, and information needs to applicants as early in the project lifecycle as possible, and section VI.B.1.i of the Directive states that it is the responsibility of the Heads of Offices, Programs, and Directorates in FEMA to integrate EHP considerations early into their decision making. In addition, the FEMA Instruction in section 3.1 addresses steps for applying NEPA early in the decision-making process.

Lead Agency

Paragraph (b) of § 10.7 states that to determine the lead agency for policy making in which more than one FEMA office or administration is involved or any action in which another Federal agency is involved, FEMA offices and administrations shall apply criteria defined in § 1501.5 of the CEQ regulation,[23] and if there is disagreement, the FEMA offices and/or administrations shall forward a request for lead agency determination to the Environmental Officer. The regulation states that the Environmental Officer will determine lead agency responsibility among FEMA offices and administration, and in those cases involving a FEMA office or administration and another Federal agency, the Environmental Officer will attempt to resolve the differences.[24] Finally, the regulation states that if unsuccessful, the Environmental Officer will file the request with CEQ for determination.[25]

The FEMA Directive, at section VI.G.2.iv, assigns the Environmental Officer the responsibility of assigning lead agency responsibility when more than one FEMA office or administration is involved in the preparation of environmental documentation. The FEMA Instruction more fully addresses ''Lead and Cooperating Agencies,'' including the involvement of other Federal agencies, in section 3.3. The DHS Instruction, section V.F, provides the overarching general requirements for ''Cooperating and Joint Lead Agency Relationships.'' As FEMA is a component of DHS, DHS acts as the liaison with CEQ; if the Environmental Officer is unable to resolve any differences with another Federal agency, the Environmental Officer would raise it to DHS which in turn may liaise with CEQ on the matter.

Technical Assistance to Applicants

Paragraph (c) of § 10.7 addresses the requirements of § 1501.2(d) of the CEQ regulations which require agencies to provide for early involvement in action which, while planned by private applicants or other non-Federal entities, require some form of Federal approval. The FEMA Instruction addresses technical assistance in section 2.2.B.

Paragraph (c)(1)(i) states that the heads of the FEMA offices and administration shall prepare where practicable, generic guidelines

[23] 40 CFR 1501.5 addresses when a lead agency is required, the process for determining a lead agency, and the responsibilities of the lead agency.

[24] 44 CFR 10.7(b)(1) & (2).

[25] 44 CFR 10.7(b)(2).

describing the scope and level of environmental information required from applicants as a basis for evaluating their proposed actions, and make those guidelines available upon request. Section 2.2.B.3 of the FEMA Instruction discusses program responsibilities in providing guidance to applicants for collection of information for EHP review.

Paragraph (c)(1)(ii) requires the Regional Administrator to provide the guidance on a project-by-project basis to applicants seeking assistance from FEMA. Section 2.2 of the FEMA Instruction describes in detail how Programs and EHP staff will provide guidance to all applicants whenever there is a proposed action.

Paragraph (c)(1)(iii) states that upon receipt of an application for agency approval, or notification that an application will be filed, the Regional Administrator shall consult as required with other appropriate parties to initiate and coordinate the necessary environmental analyses. Section 2.2.B.5 of the FEMA Instruction mirrors this language.

Paragraph (c)(2) lists the responsibilities of applicants and other non-Federal entities to facilitate the requirements of § 1501.2(d) of the CEQ regulations. The FEMA Directive and Instruction apply to FEMA, not directly to applicants or other non-Federal entities. As the EHP procedures will now appear in guidance documents (the FEMA Directive and Instruction), FEMA is not including direct requirements on applicants in those documents. However, the guidance does require FEMA to provide the same information to applicants as is included in paragraph (c)(2) of § 10.7 (*e.g.,* information regarding studies and surveys the applicant may conduct, when to submit applications, and the process for consulting with Federal, regional, State, and local agencies).

H. 44 CFR 10.8 Determination of Requirement for Environmental Review

The introduction to § 10.8 addresses the first step in applying the NEPA process, namely, the determination of whether to prepare an EA or an EIS. The introduction to § 10.8 states that early determination will help ensure that necessary environmental documentation is prepared and integrated into the decision making process. It also states that EISs will be prepared for all major Agency actions significantly affecting the quality of the human environment. Paragraph (a) states that in determining whether to prepare an EIS, the Regional Administrator will first determine whether the proposal is one which normally requires an EIS, or normally does not require either an EIS or an EA (CATEX).

Sections 3.1 and 3.2 of the FEMA Instruction address NEPA implementing procedures for FEMA and comprehensively address the elements in the introduction and paragraph (a) of § 10.8. Specifically, section 3.1 of the FEMA Instruction addresses the application of NEPA early in the FEMA decision making process. Section 3.2 of the FEMA Instruction explains the process of determining the appropriate level of NEPA review, as part of a process referred to as ''scoping,'' and also covers the process of determining whether a statutory exclusion or CATEX applies. Section 3.2.B explains the process for determining the significance of a proposed action. Section 3.2.B.1 lists typical classes of actions that require an EA, and sections 3.2.B.2 list typical classes of actions that require an EIS.

1. 10.8(b): Actions That Normally Require an EIS

Paragraph (b) of § 10.8 addresses actions that normally require an EIS. Paragraph (b)(1) states that in some cases, it will be readily apparent that a proposed action will have significant impact on the environment, in which case, the Regional Administrator will begin the process of preparing an EIS. While there is not an exact correspondence to this provision in the FEMA Directive or Instruction, the procedures set out in the FEMA Instruction at section 3.2.B will capture any actions that seem likely, without the need for in-depth analysis, to have significant impact on the environment.

Paragraph (b)(2) sets out criteria for determining those actions that normally do require an EIS: (i) An action that will result in an extensive change in land use or the commitment of a large amount of land, (ii) an action that will result in a land use change which is incompatible with the existing or planned land use of the surrounding area, (iii) an action where many people will be affected, (iv) an action where the environmental impact of the project is likely to be controversial, (v) an action that will, in large measure, affect wildlife populations and their habitats, important natural resources, floodplains, wetlands, estuaries, beaches, dunes, unstable soils, steep slopes, aquifer recharge areas, or delicate or rare ecosystems, including endangered species; (vi) an action that will result in a major adverse impact upon air or water quality; (vii) an action that will adversely affect a property listed on the National Register of Historic Places; (viii) an action that is one of several actions underway or planned for an area and the cumulative impact of these projects is considered significant; (ix) an action that holds potential for threat or hazard to the public; and (x) an action that is similar to previous actions that were determined to require an EIS. The FEMA Instruction includes an updated list of these elements in section 3.2.B.2. The list in section 3.2.B.2 includes an additional element to reflect that an EIS may be required for the creation, modifications to the implementation, or reformation of a nationwide FEMA program, with known or potentially significant impacts to the environment. FEMA also removed elements from the list that are no longer necessary to include, in conformance with the DHS Directive and Instruction.

Paragraph (b)(3) of § 10.8 states that in any case involving an action that normally does not require an EIS, the Regional Administrator may prepare an EA to determine if an EIS is required. There is no direct corollary to this provision in the FEMA Directive or Instruction; however, under section 3.2.B.1 of the FEMA Instruction, the Regional Environmental Officer or other FEMA official with EHP Approval Authority may prepare an EA as part of the process of determining the significance of an action.

2. 10.8(c): Statutory Exclusions

Paragraph (c) of § 10.8 lists the actions that are statutorily excluded from NEPA by section 316 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act [26] (Stafford Act); these actions include action taken or assistance provided under sections 402,[27] 403,[28] 407,[29] or 502 [30] of the Stafford Act, and action taken or assistance provided under section 406 [31] of the Stafford Act that has the effect of restoring facilities substantially as they existed before a major disaster or emergency.[32] Neither the DHS Directive and Instruction nor the FEMA Directive

[26] 42 U.S.C. 5121–5207.

[27] 42 U.S.C. 5170a, General Federal assistance FEMA may provide under a Presidential major disaster declaration.

[28] 42 U.S.C. 5170b, Essential assistance (often referred to as ''emergency protective measures'') FEMA may provide under a Presidential major disaster declaration.

[29] 42 U.S.C. 5173, Assistance FEMA may provide for debris removal.

[30] 42 U.S.C. 5192, Federal emergency assistance FEMA may provide under a Presidential emergency declaration.

[31] 42 U.S.C. 5172, Assistance FEMA may provide for the repair, restoration, and replacement of damaged facilities.

[32] See 42 U.S.C. 5159.

and Instruction contain these statutory exclusions. The appearance of the exclusions in statute (at 42 U.S.C. 5159) precludes the necessity of listing them in guidance. The exclusions still apply to actions that fall under them, but FEMA is no longer listing these exclusions in either regulation or guidance.

3. 10.8(d): CATEXs

The introduction to paragraph (d) of § 10.8 reiterates CEQ regulation 40 CFR 1508.4 which provides for the categorical exclusion of actions that do not individually or cumulatively have a significant impact on the human environment and for which, therefore, neither an EA nor EIS is required. The DHS Instruction at section V.B.1 reiterates the CEQ regulation. As described more fully below, the DHS Instruction in Appendix A includes a list of all DHS CATEXs, including FEMA's CATEXs.

10.8(d)(1): CATEXs: Criteria

Paragraph (d)(1) of § 10.8 addresses the criteria FEMA uses for determining those categories of actions that normally do not require either an EA or EIS, including actions that have (i) minimal or no effect on environmental quality, (ii) no significant change to existing environmental conditions, and (iii) no significant cumulative environmental impact. There is no direct correlation of paragraph (d)(1) to the DHS Directive or Instruction; however, section V.B of the DHS Instruction details the DHS process for adding to, revising, or deleting items on the DHS list of CATEXs. Under section V.B.2 of the DHS Instruction, a proposed action must meet three conditions in order to be categorically excluded: (1) It must clearly fit into a CATEX category listed in Appendix A, (2) it is not a piece of a larger action, and (3) no extraordinary circumstances exist. Extraordinary circumstances are discussed more fully below.

10.8(d)(2): CATEXs: List of Exclusion Categories

Paragraph (d)(2) of § 10.8 lists FEMA's CATEXs. For the most part, the list is unchanged in the DHS Instruction. The DHS Instruction lists the CATEXs that apply to the entire Department in sections A through G, and N of Appendix A.[33] It lists the CATEXs that apply only to FEMA in section M of Appendix A. The CATEXs that are listed in paragraph (d)(2), along with any differences between (d)(2) and the DHS Instruction, are noted as follows:

44 CFR 10.8(d)(2)(i): Administrative actions such as personnel actions, travel, or procurement of supplies in support of normal day-to-day activities and disaster related activities. The DHS Instruction covers administrative actions generally in section A of Appendix A. It covers personnel actions and travel in CATEX A1, and it covers procurement in CATEX A6.

44 CFR 10.8(d)(2)(ii): Preparation, revision, and adoption of regulations, directives, manuals, and other guidance documents related to actions that qualify for CATEXs. There is no direct correlation to this CATEX in the DHS Instruction. However, the DHS Instruction does include a CATEX (A3) for these documents if they are (1) strictly of an administrative or procedural nature, (2) they implement, without substantive change, statutory or regulatory requirements, (3) they implement, without substantive change, procedures, manuals, and other guidance documents, (4) they interpret or amend an existing regulation without changing its environmental effect, (5) they provide technical guidance on safety or security matters, or, (6) they provide guidance for the preparation of security plans.

44 CFR 10.8(d)(2)(iii): Studies that involve no commitment of resources other than manpower and associated funding. There is no direct correlation to this CATEX in the DHS Instruction. However, the DHS Instruction does include a CATEX (A4) for information gathering, data analysis and processing, information dissemination, review, interpretation, and development of documents, including studies, reports, proposals, analyses, literature reviews; computer modeling; and non-intrusive intelligence gathering activities.

44 CFR 10.8(d)(2)(iv): Inspection and monitoring activities, granting of variances, and actions to enforce Federal, State, or local codes, standards, or regulations. There is no direct correlation to this CATEX in the DHS Instruction. The DHS Instruction does not include a CATEX for the granting of variances. It does include several CATEXs that cover inspection, monitoring, and enforcement activities as follows: CATEX C10, Real property inspections to ensure compliance with deed or easement restrictions; CATEX M1, with respect to FEMA's administration of the National Flood Insurance Program, actions associated with inspections and monitoring, enforcement of Federal, State, Tribal, or local floodplain management codes, standards, or regulations, except for the suspension of communities from the National Flood Insurance Program; CATEX M11, information and data gathering and reporting in support of emergency and disaster response and recovery activities, including ground and aerial reconnaissance and structure inspection; and CATEX N1, with respect to administrative actions associated with grants management, conducting inspections, financial audits, and monitoring activities.

44 CFR 10.8(d)(2)(v): Training activities and both training and operational exercises utilizing existing facilities in accordance with established procedures and land use designations. Section G of Appendix A of the DHS Instruction covers training and exercises. In particular, it covers in CATEX G1 training of homeland security personnel, including international, Tribal, State, and local agency representatives using existing facilities where the training occurs in accordance with applicable permits and other requirements for the protection of the environment. In addition, CATEX G2 covers projects, grants, cooperative agreements, contracts, or activities to design, develop, and conduct national, State, local, or international exercises to test the readiness of the nation to prevent or respond to a terrorist attack or a natural or manmade disaster and where conducted in accordance with existing facility or land use designations.

44 CFR 10.8(d)(2)(vi): Procurement of goods and services for support of day-to-day and emergency operational activities, and the temporary storage of goods other than hazardous materials, so long as storage occurs on previously disturbed land or in existing facilities. CATEX A6 of the DHS Instruction covers procurement of non-hazardous goods and services, and storage, recycling, and disposal of non-hazardous materials and wastes, that complies with applicable requirements and is in support of routine administrative, operational, or maintenance activities. Storage activities must occur on previously disturbed land or in existing facilities. Examples include but are not limited to: Office supplies, equipment, mobile assets, utility services, chemicals and low level radio nuclides for laboratory use, deployable emergency response supplies and equipment, and waste

[33] Each section covers specific activities, as follows: Section A, Administrative and Regulatory Activities; Section B, Operational Activities; Section C, Real Estate Activities; Section D, Repair and Maintenance Activities; Section E, Construction, Installation, and Demolition Activities; Section F, Hazardous/Radioactive Materials Management and Operations; Section G, Training and Exercises; Section N, Federal Assistance Activities. CATEXs are numbered within each section; for example, A1, A2, A3; B1, B2, B3.

disposal and contracts for waste disposal in established permitted landfills and facilities.

44 CFR 10.8(d)(2)(vii): The acquisition of properties and the associated demolition/removal or relocation of structures under any applicable authority when the acquisition is from a willing seller, the buyer coordinated acquisition planning with affected authorities, and the acquired property will be dedicated in perpetuity to uses that are compatible with open space, recreational, or wetland practices. CATEX N3 of the DHS Instruction covers Federal assistance for the acquisition of properties and associated demolition/removal when the acquisition is from a willing seller and land is deed restricted to open space, recreational, wildlife habitat, or wetland uses in perpetuity. CATEX N6 covers Federal assistance for the relocation of structures and facilities, including the realignment of linear facilities that are part of a bigger system, when they do not involve ground disturbance of more than one acre. This category does not apply to the following: Actions that involve hardening or armoring of stream banks, unless they use stream or stream bank bioengineering techniques that improve fish passage or habitat; realignment actions affecting a regulatory floodway if they result in any increase in flood levels during the base flood discharge; or actions occurring seaward of the limit of moderate wave action (or V zone when the limit of moderate wave action has not been identified).

44 CFR 10.8(d)(2)(viii): Acquisition or lease of existing facilities where planned uses conform to past use or local land use requirements. CATEX C1 of the DHS Instruction covers acquisition of an interest in real property that is not within or adjacent to environmentally sensitive areas, including interests less than a fee simple, by purchase, lease, assignment, easement, condemnation, or donation, which does not result in a change in the functional use of the property.

44 CFR 10.8(d)(2)(ix): Acquisition, installation, or operation of utility and communication systems that use existing distribution systems or facilities, or currently used infrastructure rights-of-way. CATEX E1 of the DHS Instruction covers construction, installation, operation, maintenance, and removal of utility and communication systems (such as mobile antennas, data processing cable, and similar electronic equipment) that use existing rights-of-way, easements, utility distribution systems, and/or facilities. This is limited to activities with towers where the resulting total height does not exceed 200 feet and where the Federal Communications Commission would not require an EA or EIS for the acquisition, installation, operation or maintenance.

44 CFR 10.8(d)(2)(x): Routine maintenance, repair, and grounds-keeping activities at FEMA facilities. CATEX D3 in the DHS Instruction covers repair and maintenance of Department [34]-managed buildings, roads, airfields, grounds, equipment, and other facilities which do not result in a change in functional use or an impact on a historically significant element or setting (*e.g.,* replacing a roof, painting a building, resurfacing a road or runway, pest control activities, restoration of trails and firebreaks, culvert maintenance, grounds maintenance, existing security systems, and maintenance of waterfront facilities that does not require individual regulatory permits).

44 CFR 10.8(d)(2)(xi): Planting of indigenous vegetation. CATEX N12 of the DHS Instruction covers Federal assistance for planting of indigenous vegetation.

44 CFR 10.8(d)(2)(xii): Demolition of structures and other improvements or disposal of uncontaminated structures and other improvements to permitted off-site locations, or both. CATEX E4 of the DHS Instruction covers the removal or demolition, along with subsequent disposal of debris to permitted or authorized off-site locations, of non-historic buildings, structures, other improvements, and/or equipment in compliance with applicable environmental and safety requirements.

44 CFR 10.8(d)(2)(xiii): Physical relocation of individual structures where FEMA has no involvement in the relocation site selection or development. Although the DHS Instruction does not include a CATEX exactly on point with this provision, CATEX N6, which covers Federal assistance for the relocation of structures and facilities, including the realignment of linear facilities that are part of a bigger system, when they do not involve ground disturbance of more than one acre, addresses it most closely.

44 CFR 10.8(d)(2)(xiv): Granting of community-wide exceptions for floodproofed residential basements meeting the requirements of 44 CFR 60.6(c) under the National Flood Insurance Program. This CATEX is not discussed in the FEMA Directive or Instruction because since the addition of this CATEX, the National Flood Insurance Program has concluded it is unnecessary, as work on basements is not considered a major Federal action subject to NEPA review.

44 CFR 10.8(d)(2)(xv): Repair, reconstruction, restoration, elevation, retrofitting, upgrading to current codes and standards, or replacement of any facility in a manner that substantially conforms to the preexisting design, function, and location. This CATEX is covered in part by the statutory exclusion at 42 U.S.C. 5159, and in part by CATEX N7 of the DHS Instruction which covers Federal assistance for the reconstruction, elevation, retrofitting, upgrading to current codes and standards, and improvements of pre-existing facilities in existing developed areas with substantially completed infrastructure, when the immediate project area has already been disturbed, and when those actions do not alter basic functions, do not exceed capacity of other system components, or modify intended land use. CATEX N7 also states that this category does not include actions within or affecting streams or stream banks or actions seaward of the limit of moderate wave action (or V zone when the limit of moderate wave action has not been identified).

44 CFR 10.8(d)(2)(xvi): Improvements to existing facilities and the construction of small scale hazard mitigation measures in existing developed areas with substantially completed infrastructure, when the immediate project area has already been disturbed, and when those actions do not alter basic functions, do not exceed capacity of other system components, or modify intended land use, provided the operation of the completed project will not, of itself, have an adverse effect on the quality of the human environment. This FEMA CATEX, similar to the FEMA CATEX at 44 CFR 10.8(d)(2)(xv), is covered by CATEX N7 of the DHS Instruction.

44 CFR 10.8(d)(2)(xvii): Actions conducted within enclosed facilities where all airborne emissions, waterborne effluent, external radiation levels, outdoor noise, and solid and bulk waste disposal practices comply with existing Federal, State, and local laws and regulations. CATEX B1 of the DHS Instruction, while slightly different than the FEMA CATEX, covers actions within enclosed facilities; specifically, CATEX B1 covers research, development, testing, and evaluation activities, or laboratory operations conducted within existing enclosed facilities consistent with previously established safety levels and in compliance with applicable Federal, Tribal, State, and local requirements to protect the environment when it will

[34] The DHS Instruction in Section II defines ''Department'' to include FEMA.

result in no, or *de minimus,* change in the use of the facility. CATEX B1 requires an EA (and possibly an EIS) if the operation will substantially increase the extent of potential environmental impacts or is controversial.

44 CFR 10.8(d)(2)(xviii): Planning and administrative activities in support of emergency and disaster response and recovery. Paragraphs (A) through (E) of § 10.8(d)(2)(X)(viii) cover these activities as follows:

44 CFR 10.8(d)(2)(xviii)(A): Activation of the Emergency Support Team and convening of the Catastrophic Disaster Response Group at FEMA headquarters. CATEX M10 of the DHS Instruction covers activation of response and recovery frameworks and operations (*e.g.,* National Response Framework, National Disaster Recovery Framework, National Response Coordination Center, Regional Response Coordination Center, Emergency Response Teams, Incident Management Assistance Teams, Emergency Support Functions, Recovery Support Functions).

44 CFR 10.8(d)(2)(xviii)(B): Activation of the Regional Operations Center and deployment of the Emergency Response Team, in whole or in part. This FEMA CATEX, similar to the FEMA CATEX at 44 CFR 10.8(d)(2)(xviii)(A), is covered by CATEX M10 of the DHS Instruction.

44 CFR 10.8(d)(2)(xviii)(C): Deployment of Urban Search and Rescue teams. CATEX M3 of the DHS Instruction covers Urban Search and Rescue (USR) activities, including deployment of USR teams.

44 CFR 10.8(d)(2)(xviii)(D): Situation Assessment including ground and aerial reconnaissance. CATEX M11 of the DHS Instruction covers information and data gathering and reporting in support of emergency and disaster response and recovery activities, including ground and aerial reconnaissance and structure inspection.

44 CFR 10.8(d)(2)(xviii)(E): Information and data gathering and reporting efforts in support of emergency and disaster response and recovery and hazard mitigation. This FEMA CATEX, similar to the FEMA CATEX at 44 CFR 10.8(d)(2)(xviii)(D), is covered by CATEX M11 of the DHS Instruction.

44 CFR 10.8(d)(2)(xix): Emergency and disaster response, recovery and hazard mitigation activities under the Stafford Act. Paragraphs (A) through (O) of § 10.8(d)(2)(xix) cover these activities as follows:

44 CFR 10.8(d)(2)(xix)(A): General Federal Assistance (section 402 of the Stafford Act). This provision is statutorily excluded from NEPA by 42 U.S.C. 5159. The DHS Instruction does not include statutory exclusions in its list of CATEXs.

44 CFR 10.8(d)(2)(xix)(B): Essential Assistance (section 403 of the Stafford Act). This provision is statutorily excluded from NEPA by 42 U.S.C. 5159. The DHS Instruction does not include statutory exclusions in its list of CATEXs.

44 CFR 10.8(d)(2)(xix)(C): Debris Removal (section 407 of the Stafford Act). This provision is statutorily excluded from NEPA by 42 U.S.C. 5159. The DHS Instruction does not include statutory exclusions in its list of CATEXs.

44 CFR 10.8(d)(2)(xix)(D): Temporary Housing (section 408 of the Stafford Act), except locating multiple mobile homes or other readily fabricated dwellings on sites, other than private residences, not previously used for such purposes. CATEX N14(b) of the DHS Instruction generally covers the Individuals and Households Program (IHP) (authorized by section 408 of the Stafford Act), which includes temporary housing. However, CATEX N14(b) excludes any grant that will be used for purchasing mobile homes or other readily fabricated dwellings.

44 CFR 10.8(d)(2)(xix)(E) Unemployment Assistance (section 410 of the Stafford Act). CATEX N14(a) of the DHS Instruction covers unemployment assistance under section 410 of the Stafford Act.

44 CFR 10.8(d)(2)(xix)(F): Individual and Family Grant Program (section 411 of the Stafford Act), except for grants that will be used for restoring, repairing or building private bridges, or purchasing mobile homes or other readily fabricated dwellings. The Individual and Family Grant Program is a defunct program (the IHP superseded it) and the DHS Instruction does not include it in its list of CATEXs.

44 CFR 10.8(d)(2)(xix)(G): Food Coupons and Distribution (section 412 of the Stafford Act). CATEX N14(c) of the DHS Instruction covers food coupons and distribution under section 412 of the Stafford Act.

44 CFR 10.8(d)(2)(xix)(H): Food Commodities (section 413 of the Stafford Act). CATEX N14(d) of the DHS Instruction covers food commodities under section 413 of the Stafford Act.

44 CFR 10.8(d)(2)(xix)(I): Legal Services (section 415 of the Stafford Act). CATEX N14(e) of the DHS Instruction covers legal services under section 415 of the Stafford Act.

44 CFR 10.8(d)(2)(xix)(J): Crisis Counseling Assistance and Training (section 416 of the Stafford Act). CATEX N14(f) of the DHS Instruction covers crisis counseling and training under section 416 of the Stafford Act.

44 CFR 10.8(d)(2)(xix)(K): Community Disaster Loans (section 417 of the Stafford Act). CATEX N14(g) of the DHS Instruction covers community disaster loans under section 417 of the Stafford Act.

44 CFR 10.8(d)(2)(xix)(L): Emergency Communications (section 418 of the Stafford Act). CATEX N14(h) of the DHS Instruction covers emergency communications under section 418 of the Stafford Act.

44 CFR 10.8(d)(2)(xix)(M): Emergency Public Transportation (section 419 of the Stafford Act). CATEX N14(i) of the DHS Instruction covers emergency public transportation under section 419 of the Stafford Act.

44 CFR 10.8(d)(2)(xix)(N): Fire Management Assistance Grants (section 420 of the Stafford Act). CATEX N14(j) of the DHS Instruction covers fire management assistance grants under section 420 of the Stafford Act.

44 CFR 10.8(d)(2)(xix)(O): Federal Emergency Assistance (section 502 of the Stafford Act). This provision is statutorily excluded from NEPA by 42 U.S.C. 5159. The DHS Instruction does not include statutory exclusions in its list of CATEXs.

44 CFR 10.8(d)(3): CATEXs: Extraordinary circumstances.

Paragraph (d)(3) of § 10.8 covers extraordinary circumstances. It requires an EA to be prepared if extraordinary circumstances exist such that an action that is categorically excluded from NEPA may have a significant adverse environmental impact. Similarly, under the DHS Instruction at section V.B.2.c, the presence of an extraordinary circumstance precludes the application of a CATEX. Paragraphs (i) through (x) of § 10.8(d)(3) list the extraordinary circumstances that may have a significant environmental impact. The extraordinary circumstances listed in paragraphs (d)(3)(i) through (x), along with any differences between (d)(3)(i) through (x) and the DHS Instruction, are as follows:

44 CFR 10.8(d)(3)(i) Greater scope or size than normally experienced for a particular category of action. The DHS Instruction at section V.B.2.c.viii correlates almost exactly to this provision, but adds the word ''significantly'' before ''greater scope or size.''

44 CFR 10.8(d)(3)(ii) Actions with a high level of public controversy. The DHS Instruction at section V.B.2.c.vi covers actions likely to be controversial. Specifically, it covers actions where the effect on the quality of the human environment is likely to be highly

controversial in terms of scientific validity, likely to be highly uncertain, or likely to involve unique or unknown environmental risks, including effects that may result from the use of new technology or unproven technology. However, it states that controversy over, including public opposition to, a proposed action absent any demonstrable potential for significant environmental impacts does not itself constitute an extraordinary circumstance.

44 CFR 10.8(d)(3)(iii) Potential for degradation, even though slight, of already existing poor environmental conditions. The DHS Instruction in section V.B.2.c.ix covers actions that have the potential for significant degradation of already existing poor environmental conditions, as well as the initiation of a potentially significant environmental degrading influence, activity, or effect in areas not already significantly modified from their natural condition.

44 CFR 10.8(d)(3)(iv) Employment of unproven technology with potential adverse effects or actions involving unique or unknown environmental risks. As noted above, the DHS Instruction at section V.B.2.c.vi covers effects that may result from the use of unproven technology likely to involve unique or unknown environmental risks.

44 CFR 10.8(d)(3)(v) Presence of endangered or threatened species or their critical habitat, or archaeological, cultural, historical, or other protected resources. The DHS Instruction at section V.B.2.c.iii covers actions that may have a potentially significant effect on historic properties (*e.g.,* districts, sites, buildings, structures, or objects) that are listed in or eligible for listing in the National Register of Historic Places, affect traditional cultural properties or sacred sites, or lead to the loss or destruction of a significant scientific, cultural, or historical resource.

44 CFR 10.8(d)(3)(vi) Presence of hazardous or toxic substances at levels which exceed Federal, State, or local regulations or standards requiring action or attention. The DHS Instruction at section V.B.2.c.v covers a potential or threatened violation of a Federal, State, or local law or requirement imposed to protect the environment, including Federal, Tribal, State, or local requirements to control hazardous or toxic substances.

44 CFR 10.8(d)(3)(vii) Actions with the potential to affect special status areas adversely or other critical resources such as wetlands, coastal zones, wildlife refuge and wilderness areas, wild and scenic rivers, sole or principal drinking water aquifers. The DHS Instruction at section V.B.2.c.ii covers actions that may have a potentially significant effect on species or habitats protected by the Endangered Species Act, Marine Mammal Protection Act, Migratory Bird Treaty Act, Magnuson-Stevens Fishery Conservation and Management Act, or other law protecting a species or habitat. In addition, the DHS Instruction at section V.B.2.c.iv covers actions that may have a potentially significant effect on an environmentally sensitive area.[35]

44 CFR 10.8(d)(3)(viii) Potential for adverse effects on health or safety. The DHS Instruction at section V.B.2.c.i covers actions that may have a potentially significant effect on public health or safety.

44 CFR 10.8(d)(3)(ix) Potential to violate a Federal, State, local, or Tribal law or requirement imposed for the protection of the environment. The DHS Instruction at section V.B.2.c.v covers actions that may have a potential or threatened violation of a Federal, State, or local law or requirement imposed to protect the environment.

44 CFR 10.8(d)(3)(x) Potential for significant cumulative impact when the proposed action is combined with other past, present, and reasonably foreseeable future actions, even though the impacts of the proposed action may not be significant by themselves. The DHS Instruction at section V.B.2.c.x covers actions related to other actions with individually insignificant, but cumulatively significant impacts.

44 CFR 10.8(d)(4): CATEXs: Documentation.

Paragraph (d)(4) of § 10.8 requires the Regional Administrator to prepare and maintain an administrative record of each proposal that is determined to be categorically excluded from the preparation of an EA or EIS. The DHS Instruction at section V.B.4 requires a record of environmental consideration whenever a CATEX denoted by an asterisk is applied [36] in order to document that potential impacts to the human environment have been appropriately considered and the determination that the proposed action is either appropriately categorically excluded or must be analyzed further through an EA or EIS process. In addition, the DHS Instruction acknowledges there may be instances where a DHS component may choose to prepare a record of environmental consideration when it is not otherwise required. It is not mandatory, however.

44 CFR 10.8(d)(5): CATEXs: Revocation.

Paragraph (d)(5) of § 10.8 requires the Regional Administrator to revoke a determination of a CATEX and require full environmental review if, subsequent to granting an exclusion, the Regional Administrator determines that due to changes in the proposed action or in light of new findings, the action no longer meets the requirements for a CATEX. Although there is no specific provision directly on point in the new DHS or FEMA Directives or Instructions, the FEMA Instruction in section 2.2.E does require FEMA to communicate to applicants the need to notify FEMA of any changes to the proposed action, alternatives, or project schedule; the FEMA Instruction specifically states that when changes to project plans create substantial changes or significant new circumstances or information relevant to EHP reviews, FEMA will seek assistance from applicants so FEMA can prepare supplemental or additional EHP analyses as required under EHP requirements.

44 CFR 10.8(d)(6): CATEXs: Changes to the list of exclusion categories.

Paragraph (d)(6) of § 10.8 requires FEMA to continually review and refine the list of exclusion categories as additional categories are identified and experience is gained in the CATEX process. Paragraph (d)(6) also outlines the internal process for a FEMA entity to recommend additions or changes to the list. The DHS Instruction in section V.B.3 addresses the establishment, deletion, and revision of CATEXs. Under the DHS Instruction, components forward proposals to substantively revise or establish new CATEXs (together with justification) to the Director of SEP for approval. Proposals to substantively revise or establish new CATEXs require an administrative record that meets CEQ standards and are subject to both CEQ review and public comment. SEP reviews such proposals to determine whether the CATEX is appropriate for inclusion in the DHS-wide list or a component-specific list. SEP revises Appendix A, Table 1 to

[35] The DHS Instruction defines ''environmentally sensitive area'' as an area designated by law, regulation, or executive order that merits special protection or stewardship because of its value as a natural, historic, or cultural resource. Examples include, but are not limited to: (1) Proposed or designated critical habitat for threatened or endangered species; (2) properties listed or eligible for listing on the National Register of Historic Places; and (3) areas having special designation or recognition such as prime or unique agricultural lands, *coastal zones, designated wilderness or wilderness study areas, wild and scenic rivers,* 100 year floodplains, *wetlands, sole source aquifers,* Marine Sanctuaries, National Wildlife Refuges, National Parks, National Monuments, essential fish habitat, etc. (emphasis added).

[36] CATEXs denoted by an asterisk include classes of actions that have a higher possibility of involving extraordinary circumstances that may preclude the use of a CATEX. See DHS Instruction section V.B.4.

include approved new or substantially revised CATEXs. In addition, components notify SEP of non-substantive revisions to or deletions of component-specific CATEXs so that SEP can amend the table accordingly. Finally, all CATEXs and the list of extraordinary circumstances are reviewed by SEP in consultation with the components at least every 7 years to ensure they are still appropriate, and to identify any changes that may be needed in light of additional experience gained in applying the CATEXs to proposed DHS actions.

4. 44 CFR 10.8(e): Actions That Normally Require an EA

Paragraph (e) of § 10.8 requires the Regional Administrator to prepare an EA when a proposal is not one that normally requires an EIS and does not qualify as a CATEX. Similarly, the DHS Instruction in section V.C.2.a states that when a proposed action is not in a category of actions described in an available DHS CATEX and there is not enough information to determine that the proposed action will have significant environmental impacts requiring an EIS, the EA process is used to determine, through environmental impact evaluation and opportunity for public involvement, if the impacts on the quality of the human environment would be significant or not.

5. 44 CFR 10.8(f): Documentation

This paragraph 10.8(f) is duplicative of paragraph 10.8(d)(4), which is addressed earlier in this preamble.

6. 44 CFR 10.8(g): Actions That Normally Require an EA

This paragraph 10.8(g) is duplicative of paragraph 10.8(e), which is addressed earlier in this preamble.

I. 44 CFR 10.9 Preparation of EAs.

1. 44 CFR 10.9(a) When To Prepare.

Paragraph (a) of § 10.9 requires the Regional Administrator to begin preparation of an EA as early as possible after the determination that an assessment is required, and may prepare an assessment at any time to assist planning and decision making. The DHS Instruction covers preparation of an EA in section V.C. It does not specifically state that an EA should be prepared as early as possible, but it does state that a component can decide to prepare an EA as a best practice planning tool to inform decision-makers on the environmental impacts of its actions.

2. 44 CFR 10.9(b) Content and Format

Paragraph (b) of § 10.9 covers the content and format of an EA, and requires the EA to include the purpose and need for the proposed action, a description of the proposed action, alternatives considered, environmental impact of the proposed action and alternatives, listing of agencies and persons consulted, and a conclusion of whether to prepare an EIS. The DHS Instruction includes the same requirements in section V.C.8.

3. 44 CFR 10.9(c) Public Participation

Paragraph (c) of § 10.9 requires the Regional Administrator to involve environmental agencies, applicants, and the public, to the extent practicable, in preparing EAs. In determining ''to the extent practicable,'' it requires the Regional Administrator to consider the magnitude of the proposal, likelihood of public interest, the need to act quickly, the likelihood of meaningful public comment, national security classification issues, the need for permits, and the statutory authority of the environmental agency regarding the proposal.

The DHS Instruction at section V.C.7 covers the public involvement process involving an EA. It states that public involvement requirements can be met during scoping at the start of an evaluation and/or by distributing a draft EA and draft finding of no significant impact for public review. It states that where a good faith effort has been used to seek out and involve the public in the drafting of an EA and no significant impacts (including potential for an impact on the quality of the human environment that is highly controversial) have been identified, a component can complete an EA and finding of no significant impact without circulating a draft document for public review. It states that a good faith effort includes consideration of the extent of other related public involvement efforts, as well as consideration of the following factors found in section IV.G of the DHS Instruction:

- The size and type of the proposed action.
- Whether the proposed action is of international, national, regional, or local interest.
- The potential environmental impacts of the proposed action.
- Extent of previous environmental analysis for the proposed action and/or the geographical location where the action would occur.
- Extent of anticipated controversy over the potential environmental effects of the proposed action, based on DHS experience with similar proposed actions.
- Urgency of the proposed action.
- National security classification of the proposed action.
- The presence of Tribal, minority, or low-income populations that may be impacted by the proposed action.
- Other laws and requirements to protect the environment that may require public review; for example, a determination of conformity with a State air quality implementation plan may require public review.

In addition, the FEMA Instruction at section 3.4.D.3 addresses public involvement, stating that FEMA will involve environmental agencies, applicants, tribes, and the public, to the extent practicable, in preparing EAs and EISs. It states that in determining ''to the extent practicable'' and appropriate public involvement methods and timing, FEMA will consider the following (which mirror paragraph (c) of § 10.9):

- Magnitude of the proposal;
- Likelihood of public interest;
- Need to act quickly;
- Likelihood of meaningful public comment;
- National security classification issues;
- Need for permits; and
- Statutory authority of environmental agency regarding the proposal.

4. 44 CFR 10.9(d) When To Prepare an EIS

Paragraph (d) of § 10.9 requires the Regional Administrator to prepare an EIS for all major Agency actions significantly affecting the quality of the human environment. It states that the test of what is a ''significant'' enough impact to require an EIS is found in the CEQ regulations at 40 CFR 1508.27 (defining ''significantly''). Similarly, the DHS Instruction at section V.D.1 states that an EIS is prepared for major Federal actions significantly affecting the quality of the human environment (see 40 CFR part 1502, criteria for an EIS), and in section V.D.2 states that a component prepares an EIS when its proposed action and/or any reasonable alternative(s) would have significant environmental effects, including actions where an EA concluded that there would be significant impacts, and therefore preparation of an EIS was necessary. In addition, the FEMA Instruction at section 3.2.B.2 lists the types of actions likely to be significant and thus may trigger the preparation of an EIS.

5. 44 CFR 10.9(e) Finding of No Significant Impact

Paragraph (e) of § 10.9 states that if the Regional Administrator determines

on the basis of the EA not to prepare an EIS, the Regional Administrator shall prepare a finding of no significant impact in accordance with 40 CFR 1501.4(e) of the CEQ regulations. It states that the assessment and the finding shall be submitted to the Environmental Officer and the Office of Chief Counsel for approval, and if such approval is obtained, the Regional Administrator shall then make the finding of no significant impact available to the public as specified in 40 CFR 1506.6 of the CEQ regulations. Finally, paragraph (e) states that a finding of no significant impact is not required when the decision not to prepare an EIS is based on a CATEX.

The DHS Instruction in section V.C.9 states that a component's final determination on the environmental impacts of a proposed action is required upon the completion of an EA. It states that the EA process concludes with a finding of no significant impact when (1) the evaluation of the impacts of the proposed action on the human environment indicates that the environmental effects would not be significant, or (2) the component commits to including measures in the proposed action that mitigate impacts to a level of insignificance. The DHS Instruction states that a finding of no significant impact is a separate document from an EA, but may be integrated into any other appropriate decision-making document that can be made publicly available, provided it includes the minimum content requirements in Section V.C.10 of the DHS Instruction.

The FEMA Instruction in section 3.2.A.2.b states that upon documenting a CATEX, the NEPA process is complete (implying a finding of no significant impact is not required). Section VII of the FEMA Directive describes procedures, program requirements, and delegation of EHP Approval Authority required to approve findings of no significant impacts.

6. 44 CFR 10.9(f) Environmental Officer or Office of Chief Counsel Disallowance

Paragraph (f) of § 10.9 states that if the Environmental Officer or Office of Chief Counsel disagrees with the finding of no significant impact, the Regional Administrator shall prepare an EIS, and prior to preparation of an EIS, the Regional Administrator shall forward a notice of intent to prepare an EIS to the Environmental Officer, who shall publish such notice in the **Federal Register**.

As stated above, section VII of the FEMA Directive addresses program requirements and delegations of EHP Approval Authority for findings of no significant impacts. The dual signatory process outlined in section VII of the FEMA Directive is an updated structure that operates similarly to the structure outlined in 44 CFR part 10. Under the FEMA Directive, the Director of OEHP or delegate must approve a finding of no significant impact, and the Office of Chief Counsel serves in an advisory role. The Environmental Officer or delegate would consult with the Office of Chief Counsel and take under advisement the legal counsel provided.

7. 44 CFR 10.9(g) EIS Determination of Regional Administrator

Paragraph (g) of § 10.9 states that the Regional Administrator [37] may decide on his/her own to prepare an EIS, and in such case, the Regional Administrator shall forward a notice of intent to prepare the EIS to the Environmental Officer who shall publish such notice in the **Federal Register**. EHP responsibilities outlined in the FEMA Directive represent a new structure which operates differently than the structure set out in 44 CFR part 10. Under the new structure, the Regional Administrator would notify the appropriate EHP personnel in his/her region to prepare the notice of intent (FEMA Instruction section 3.2.B.2).

J. 44 CFR 10.10 Preparation of EISs

1. 44 CFR 10.10(a) Scoping

Paragraph (a) of § 10.10 states that after determination that an EIS will be prepared and publication of the notice of intent, the Regional Administrator will initiate the scoping process in accordance with 40 CFR 1501.7 of the CEQ regulations. The FEMA Instruction in section 3.2.A.1 states that FEMA will determine the range of issues that need to be addressed and the level of documentation required during the scoping process, and as part of the scoping process, FEMA may establish time limits for the NEPA process and hold early scoping meetings to engage stakeholders and the public at large. It states that the FEMA official with the appropriate level of EHP approval authority will lead these scoping efforts.

2. 44 CFR 10.10(b) Preparation

Paragraph (b) of § 10.10 states that based on the scoping process, the Regional Administrator will begin preparation of the EIS, and detailed procedures for preparation of the EIS are provided in Part 1502 of the CEQ regulations. The DHS Instruction addresses preparation of the EIS in section V.D and also refers to Part 1502 of the CEQ regulations. The FEMA Instruction discusses EIS preparation in Chapter 3 and includes appropriate references to the DHS Instruction and CEQ regulations.

3. 44 CFR 10.10(c) Supplemental EISs

Paragraph (c) of § 10.10 states that the Regional Administrator may at any time supplement a draft or final EIS, and that the Regional Administrator shall prepare a supplement to either a draft or final EIS when required under the criteria set forth in 40 CFR 1502.9(2).[38] It states that the Regional Administrator will prepare, circulate, and file a supplement to a statement in the same fashion (exclusive of scoping) as a draft or final statement and will introduce the supplement into their formal administrative record.

The DHS Instruction in section V.D.6 addresses supplemental EISs. It states that a component may prepare a supplemental EIS (SEIS) if there are substantial changes to the proposal that are relevant to environmental concerns or if there are significant new circumstances or information relevant to environmental concerns and bearing on the proposal or its impacts, and refers to 40 CFR 1502.9(c)(1). It states that a component may also supplement a draft EIS (DEIS) or Final EIS (FEIS) at any time to further the evaluation presented in the original EIS.

The DHS Instruction further states that components prepare, circulate, and file a supplement to a DEIS or FEIS in the same manner as any other DEIS or FEIS, except that scoping is optional for an SEIS (referring to 40 CFR 1502.9(c)(4)), and that public notice methods are chosen that are appropriate for reaching persons who may be interested in or affected by the proposal; if an FEIS is supplemented after a record of decision has been completed, the component must complete a new record of decision and publishes a notice of availability of the record of decision and the supplemental information in the **Federal Register**.

The FEMA Instruction briefly addresses supplemental analyses at section 3.6.F and refers back to the DHS Instruction at section V.D.6.

[37] The regulatory text incorrectly refers to ''Regional Director''; FEMA updated internal titles by technical amendment in 2009 (74 FR 15328) but overlooked the update for this reference.

[38] This appears to be a typo, as there is no 40 CFR 1502.9(2). The correct cite is most likely 40 CFR 1502.9(c), which addresses circumstances that would warrant a supplemental EIS and procedures for preparing one.

4. 44 CFR 10.10(d) Circulation of EISs

Paragraph (d) of § 10.10 requires the Regional Administrator to circulate draft and final EISs as prescribed in 40 CFR 1502.19 [39] of the CEQ regulations, and that prior to signing off on a draft or final EIS, the Regional Administrator shall obtain the approval of the Environmental Officer and the Office of Chief Counsel. The FEMA Instruction at section 3.5.B.3. requires FEMA to follow 40 CFR 1502.19. As discussed above, the FEMA Directive addresses EHP Approval Authority of FEMA personnel, which reflects a different internal agency approval structure than that outlined in 44 CFR part 10.

K. 44 CFR 10.11 Environmental information

Section 10.11 states that interested persons may contact the Environmental Officer or the Regional Administrator for information regarding FEMA's compliance with NEPA. The FEMA Directive is intended for internal circulation within FEMA, not as a general reference for the public, so it does not include guidance for the general public. The FEMA Instruction at section 2.2 discusses Program responsibilities for supporting applicants throughout the EHP process including meeting requirements for notification and consultation with affected and interested parties (section 2.2.B.3). In addition, the DHS Directive and Instruction are on the DHS Web site at *http://www.dhs.gov/national-environmental-policy-act,* and FEMA will post the FEMA Directive and Instruction on the FEMA public Web site at *www.fema.gov/media-library/assets/documents/118323.* The public may find further information about FEMA's EHP process and requirements at *www.fema.gov/office-environmental-planning-and-historic-preservation.*

L. 44 CFR 10.12 Pre-implementation Actions

1. 44 CFR 10.12(a) Decision Making

Paragraph (a) of § 10.12 requires the Regional Administrator to ensure that decisions are made in accordance with the policies and procedures of NEPA, and that the NEPA process is integrated into the decision making process. The FEMA Directive in section VI.A requires the FEMA Administrator to consider the impacts of decisions on the human environment before actions are taken or decisions are made (VI.A.2.i), to regularly articulate the value of EHP (which includes NEPA) in the FEMA decision making process to managers and staff (VI.A.1.ii), and to fully integrate the EHP requirements into planning and decision-making for all policies, programs, activities, and operations of FEMA (VI.A.1.v).

Paragraph (a) of § 10.12 also addresses the existence of a variety of FEMA programs, notes that each program will necessarily have different decision making procedures, and notes that review and approval authority may be exercised at various levels. As noted above, the FEMA Directive addresses EHP Approval Authority which can exist at various different FEMA levels (*e.g.,* Heads of Offices, Programs, or Directorates; the Regional Administrators; Federal Coordinating Officers; Regional Environmental Officers), as well as the option for delegation of authority to appropriate personnel.

Finally, paragraph (a) of § 10.12 lists specific requirements that the Regional Administrator must follow under NEPA, for example, to consider the specific alternatives analyzed in an EIS when evaluating the proposal which is the subject of the EIS. The DHS Directive and Instruction and FEMA Directive and Instruction (section 3.2.C) include the same requirements and do not deviate from those listed in § 10.12, as these requirements are dictated by NEPA and the CEQ regulations.

2. 44 CFR 10.12(b) Record of Decision

Paragraph (b) of § 10.12 states that in those cases requiring an EIS, the Regional Administrator at the time of his/her decision, or if appropriate, his/her recommendation to Congress, shall prepare a concise public record of that decision. It states that the record of decision is not intended to be an extensive, detailed document for the purpose of justifying the decision, but rather, it is a concise document that sets forth the decision and describes the alternatives and relevant factors considered as specified in 40 CFR 1505.2. Finally, it states that the record of decision will normally be less than 3 pages in length.

The DHS Instruction in section V.D.10 addresses the record of decision. It states that when a component decides whether or not to take action on a proposal covered by an EIS, it prepares a record of decision which contains the requirements listed in 40 CFR 1505.2. It states that a record of decision is a separate document from the EIS, and may be integrated into any other appropriate decision-making document that can be made publicly available provided that the content requirements are met, presents all the factors an agency considered when it reached its decision on whether to, and if so how to, proceed with the proposed action.

The FEMA Instruction in section 3.5.B.3 also addresses the record of decision, stating that an EIS will conclude with a record of decision to provide a concise public record of the decision whether to proceed with a proposed action. It states that a record of decision will complete the NEPA process, and will include the basis for the decision, summarize any EHP mitigation measures, and describe the alternatives and relevant factors considered during the NEPA process. It states that it will identify the environmentally preferred alternative, which is the alternative that will promote the national environmental policy as expressed in NEPA Section 101.

Neither the DHS Instruction nor the FEMA Instruction recommends a specific page length, but both refer to the ''concise'' nature of the document.

3. 44 CFR 10.12(c) Mitigation & 44 CFR 10.12(d) Monitoring

Paragraph (c) of § 10.12 addresses mitigation throughout the NEPA process and paragraph (d) of § 10.12 addresses monitoring of the mitigation. Specifically, paragraph (c) states that the Regional Administrator shall consider mitigating measures to avoid or minimize environmental harm and, in particular, harm to or within flood plains and wetlands. It states that mitigation measures or programs will be identified in the EIS and made available to decision makers, and that mitigation and other conditions established in the EIS or during its review and committed as part of the decision shall be implemented by the Regional Administrator.

Paragraph (d) states that if the Regional Administrator determines that monitoring is applicable for established mitigation, a monitoring program will be adopted to assure the mitigation measures are accomplished, and that the Regional Administrator shall provide monitoring information, upon request, as specified in 40 CFR 1505.3 (regarding monitoring). Finally, it states that this does not include standing or blanket requests for periodic reporting.

The DHS Instruction at section V.E addresses mitigation and monitoring together and provides requirements

[39] 40 CFR 1502.19 addresses circulation of the EIS and requires agencies to circulate it to (1) any Federal agency which has jurisdiction by law or special expertise with respect to any environmental impact involved, (2) any appropriate Federal, State or local agency authorized to develop and enforce environmental standards, (3) the applicant, (4) any person, organization, or agency requesting the EIS, and (5) in the case of a final EIS, any person, organization, or agency which submitted substantive comments on the draft.

similar to those stated in § 10.12. It states that when a component commits to mitigation measures to reduce or eliminate potential adverse effects of an action, it is essential that the component implements the measures and monitors their effectiveness. It states that components commit to appropriate, practical, and implementable mitigation measures identified in a finding of no significant impact or record of decision that they have sufficient legal authority to implement or impose on applicants.

The DHS Instruction describes mitigation measures as practical and implementable, *i.e.,* those that are reasonably expected to achieve their intended purpose; implementable mitigation measures require not only that the component have the appropriate legal authority, but also that it can reasonably foresee the availability of resources for performing the mitigation. It states that where the mitigation is being imposed on an applicant for DHS funding or approval to perform their proposed action, components make the mitigation a condition of DHS approval of the applications from persons or organizations external to DHS (referring to the CEQ regulation on monitoring at 40 CFR 1505.3).

The DHS Instruction stresses that adequately documenting and monitoring mitigation advances NEPA's purpose of informed and transparent environmental decision-making, and that failure to implement, document, and/or monitor mitigation may undermine the integrity of the NEPA analysis, and may compromise the adequacy of the NEPA compliance effort. Once a component has committed to mitigation measures, the DHS Instruction requires all decisions to modify or suspend those measures to be made in consultation with the DHS Office of General Counsel and the component's respective Environmental Planning Program Manager.[40]

The FEMA Instruction also addresses mitigation and monitoring together, in section 2.3.A. It states FEMA will consider EHP mitigation measures to avoid or minimize impacts identified during the EHP review process. It states that avoidance measures are the preferred method of EHP mitigation, and only when avoidance cannot be achieved because it is not feasible, practicable, or reasonable, may FEMA consider minimizing, rectifying, or compensating for the impacts of the action, in that order. It states that EHP mitigation measures will be identified in EHP review documentation as well as appropriate award documents and made available to decision makers, and that if FEMA determines that monitoring is applicable for established EHP mitigation, a monitoring program will be adopted to assure EHP mitigation measures are implemented and intended outcomes are accomplished (section 2.3.B.2).

M. 44 CFR 10.13 Emergencies

Section 10.13 states that in the event of an emergency, the Regional Administrator may be required to take immediate action with significant environmental impact. It states that the Regional Administrator shall notify the Environmental Officer of the emergency action at the earliest possible time so that the Environmental Officer may consult with CEQ, and in no event shall any Regional Administrator delay an emergency action necessary for the preservation of human life for the purpose of complying with the provision of this directive or the CEQ regulations. Section VI of the DHS Instruction addresses emergency actions, outlining four phases to apply when performing NEPA activities during an emergency: (1) Secure lives and protect property, (2) determine applicability of NEPA, (3) notification of SEP, (4) determine level of NEPA evaluation.

The FEMA Instruction addresses emergencies in § 2.5 and covers the following circumstances: (1) Legal Exemption. FEMA will determine whether a legal exemption related to the proposed emergency action exists and, if so, the EHP requirements to which the exemption applies; (2) Principles, Requirements, and Guidelines do not apply when there is emergency work essential to save lives and protect property, public health, and safety performed under Sections 403 and 502 of the Stafford Act (42 U.S.C. 5170b and 5192); (3) Stafford Act declaration: FEMA may provide funding for emergency actions taken in direct response to a disaster event that were not subject to EHP review provided the actions satisfy other eligibility requirements as established by FEMA programs; (4) Programmatic EHP Review and Existing Documentation: In cases where programmatic consultations, memoranda of agreement, biological assessments, general permits, and environmental analyses have already been conducted for the emergency action, FEMA will incorporate the existing documentation into its own analyses and documentation; (5) Emergency Consultations and Notifications: If the emergency action is not legally exempted and a previous analysis covering the action does not exist, emergency consultation with the appropriate resource/regulatory agency may be required. FEMA will consult with the appropriate resource/regulatory agency as soon as possible. The FEMA Instruction defines ''emergency'' for purposes of this section.[41]

N. 44 CFR 10.14 Flood Plains and Wetlands

Section 10.14 states that for any action taken by FEMA in a flood plain or wetland, the provisions of Part 10 are supplemental to, and not instead of, the provisions of the FEMA regulation implementing Executive Order 11988, Floodplain Management, and Executive Order 11990, Protection of Wetlands (44 CFR part 9). The introduction paragraph of Chapter 2 of the FEMA Instruction refers to other EHP requirements including Executive Orders 11988 and 11990, and indicates that the FEMA Directive and Instruction do not serve as implementing procedures for those requirements. The FEMA Directive and Instruction do not take the place of 44 CFR part 9.

O. 44 CFR Part 60 Criteria for Land Management and Use

Section 60.6 states that the decision whether an EIS or other environmental document will be prepared, will be made in accordance with the procedures set out in 44 CFR part 10. Because NEPA compliance procedures will no longer be set out in Part 10, but are set out in CEQ regulations, DHS implementing procedures, and supplemental instructions, FEMA is removing the reference to Part 10 and stating that the decision will be made in accordance with applicable environmental and historic preservation laws, regulations, Executive Orders, and agency policy.

[40] This is FEMA's Director of the Office of Environmental Planning and Historic Preservation. See FEMA Directive section VI.E.

[41] The FEMA Instruction defines ''emergency'' as ''A natural or man-made disaster or other phenomenon of an exceptional, inevitable, and irresistible character demanding immediate action for the protection of human life, public safety, public health, or the environment and avoidance of significant loss of property if it relates to one of the other factors. This definition includes but is not limited to situations triggering emergency and major disaster declarations by the President under the Stafford Act.'' The Stafford Act defines ''emergency'' for purposes of a Presidential emergency declaration as ''any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States.'' See 42 U.S.C. 5122(1).

P. 44 CFR Part 78 Flood Mitigation Assistance

Section 78.11 states that projects must be in conformance with 44 CFR part 10, and any applicable environmental laws and regulations. FEMA is simply removing the reference to Part 10. This change reflects that projects must conform with applicable environmental laws and regulations, including NEPA requirements, even though those requirements are no longer set out in Part 10.

Q. 44 CFR Part 79 Flood Mitigation Grants

Section 79.3 states that it is FEMA's responsibility to ''[c]omply with applicable Federal statutory, regulatory, and Executive Order requirements related to environmental and historic preservation compliance, including reviewing and supplementing, if necessary, the environmental analyses conducted by the State and subgrantee in accordance with part 10 of this chapter.'' 44 CFR 79.3(a)(6). FEMA is replacing the reference to Part 10 with a reference to applicable laws, regulations, and agency policy, as FEMA will comply with applicable CEQ regulations and Department and Agency-wide NEPA implementing procedures.

Section 79.6 states that mitigation grant projects must be in conformance with ''part 9 of this chapter, Floodplain management and protection of wetlands, part 10 of this chapter, Environmental Considerations, § 60.3 of this subchapter, Flood plain management criteria for flood-prone areas, and other applicable Federal, State, tribal, and local laws and regulations.'' 44 CFR 79.6(d)(2). FEMA is simply removing the reference to Part 10. This change reflects that projects must conform with applicable environmental laws and regulations, including NEPA requirements, even though those requirements are no longer set out in Part 10.

R. 44 CFR Part 80 Property Acquisition and Relocation for Open Space

Section 80.5 describes FEMA's responsibility to ''[c]omply with applicable Federal statutory, regulatory, and Executive Order requirements related to environmental and historic preservation compliance, including reviewing and supplementing, if necessary, the environmental analyses conducted by the State and subgrantee in accordance with part 10 of this chapter.'' 44 CFR 80.5(a)(5). FEMA is replacing the reference to Part 10 with a reference to applicable laws, regulations, and agency policy, as FEMA will comply with applicable CEQ regulations and Department and Agency-wide NEPA implementing procedures.

S. 44 CFR Part 206 Federal Disaster Assistance

Section 206.110 states that ''[a]ssistance provided under this subpart must comply with the National Environmental Policy Act (NEPA) and other environmental laws and Executive Orders, consistent with 44 CFR part 10.'' 44 CFR 206.110(l). Because NEPA compliance procedures are set out in CEQ regulations, DHS implementing procedures, and supplemental instructions, FEMA is removing the reference to Part 10 and revising the paragraph to reflect that NEPA compliance procedures are set out in applicable laws, regulations, and policies.

Section 206.117, Housing Assistance, states that ''[a]ny site upon which a FEMA-provided housing unit is placed must comply with applicable State and local codes and ordinances, as well as 44 CFR part 9, Floodplain Management and Protection of Wetlands, and 44 CFR part 10, Environmental Considerations, and all other applicable environmental laws and Executive Orders.'' 44 CFR 206.117(b)(1)(ii)(C). Because NEPA compliance procedures are set out in CEQ regulations, DHS implementing procedures, and supplemental instructions, FEMA is removing the reference to Part 10 and revising the paragraph to reflect that NEPA compliance procedures are set out in applicable laws, regulations, and policies.

Section 206.220, Public Assistance Eligibility, states that the regulations under 44 CFR part 10 apply to public assistance. Because the requirements formerly in Part 10 are now set out in applicable regulation, implementing procedures, and supplemental instructions, FEMA is removing the reference to Part 10 and clarifying that public assistance must conform to requirements in applicable environmental and historic preservation laws, regulations, and agency policies.

Section 206.434 states that in order to be eligible for the Hazard Mitigation Grant Program, a project must be in comformance with 44 CFR part 10. Because the requirements formerly in Part 10 are now set out in applicable regulation, implementing procedures, and supplemental instructions, FEMA is removing the reference to Part 10 and clarifying that a project must conform to requirements in applicable environmental and historic preservation laws, regulations, and agency policies.

Section 206.436 requires that the hazard mitigation application include environmental information consistent with 44 CFR part 10. FEMA is removing the reference to Part 10 and replacing it with a reference to applicable environmental and historic preservation laws, regulations, and agency implementing policies.

T. 44 CFR Part 209 Supplemental Property Acquisition and Elevation Assistance

Section 209.6 states that in order to be eligible, projects must conform with 44 CFR part 9, Floodplain Management and Protection of Wetlands; 44 CFR part 10, Environmental Considerations; and any applicable environmental and historic preservation laws and regulations. 44 CFR 209.6(b)(3). Because the requirements formerly in Part 10 are now set out in applicable regulation, implementing procedures, and supplemental instructions, FEMA is removing the reference to Part 10 and clarifying that projects must conform to requirements in applicable environmental and historic preservation laws, regulations, and agency policies.

IV. Regulatory Analysis

Administrative Procedure Act

The Administrative Procedure Act (APA) requires agencies to provide public notice and seek public comment on substantive regulations. See 5 U.S.C. 553. The APA, however, provides limited exceptions to this requirement for notice and public comment. See 5 U.S.C. 553(b). FEMA did not undertake notice and comment for this final rule because this final rule is a rule of ''agency organization, procedure, or practice'' and is exempt from notice and comment under section 553(b)(A) of the APA. 5 U.S.C. 553(b)(A). This rule addresses FEMA's internal agency procedures for carrying out NEPA, and maintains existing practice within FEMA for completing the NEPA process. FEMA is removing these internal agency procedures from regulation and replacing them with an internal Directive and Instruction. Notice and opportunity for public comment are not required because the internal procedures do not affect or impose substantive requirements on the public.

Section 553(d) of the APA also requires agencies to provide a 30-day delayed effective date for substantive rules. See 5 U.S.C. 553(d). However, FEMA finds that this final rule may be made effective immediately because it

has good cause pursuant to section 553(d)(3) of the APA (5 U.S.C. 553(d)). This final rule removes internal agency NEPA procedures from the Code of Federal Regulations and replaces them with a Directive and Instruction. These procedures do not affect or impose substantive requirements on the public, but rather apply to internal agency procedure. Moreover, the Directive and Instruction maintain existing practice within FEMA for completing the NEPA process. Therefore, FEMA finds that this final rule may be made effective immediately upon publication in the **Federal Register**.

Executive Order 12866, as Amended, Regulatory Planning and Review; Executive Order 13563, Improving Regulation and Regulatory Review

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

This rule removes FEMA regulations in 44 CFR part 10 which have been replaced by new Department of Homeland Security procedures. FEMA will no longer be implementing Environmental and Historic Preservation requirements through regulation. Instead, it will follow DHS procedures and supplement them through the issuance of an internal Directive and Instruction. As such, this rule change will remove unnecessary FEMA regulations. The policies and procedures in this final rule maintain the existing practice within FEMA for completing the NEPA process and thus, no additional costs on the public are expected. FEMA expects this rule to result in additional opportunity costs to FEMA staff that are estimated to cost $619,242 over ten years at a 7% discount rate.

The Directive describes the responsibilities of senior FEMA staff with regards to Environmental and Historic Preservation (EHP) policies as well as procedures for all EHP analyses and associated decision documents. The Instruction, which is more detailed than the Directive, provides guidance for the implementation of NEPA and other EHP requirements across FEMA.

The transition to the Directive and Instruction only makes minimal changes to the procedures identified in 44 CFR part 10 with regards to responsibilities. For example, 44 CFR part 10.3(c) defines the Environmental Officer as the Director of the Office of Environmental and Historic Preservation (OEHP) or his or her designee while the Directive establishes the Environmental Officer as a separate position. By policy, the Environmental Officer has been a separate position designated by the Director of OEHP. Thus, there is no impact to current procedures. The Directive also shifts responsibility for reviewing proposed changes to Categorical Exclusions (CATEXs) from the Office of Chief Counsel to the Environmental Officer with support from the chief counsel. In practice, the review of CATEXs has always had significant input from the Environmental Officer, so this rule only shifts the final sign-off from the Chief Counsel to the Environmental Officer while not dramatically impacting the workload of either office.

Other associated changes involve shifting responsibilities to DHS. For instance, the Department is now responsible for adding to, revising, or deleting items on the DHS list of CATEXs. In addition, the DHS Director of Sustainability and Environmental Programs is now the liaison with the CEQ, EPA, OMB, and other Federal agencies which was previously the responsibility of the FEMA Environmental Officer.

The Directive and Instruction provide instruction on the implementation of the new internal requirements to FEMA programs. Specifically, FEMA programs are now required to develop EHP implementation plans and update them every 3 years. FEMA estimates this will entail an average of 200 hours per program including staff work and management review. To estimate cost, FEMA uses the equivalent of a GS–13 Step 5 in the Washington Metro Area. Wage rates have been multiplied by 1.46 to account for benefits, and other associated employment costs to estimate the fully-loaded wage rate.[42] The fully loaded wage of a GS–13 Step 5 is $72.01 ($49.32 × 1.46 = $72.01).[43] This equates to an initial cost of $14,401 (200 hours × $72.01 = $14,401) per program. FEMA expects that development of EHP implementation plans will impact the 3 major grant programs and have a limited effect on FEMA facilities staff which FEMA equates to 0.5 of a program for the purposes of analysis. This results in an estimated total of $50,405 ($14,401 × 3.5 programs = $50,405) across FEMA. FEMA anticipates these requirements will be completed with existing resources and do not require any new Federal or contractor employees and thus considered as opportunity costs. FEMA estimates the 3 year updates will require an average of 100 hours to review. This results in an estimated review cost of $25,203 ($72.01 × 00 hours × 3.5 programs = $25,203).

FEMA programs with EHP responsibilities are also required to undergo an EHP concurrence process that is expected to entail between 200 and 500 hours per program annually. To estimate cost, FEMA uses the equivalent of a GS–12 Step 5 in the Washington Metro Area at a fully loaded wage of $60.56 ($41.48 × 1.46 = $60.56). The resulting additional unit cost across the major programs ranges between $12,112 ($60.56 × 200hrs = $12,112) and $30,280 ($60.56 × 500 hours = $30,280), with a primary estimate of $21,196 ($60.56 × 350 hours = $21,196) annually. The total annual EHP concurrence process costs ranges between $42,392 ($12,112 × 3.5 = $42,392) and $105,981 ($30,280 × 3.5 = $105,981) with a primary estimate of $74,187 ($21,196 × 3.5 = $74,187). FEMA intends to use its existing staff and funding to carry out these functions and thus such costs are again only considered as opportunity costs.

Based on the above cost estimates, the estimated first year costs of the new procedures range from $92,797 ($50,405 + $42,392) to $156,386 ($50,405 + $105,981)with a primary estimate of $124,592 ($50,405 + $74,187). The estimated annual costs after the first year range from $42,392 to $105,981 with a primary estimate of $74,187 per year except in years with EHP Implementation Plan Updates. These updates are anticipated to occur in years three, six, and nine. The estimated total undiscounted costs over 10 years ranges from $549,934 to $1,185,824 with a

[42] Bureau of Labor Statistics, Employer Costs for Employee Compensation, Table 1. ''Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Civilian workers, by major occupational and industry group, December 2015.'' Available at *http://www.bls.gov/news.release/archives/ecec_03102016.htm.* Accessed July 12, 2016. Calculated by dividing total compensation for all workers of $33.58 by wages and salaries for all workers of $23.06 per hour (yields a benefits multiplier of approximately 1.46×wages).

[43] Office of Personnel Management 2015 General Schedule hourly wage for the locality pay area of Washington—Baltimore-Northern Virginia, DC–MD–VA–WV–PA retrieved from *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/DCB_h.pdf.*

primary estimate of $867,884. Discounted at 3% over 10 years leads to an estimated annualized cost ranging from $55,572 to $119,161 with a primary estimate of $87,367. At a 7% discount rate, the annualized costs range from $56,371 to $119,960 with a primary estimate of $88,166. See Table 1 for additional details.

TABLE 1—10-YEAR COSTS OF DIRECTIVE AND INSTRUCTION CHANGES

Year	Low	Primary	High
1	$92,797	$124,592	$156,386
2	42,392	74,187	105,981
3	67,595	99,390	131,184
4	42,392	74,187	105,981
5	42,392	74,187	105,981
6	67,595	99,390	131,184
7	42,392	74,187	105,981
8	42,392	74,187	105,981
9	67,595	99,390	131,184
10	42,392	74,187	105,981
10-Year Undiscounted Total	549,934	867,884	1,185,824
10-Year Discounted at 3%	474,037	745,254	1,016,464
Annualized at 3%	55,572	87,367	119,161
10-Year Discounted at 7%	395,927	619,242	842,549
Annualized at 7%	56,371	88,166	119,960

As the rule only applies to DHS and FEMA internal procedures and does not impact the requirements of entities going through NEPA and EHP procedures, FEMA does not anticipate any impacts to entities outside of the Department of Homeland Security.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), as amended, 5 U.S.C. 601–612, agencies must consider the impact of their rulemakings on ''small entities'' (small businesses, small organizations and local governments) when issuing a notice of proposed rulemaking. As FEMA is not issuing a proposed rule for this action, the RFA does not apply.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year (approximately $157 million in 2015 dollars). The final rule does not result in the expenditure of State, local, and Tribal governments of greater than $157 million in any given year. Therefore, this rule is not an unfunded Federal mandate under that Act.

National Environmental Policy Act of 1969 (NEPA)

Under the National Environmental Policy Act of 1969 (NEPA), as amended, 42 U.S.C. 4321, 4331–4335, 4344, 4365, an agency must prepare an EA and EIS for any rulemaking that significantly affects the quality of the human environment. FEMA has determined that this rulemaking does not significantly affect the quality of the human environment and consequently has not prepared an EA or EIS.

Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA), as amended, 44 U.S.C. 3501–3520, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the agency obtains approval from OMB for the collection and the collection displays a valid OMB control number. See 44 U.S.C. 3506, 3507. There are no information collections required under 44 CFR part 10. There are specific FEMA programs that do collect information regarding environmental considerations for certain projects;[44] however, those collections are sponsored by separate program information collections and not under Part 10. Those collections are not affected by the removal of Part 10.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' 65 FR 67249, November 9, 2000, applies to agency regulations that have Tribal implications, that is, regulations that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Under this Executive Order, to the extent practicable and permitted by law, no agency shall promulgate any regulation that has Tribal implications, that imposes substantial direct compliance costs on Indian Tribal governments, and that is not required by statute, unless funds necessary to pay the direct costs incurred by the Indian Tribal government or the Tribe in complying with the regulation are provided by the Federal Government, or the agency consults with Tribal officials.

This rule does not have Tribal implications. It governs internal agency procedure and does not place any requirements on Tribes.

Executive Order 13132, Federalism

Executive Order 13132, ''Federalism,'' 64 FR 43255, August 10, 1999, sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, that is, regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Federal agencies must closely examine the statutory authority supporting any action that would limit the policymaking discretion of the States, and to the extent practicable, must consult with State and local officials before implementing any such action.

[44] E.g., OMB No. 1660–0017 for the Public Assistance Program; OMB No. 1660–0072 for the Hazard Mitigation Grant Program; OMB No. 1660–0022 for the Community Rating System (CRS) program.

FEMA has reviewed this rule under Executive Order 13132 and has determined that this rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore does not have federalism implications as defined by the Executive Order.

Executive Order 11988, Floodplain Management

Pursuant to Executive Order 11988, each agency is required to provide leadership and take action to reduce the risk of flood loss, to minimize the impact of floods on human safety, health and welfare, and to restore and preserve the natural and beneficial values served by floodplains in carrying out its responsibilities for: (1) Acquiring, managing, and disposing of Federal lands and facilities; (2) providing Federally undertaken, financed, or assisted construction and improvements; and (3) conducting Federal activities and programs affecting land use, including but not limited to water and related land resources planning, regulating, and licensing activities. In carrying out these responsibilities, each agency must evaluate the potential effects of any actions it may take in a floodplain; to ensure that its planning programs and budget requests reflect consideration of flood hazards and floodplain management; and to prescribe procedures to implement the policies and requirements of the Executive Order.

Before promulgating any regulation, an agency must determine whether the proposed regulations will affect a floodplain(s), and if so, the agency must consider alternatives to avoid adverse effects and incompatible development in the floodplain(s). If the head of the agency finds that the only practicable alternative consistent with the law and with the policy set forth in Executive Order 11988 is to promulgate a regulation that affects a floodplain(s), the agency must, prior to promulgating the regulation, design or modify the regulation in order to minimize potential harm to or within the floodplain, consistent with the agency's floodplain management regulations and prepare and circulate a notice containing an explanation of why the action is proposed to be located in the floodplain. The changes in this final rule will not have an effect on floodplain management. This rule addresses FEMA's internal agency procedures for carrying out NEPA, and maintains existing practice within FEMA for completing the NEPA process. When FEMA undertakes specific actions that may have effects on floodplain management, FEMA follows the procedures set forth in 44 CFR part 9 to assure compliance with this Executive Order. This serves as the notice that is required by the Executive Order.

Executive Order 11990, Protection of Wetlands

Pursuant to Executive Order 11990, each agency must provide leadership and take action to minimize the destruction, loss or degradation of wetlands, and to preserve and enhance the natural and beneficial values of wetlands in carrying out the agency's responsibilities for: (1) Acquiring, managing, and disposing of Federal lands and facilities; and (2) providing Federally undertaken, financed, or assisted construction and improvements; and (3) conducting Federal activities and programs affecting land use, including but not limited to water and related land resources planning, regulating, and licensing activities. Each agency, to the extent permitted by law, must avoid undertaking or providing assistance for new construction located in wetlands unless the head of the agency finds: (1) That there is no practicable alternative to such construction, and (2) that the proposed action includes all practicable measures to minimize harm to wetlands which may result from such use. In making this finding the head of the agency may take into account economic, environmental and other pertinent factors.

In carrying out the activities described in the Executive Order, each agency must consider factors relevant to a proposal's effect on the survival and quality of the wetlands. Among these factors are: Public health, safety, and welfare, including water supply, quality, recharge and discharge; pollution; flood and storm hazards; and sediment and erosion; maintenance of natural systems, including conservation and long term productivity of existing flora and fauna, species and habitat diversity and stability, hydrologic utility, fish, wildlife, timber, and food and fiber resources; and other uses of wetlands in the public interest, including recreational, scientific, and cultural uses.

The changes in this final rule will not have an effect on land use or wetlands. This rule addresses FEMA's internal agency procedures for carrying out NEPA, and maintains existing practice within FEMA for completing the NEPA process. When FEMA undertakes specific actions that may have such effects, FEMA follows the procedures set forth in 44 CFR part 9 to assure compliance with this Executive Order.

Congressional Review of Agency Rulemaking

Under the Congressional Review of Agency Rulemaking Act (CRA), 5 U.S.C. 801–808, before a rule can take effect, the Federal agency promulgating the rule must submit to Congress and to the Government Accountability Office (GAO) a copy of the rule, a concise general statement relating to the rule, including whether it is a major rule, the proposed effective date of the rule, a copy of any cost-benefit analysis, descriptions of the agency's actions under the Regulatory Flexibility Act and the Unfunded Mandates Reform Act, and any other information or statements required by relevant executive orders.

FEMA has sent this rule to the Congress and to GAO pursuant to the CRA. The rule is not a ''major rule'' within the meaning of the CRA. It will not have an annual effect on the economy of $100,000,000 or more, it will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, and it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

List of Subjects

44 CFR Part 10

Environmental Impact Statements.

44 CFR Part 60

Flood insurance, Flood plains, Reporting and recordkeeping requirements.

44 CFR Parts 78 and 79

Flood insurance, Grant programs.

44 CFR Part 80

Disaster assistance, Grant programs.

44 CFR Part 206

Administrative practice and procedure, Coastal zone, Community facilities, Disaster assistance, Fire prevention, Grant programs-housing and community development, Housing, Insurance, Intergovernmental relations, Loan programs-housing and community development, Natural resources, Penalties, Reporting and recordkeeping requirements.

44 CFR Part 209

Administrative practice and procedure, Disaster assistance, Grant programs, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, and under the authority of the Homeland Security Act of 2002, 6 U.S.C. 101 *et seq.*, Department of Homeland Security Delegation 9001.1, and the National Environmental Policy Act, 42 U.S.C. 4321, 4331–4335, 4344, 4365, the Federal Emergency Management Agency amends 44 CFR Chapter I, as follows:

PART 10—[REMOVED AND RESERVED]

■ 1. Remove and reserve part 10, consisting of §§ 10.1 through 10.14.

PART 60—CRITERIA FOR LAND MANAGEMENT AND USE

■ 2. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127 of Mar. 31, 1979, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

■ 3. In § 60.6, revise the second sentence of paragraph (b)(2) to read as follows:

§ 60.6 Variances and exceptions.

* * * * *

(b) * * *

(2) * * * The decision whether an Environmental Impact Statement or other environmental document will be prepared, will be made in accordance with applicable environmental and historic preservation laws, regulations, Executive Orders, and agency policy. * * *

* * * * *

PART 78—FLOOD MITIGATION ASSISTANCE

■ 4. The authority citation for part 78 continues to read as follows:

Authority: 6 U.S.C. 101; 42 U.S.C. 4001 *et seq.*; 42 U.S.C. 4104c, 4104d; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376; E.O. 12148, 44 FR 43239, 3 CFR, 1979 Comp., p. 412; E.O. 13286, 68 FR 10619, 3 CFR, 2003 Comp., p. 166.

■ 5. In § 78.11, revise paragraph (b) to read as follows:

§ 78.11 Minimum project eligibility criteria.

* * * * *

(b) Be in conformance with 44 CFR part 9, Floodplain Management and Protection of Wetlands; Executive Order 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction; and any applicable environmental laws and regulations.

* * * * *

PART 79—FLOOD MITIGATION GRANTS

■ 6. The authority citation for part 79 continues to read as follows:

Authority: 6 U.S.C. 101; 42 U.S.C. 4001 *et seq.*; 42 U.S.C. 4104c, 4104d; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376; E.O. 12148, 44 FR 43239, 3 CFR, 1979 Comp., p. 412; E.O. 13286, 68 FR 10619, 3 CFR, 2003 Comp., p. 166.

■ 7. In § 79.3, revise paragraph (a)(6) to read as follows:

§ 79.3 Responsibilities.

(a) * * *

(6) Comply with applicable Federal statutory, regulatory, and Executive Order requirements related to environmental and historic preservation compliance, including reviewing and supplementing, if necessary, the environmental analyses conducted by the State and subgrantee in accordance with applicable laws, regulations, and agency policy;

* * * * *

■ 8. In § 79.6, revise paragraph (d)(2) to read as follows:

§ 79.6 Eligibility.

* * * * *

(d) * * *

(2) Be in conformance with part 9 of this chapter, Floodplain management and protection of wetlands, § 60.3 of this subchapter, Flood plain management criteria for flood-prone areas, and other applicable Federal, State, tribal, and local laws and regulations;

* * * * *

PART 80—PROPERTY ACQUISITION AND RELOCATION FOR OPEN SPACE

■ 9. The authority citation for part 80 continues to read as follows:

Authority: Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5207; the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; Homeland Security Act of 2002, 6 U.S.C. 101; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376; E.O. 12148, 44 FR 43239, 3 CFR, 1979 Comp., p. 412; E.O. 13286, 68 FR 10619, 3 CFR, 2003 Comp., p. 166.

■ 10. In § 80.5, revise paragraph (a)(5) to read as follows:

§ 80.5 Roles and responsibilities.

* * * * *

(a) * * *

(5) Complying with applicable Federal statutory, regulatory, and Executive Order requirements related to environmental and historic preservation compliance, including reviewing and supplementing, if necessary, environmental analyses conducted by the State and subgrantee in accordance with applicable laws, regulations, and agency policy;

* * * * *

PART 206—FEDERAL DISASTER ASSISTANCE

■ 11. The authority citation for part 206 continues to read as follows:

Authority: Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5207; Homeland Security Act of 2002, 6 U.S.C. 101 *et seq.*; Department of Homeland Security Delegation 9001.1; sec. 1105, Pub. L. 113–2, 127 Stat. 43 (42 U.S.C. 5189a note).

■ 12. In § 206.110, revise paragraph (l) to read as follows:

§ 206.110 Federal assistance to individuals and households.

* * * * *

(l) *Environmental requirements.* Assistance provided under this subpart must comply with the National Environmental Policy Act (NEPA) and other environmental laws, regulations, Executive Orders, and applicable agency policy.

* * * * *

■ 13. In § 206.117, revise paragraph (b)(1)(ii)(C) to read as follows:

§ 206.117 Housing assistance.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(C) Any site upon which a FEMA-provided housing unit is placed must comply with applicable State and local codes and ordinances, as well as 44 CFR part 9, Floodplain Management and Protection of Wetlands, and all other applicable environmental and historic preservation laws, regulations, Executive Orders, and agency policy.

* * * * *

■ 14. Revise § 206.220 to read as follows:

§ 206.220 General.

This subpart provides policies and procedures for determinations of eligibility of applicants for public assistance, eligibility of work, and eligibility of costs for assistance under sections 402, 403, 406, 407, 418, 419,

421(d), 502, and 503 of the Stafford Act. Assistance under this subpart must also conform to requirements of 44 CFR part 201, Mitigation Planning, 44 CFR part 206, subparts G—Public Assistance Project Administration, I—Public Assistance Insurance Requirements, J—Coastal Barrier Resources Act, and M—Minimum Standards, 44 CFR part 9—Floodplain Management, and other applicable environmental and historic preservation laws, regulations, Executive Orders, and agency policy.

■ 15. In § 206.434, revise paragraph (c)(3) to read as follows:

§ 206.434 Eligibility.

* * * * *

(c) * * *

(3) Be in conformance with 44 CFR part 9, Floodplain Management and Protection of Wetlands, and other applicable environmental and historic preservation laws, regulations, Executive Orders, and agency policy;

* * * * *

■ 16. In § 206.436, revise paragraph (c)(10) to read as follows:

§ 206.436 Application procedures.

* * * * *

(c) * * *

(10) Environmental information consistent with 44 CFR part 9, Floodplain Management and Protection of Wetlands, and other applicable environmental and historic preservation laws, regulations, Executive Orders, and agency policy.

* * * * *

PART 209—SUPPLEMENTAL PROPERTY ACQUISITION AND ELEVATION ASSISTANCE

■ 17. The authority citation for part 209 continues to read as follows:

Authority: Pub. L. 106–113, Div. B, sec. 1000(a)(5) (enacting H.R. 3425 by cross-reference), 113 Stat. 1501, 1536; Pub. L. 106–246, 114 Stat. 511, 568; Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121, Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376; E.O. 12148, 44 FR 43239, 3 CFR, 1979 Comp., p. 412.

■ 18. In § 209.6, revise paragraph (b)(3) to read as follows:

§ 209.6 Project eligibility.

* * * * *

(b) * * *

(3) Conform with 44 CFR part 9, Floodplain Management and Protection of Wetlands, and other applicable environmental and historic preservation laws, regulations, Executive Orders, and agency policy.

* * * * *

Dated: August 2, 2016.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–19536 Filed 8–19–16; 8:45 am]

BILLING CODE 9111–A6–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 151211999–6343–02]

RIN 0648–XE811

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Gulf of Maine Cod Trimester Total Allowable Catch Area Closure for the Common Pool Fishery

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

ACTION: Temporary rule; area closure.

SUMMARY: This action closes the Gulf of Maine Cod Trimester Total Allowable Catch Area to Northeast multispecies common pool vessels fishing with trawl gear, sink gillnet gear, and longline/hook gear for the remainder of Trimester 1, through August 31, 2016. The closure is required by regulation because the common pool fishery has caught 90 percent of its Trimester 1 quota for Gulf of Maine cod. This closure is intended to prevent an overage of the common pool's quota for this stock.

DATES: This action is effective August 17, 2016, through August 31, 2016.

FOR FURTHER INFORMATION CONTACT: Liz Sullivan, Fishery Management Specialist, (978) 282–8493.

SUPPLEMENTARY INFORMATION: Federal regulations at § 648.82(n)(2)(ii) require the Regional Administrator to close a common pool Trimester Total Allowable Catch (TAC) Area for a stock when 90 percent of the Trimester TAC is projected to be caught. The closure applies to all common pool vessels fishing with gear capable of catching that stock for the remainder of the trimester.

As of August 8, 2016, the common pool fishery has caught approximately 88 percent of the Trimester 1 TAC (2.1 mt) for Gulf of Maine (GOM) cod. We project that 90 percent of the Trimester 1 TAC was caught by August 12. The fishing year 2016 common pool sub-annual catch limit (sub-ACL) for GOM cod is 7.6 mt.

Effective August 17, 2016, the GOM Cod Trimester TAC Area is closed for the remainder of Trimester 1, through August 31, 2016, to all common pool vessels fishing with trawl gear, sink gillnet gear, and longline/hook gear. The GOM Cod Trimester TAC Area consists of statistical areas 513 and 514. The area reopens at the beginning of Trimester 2 on September 1, 2016.

If a vessel declared its trip through the Vessel Monitoring System (VMS) or the interactive voice response system, and crossed the VMS demarcation line prior to August 17, 2016, it may complete its trip within the Trimester TAC Area.

Any overage of the Trimester 1 or 2 TACs must be deducted from the Trimester 3 TAC. If the common pool fishery exceeds its sub-ACL for the 2016 fishing year, the overage must be deducted from the common pool's sub-ACL for fishing year 2017. Any uncaught portion of the Trimester 1 and Trimester 2 TACs is carried over into the next trimester. However, any uncaught portion of the common pool's sub-ACL may not be carried over into the following fishing year.

Weekly quota monitoring reports for the common pool fishery are on our Web site at: *http://www.greateratlantic.fisheries.noaa.gov/ro/fso/MultiMonReports.htm.* We will continue to monitor common pool catch through vessel trip reports, dealer-reported landings, VMS catch reports, and other available information, and, if necessary, we will make additional adjustments to common pool management measures.

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA, finds good cause pursuant to 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3) to waive prior notice and the opportunity for public comment and the 30-day delayed effectiveness period because it would be impracticable and contrary to the public interest.

Regulations require the Regional Administrator to close a trimester TAC area to the common pool fishery when 90 percent of the Trimester TAC for a stock has been caught. Updated catch information only recently became available indicating that the common pool fishery will catch 90 percent of its Trimester 1 TAC for GOM cod on or around August 12, 2016. The time necessary to provide for prior notice and

comment, and a 30-day delay in effectiveness, prevents the immediate closure of the GOM Cod Trimester 1 TAC Area. Delaying the effective date of a closure increases the likelihood that the common pool fishery will exceed its quota of GOM cod to the detriment of this stock, which could undermine management objectives of the Northeast Multispecies Fishery Management Plan. Additionally, an overage of the common pool quota could cause negative economic impacts to the common pool fishery as a result of overage paybacks in a future trimester or fishing year.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 16, 2016.

Emily H. Menashes,

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

[FR Doc. 2016–19983 Filed 8–17–16; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 150903814–5999–02]

RIN 0648–XE755

Fisheries of the Northeastern United States; Scup Fishery; Adjustment to the 2016 Winter II Quota

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

ACTION: Temporary rule; inseason adjustment.

SUMMARY: NMFS adjusts the 2016 Winter II commercial scup quota. This action complies with Framework Adjustment 3 to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan, which established a process to allow the rollover of unused commercial scup quota from the Winter I period to the Winter II period.

DATES: Effective November 1, 2016, through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Reid Lichwell, Fishery Management Specialist, (978) 281–9112.

SUPPLEMENTARY INFORMATION: NMFS published a final rule in the **Federal Register** on November 3, 2003 (68 FR 62250), implementing a process to roll over unused Winter I commercial scup quota (January 1 through April 30) to be added to the Winter II period quota (November 1 through December 31). This framework also allows adjustment of the commercial possession limit for the Winter II period dependent on the amount of quota rolled over from the Winter I period.

For 2016, the initial Winter II quota is 3,262,554 lb (1,480 mt), and the best available landings information indicates that 3,192,389 lb (1,448 mt) remain of the Winter I quota of 9,232,987 lb (4,188 mt). Consistent with the intent of Framework 3, the full amount of unused 2016 Winter I quota would be transferred to Winter II, resulting in a revised 2016 Winter II quota of 6,454,943 lb (2,928 mt). Because the amount transferred is greater than 2,000,000 lb (907 mt), the possession limit per trip will increase from 12,000 lb (5,443 kg) to 18,000 lb (8,165 kg), as outlined in the final rule that established the 2016 specifications, published on December 28, 2015 (80 FR 80689).

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA (AA), has determined good cause exists pursuant to 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment on this in-season adjustment because it is impracticable and contrary to the public interest. The landings data upon which this action is based are not available on a real-time basis and, consequently, were compiled only a short time before the determination was made that this action is warranted. If implementation of this in-season action is delayed to solicit prior public comment, the objective of the fishery management plan to achieve the optimum yield from the fishery could be compromised; deteriorating weather conditions during the latter part of the fishing year will reduce fishing effort and could prevent the annual quota from being fully harvested. This would conflict with the agency's legal obligation under the Magnuson-Stevens Fishery Conservation and Management Act to achieve the optimum yield from a fishery on a continuing basis, resulting in a negative economic impact on vessels permitted to fish in this fishery. Moreover, the rollover process and potential changes in trip limits were already outlined in the 2016 to 2018 specifications published December 28, 2015, that were provided for notice and comment rulemaking. No comments were received on either part.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 17, 2016.

Emily H. Menashes,

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

[FR Doc. 2016–20031 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 150903814–5999–02]

RIN 0648–XE810

Fisheries of the Northeastern United States; Summer Flounder Fishery; Commercial Quota Harvested for the Commonwealth of Massachusetts

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces that the 2016 summer flounder commercial quota allocated to the Commonwealth of Massachusetts has been harvested. Vessels issued a commercial Federal fisheries permit for the summer flounder fishery may not land summer flounder in Massachusetts for the remainder of calendar year 2016, unless additional quota becomes available through a transfer from another state. Regulations governing the summer flounder fishery require publication of this notification to advise Massachusetts that the quota has been harvested and to advise vessel permit holders and dealer permit holders that no Federal commercial quota is available for landing summer flounder in Massachusetts.

DATES: Effective 0001 hours, August 19, 2016, through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Reid Lichwell, (978) 281–9112, or *Reid.Lichwell@noaa.gov.*

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is apportioned on a percentage basis among the coastal states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.102.

The initial commercial quota for summer flounder for the 2016 calendar year was set equal to 8,124,035 lb (3,684,997 kg) (80 FR 80689, December

28, 2015). The percent allocated to vessels landing summer flounder in Massachusetts is 6.82046 percent, resulting in an initial commercial quota of 554,097 lb (251,334 kg). This allocation was adjusted to 577,777 lb (262,075 kg) after Massachusetts received quota transfers from the states of Virginia and North Carolina.

The Administrator, Greater Atlantic Region, NMFS (Regional Administrator), monitors the state commercial landings and determines when a state's commercial quota has been harvested. NMFS is required to publish notification in the **Federal Register** advising and notifying commercial vessels and dealer permit holders that, effective upon a specific date, the state's commercial quota has been harvested and no commercial quota is no longer available to landing summer flounder in that state. The Regional Administrator has determined, based upon dealer reports and other available information, that the 2016 Massachusetts commercial summer flounder quota will be harvested by August 12, 2016.

Section 648.4(b) provides that Federal permit holders agree, as a condition of the permit, not to land summer flounder in any state that the Regional Administrator has determined no longer has commercial quota available. Therefore, effective 0001 hours, August 19, 2016, landings of summer flounder in Massachusetts by vessels holding summer flounder commercial Federal fisheries permits are prohibited for the remainder of the 2016 calendar year, unless additional quota becomes available through a transfer and is announced in the **Federal Register**. Effective 0001 hours, August 19, 2016, federally permitted dealers are also notified that they may not purchase summer flounder from federally permitted vessels that land in Massachusetts for the remainder of the calendar year, or unless additional quota becomes available through a transfer from another state.

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA (AA), finds good cause pursuant to 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment because it would be contrary to the public interest. This action closes the summer flounder fishery for Massachusetts until January 1, 2017, under current regulations. The regulations at § 648.103(b) require such action to ensure that summer flounder vessels do not exceed quotas allocated to the states. If implementation of this closure was delayed to solicit prior public comment, the quota for this fishing year would be exceeded, thereby undermining the conservation objectives of the Summer Flounder Fishery Management Plan. The AA further finds, good cause to waive the 30-day delayed effectiveness period, as outline in 5 U.S.C. 553(d)(3), for the reason stated above.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 17, 2016.

Emily H. Menashes,

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

[FR Doc. 2016–19995 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 151130999–6225–01]

RIN 0648–XE802

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfer

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the states of Florida and Delaware and the Commonwealth of Virginia are transferring portions of their 2016 commercial bluefish quota to the Commonwealth of Massachusetts. These quota adjustments are necessary to comply with the Atlantic Bluefish Fishery Management Plan quota transfer provision. This announcement informs the public of the revised commercial quotas.

DATES: Effective August 19, 2016, through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Reid Lichwell, Fishery Management Specialist, (978) 281–9112.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. The regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state are described in § 648.162.

The final rule implementing Amendment 1 to the Bluefish Fishery Management Plan published in the **Federal Register** on July 26, 2000 (65 FR 45844), provided a mechanism for transferring bluefish quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the Administrator, Greater Atlantic Region, NMFS (Regional Administrator), can transfer or combine bluefish commercial quota under § 648.162(e)(1)(i) through (iii). The Regional Administrator is required to consider the criteria in § 648.162(e) in the evaluation of requests for quota transfers or combinations.

The transfers and the final revised quotas are shown in Table 1. These quota transfers were requested by the Commonwealth of Massachusetts to ensure that its 2016 quota would not be exceeded. The Regional Administrator has determined that the criteria set forth in § 648.162(e)(1)(i) through (iii) have been met. The quotas in Table 1 are based on the final rule implementing the 2016–2018 Atlantic Bluefish Specifications that became effective August 4, 2016 (81 FR 18559), and any subsequent approved state transfers.

TABLE 1—ATLANTIC BLUEFISH TRANSFERS, BY STATE

State	Transfer		Final 2016 quota	
	lb	kg	lb	kg
Massachusetts	150,000	68,039	478,096	216,861
Delaware	−50,000	−22,679	41,746	18,935
Virginia	−50,000	−22,679	450,287	204,246
Florida	−50,000	−22,679	341,394	154,853

Classification

This action is taken under 50 CFR part 648 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 17, 2016.

Emily H. Menashes,

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

[FR Doc. 2016–19997 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 162
Monday, August 22, 2016

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8186; Directorate Identifier 2016–NM–074–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. This proposed AD was prompted by reports of skin cracking found at the corners of the aft entry and aft galley doorways. This proposed AD would require repetitive inspections for cracking of the corners of the aft entry and aft galley doorways; and repair if necessary, which would terminate the repetitive inspections of the repaired areas. We are proposing this AD to detect and correct cracking of the corners of the aft entry and aft galley doorways, which could result in rapid decompression and consequent reduced structural integrity of the airplane.

DATES: We must receive comments on this proposed AD by October 6, 2016.

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

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

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8186.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8186; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–8186; Directorate Identifier 2016–NM–074–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We received reports of skin cracking found at the corners of the aft entry and aft galley doorways. These cracks are most common at the lower forward corners and the upper aft corners of the doorways, and the crack lengths range from 0.25 to 4.50 inches. At the time of crack detection, the airplanes had accumulated between 26,896 and 73,655 total flight cycles. These cracks are caused by fatigue from cyclic pressurization of the fuselage combined with increased stress concentration due to the proximity of the fastener holes to the corners of the doorways. The cracks typically originate at the fastener holes and grow towards the corners of the doorways. This condition, if not corrected, could result in rapid decompression and consequent reduced structural integrity of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737–53A1350, dated May 6, 2016. The service information describes procedures for, among other things, external detailed inspections for cracking of the skin assembly of the corners of the aft entry and aft galley doorways, and repair of any cracking. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

Explanation of Applicability

Model 737 airplanes having line numbers 1 through 291 have a limit of validity (LOV) of 34,000 total flight cycles. These airplanes have accumulated total flight cycles beyond that LOV. Although operation of an airplane beyond its LOV is prohibited by 14 CFR 121.1115 and 129.115, this proposed AD would include those airplanes in the applicability so that these airplanes are tracked in the event the LOV is extended in the future.

Costs of Compliance

We estimate that this proposed AD affects 326 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections	22 work-hours × $85 per hour = $1,870 per inspection cycle.	$0	$1,870 per inspection cycle	$609,620 per inspection cycle.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(3) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2016–8186; Directorate Identifier 2016–NM–074–AD.

(a) Comments Due Date

We must receive comments by October 6, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes; certificated in any category; as identified in Boeing Alert Service Bulletin 737–53A1350, dated May 6, 2016.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of skin cracking found at the corners of the aft entry and aft galley doorways. We are issuing this AD to detect and correct cracking of the corners of the aft entry and aft galley doorways, which could result in rapid decompression and consequent reduced structural integrity of the airplane.

(f) Compliance

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

(g) Inspections for Group 1 Airplanes

For airplanes identified as Group 1 in Boeing Alert Service Bulletin 737–53A1350, dated May 6, 2016: Within 120 days after the effective date of this AD, inspect the airplane using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(h) Repetitive Inspections for Groups 2 Through 8 Airplanes

For airplanes identified as Groups 2 through 8 in Boeing Alert Service Bulletin 737–53A1350, dated May 6, 2016: At the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1350, dated May 6, 2016, except as required by paragraph (j) of this AD: Do low frequency eddy current and detailed inspections for cracking of the aft entry and aft galley doorway corners, as applicable, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1350, dated May 6, 2016. Repeat the inspections thereafter at the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1350, dated May 6, 2016.

(i) Repair

If any crack is found during any inspection required by paragraph (h) of this AD, repair before further flight, in accordance with Part 3 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1350, dated May 6, 2016. Accomplishment of this repair terminates the repetitive inspections required by paragraph (h) of this AD for the repaired doorway corner location only.

(j) Exception to Service Information Specifications

Where paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1350, dated May 6, 2016, specifies a compliance time ''after the original issue date of this service bulletin,'' this AD requires compliance within the specified compliance time after the effective date of this AD.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

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

(i) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(3)(i) and (k)(3)(ii) of this AD apply. The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(l) Related Information

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

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, WA, on August 11, 2016.

Paul R. Bernado,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–19935 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8845; Directorate Identifier 2016–NM–094–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87) airplanes; and Model MD–88 airplanes. This proposed AD was prompted by a report of fatigue cracking in a rear spar lower cap of the horizontal stabilizer. This proposed AD would require repetitive inspections for cracking of the rear spar lower caps of the horizontal stabilizer, post-modification and post-repair inspections, and corrective actions if necessary. This proposed AD also provides an optional terminating fatigue life enhancement modification. We are proposing this AD to detect and correct fatigue cracking in the rear spar lower caps of the horizontal stabilizer, which, paired with cracking in adjacent areas, could adversely affect the structural integrity of the airplane.

DATES: We must receive comments on this proposed AD by October 6, 2016.

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

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

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, CA 90846–0001; telephone 206–544–5000, extension 2; fax 206–766–5683; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8845.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8845; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Haytham Alaidy, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5224; fax: 562–627–5210; email: *haytham.alaidy@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–8845; Directorate Identifier 2016–NM–094–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We have received a report of a 0.513-inch crack in a rear spar lower cap of the horizontal stabilizer. The Model MD–88 airplane had accumulated 61,741 total flight hours and 45,985 total landing cycles. Lab analysis on the area adjacent to the crack shows that the crack was caused by fatigue. Such fatigue cracking, paired with cracking in adjacent areas, could adversely affect the structural integrity of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin MD80–55A072, dated April 8, 2016. The service information describes procedures for doing inspections for cracking of the rear spar lower caps of the horizontal stabilizer, post-modification and post-repair inspections, and repairs. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between this Proposed AD and the Service Information.'' For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8845.

The phrase ''corrective actions'' is used in this proposed AD. Corrective actions correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

Differences Between This Proposed AD and the Service Information

Boeing Alert Service Bulletin MD80–55A072, dated April 8, 2016, specifies to contact the manufacturer for certain instructions, but this proposed AD would require accomplishment of repair methods, modification deviations, and alteration deviations in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

Costs of Compliance

We estimate that this proposed AD affects 395 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	3 work-hours × $85 per hour = $255 per inspection cycle.	$0	$255 per inspection cycle	$100,725 per inspection cycle.

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Action	Labor cost	Parts cost	Cost per product
Modification	59 work-hours × $85 per hour = $ 5,015 per stabilizer	$1,267	$6,282 per stabilizer.

We estimate the following costs to do any necessary replacement that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	368 work-hours × $85 per hour = $31,280 per stabilizer	$31,408	$62,688 per stabilizer.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions that require repair using a method specified in paragraph (k) of this proposed AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(3) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2016–8845; Directorate Identifier 2016–NM–094–AD.

(a) Comments Due Date

We must receive comments by October 6, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87) airplanes; and Model MD–88 airplanes; certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 55, Stabilizers.

(e) Unsafe Condition

This AD was prompted by a report of fatigue cracking in a Model MD–88 rear spar lower cap of the horizontal stabilizer. We are issuing this AD to detect and correct fatigue cracking in the rear spar lower caps of the horizontal stabilizer, which, paired with cracking in adjacent areas, could adversely affect the structural integrity of the airplane.

(f) Compliance

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

(g) Repetitive Inspections and Corrective Actions

Except as specified in paragraph (i)(1) of this AD, at the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin MD80–55A072, dated April 08, 2016: Do an open hole high frequency eddy current inspection (HFEC) or surface HFEC inspection for cracking of the rear spar lower caps of the horizontal stabilizer, and do all applicable corrective actions; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD80–55A072, dated April 8, 2016, except as specified in paragraph (i)(2) of this AD. Do all applicable corrective actions before further flight. Repeat the inspection thereafter at the applicable interval specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin MD80–55A072, dated April 8, 2016, until accomplishment of the actions provided by paragraph (h) of this AD.

(h) Optional Terminating Action

Accomplishment of the fatigue life enhancement modification in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD80–55A072, dated April 8, 2016, terminates the repetitive inspections required by paragraph (g) of this AD.

(i) Service Information Exceptions

(1) Where paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin MD80–55A072, dated April 8, 2016, specifies a compliance time ''after the original issue date of this service bulletin,'' this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) If any cracking is found during any inspection required by this AD, and Boeing Alert Service Bulletin MD80–55A072, dated April 8, 2016, specifies to contact Boeing for appropriate action: Before further flight, repair the cracking using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(j) Post-Modification and Post-Repair Actions

For airplanes on which any modification or repair specified in (g) or (h) of this AD has been done: At the applicable time and intervals specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin MD80–55A072, dated April 8, 2016, do all applicable post-modification and post-repair inspections and all applicable corrective actions; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD80–55A072, dated April 8, 2016; except as specified in paragraph (i)(2) of this AD. All applicable corrective actions must be done before further flight.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

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

(4) Except as required by paragraph (i)(2) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(4)(i) and (k)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or sub-step is labeled ''RC Exempt,'' then the RC requirement is removed from that step or sub-step. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(l) Related Information

(1) For more information about this AD, contact Haytham Alaidy, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5224; fax: 562–627–5210; email: *haytham.alaidy@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, CA 90846–0001; telephone 206–544–5000, extension 2; fax 206–766–5683; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on August 11, 2016.

Paul R. Bernado,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–19936 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[REG–108792–16]

RIN 1545–BN37

User Fees for Installment Agreements

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed amendments to the regulations that provide user fees for installment agreements. The proposed amendments affect taxpayers who wish to pay their liabilities through installment agreements. The proposed effective date for these proposed amendments to the regulations is January 1, 2017. This document also provides a notice of public hearing on these proposed amendments to the regulations.

DATES: Written or electronic comments must be received by October 6, 2016. Outlines of topics to be discussed at the public hearing scheduled for October 19, 2016, at 2:00 p.m. must be received by October 6, 2016.

ADDRESSES: Send submissions to: Internal Revenue Service, CC:PA:LPD:PR (REG–108792–16), Room 5203, Post Office Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–108792–16), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224 or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (indicate IRS and REG–108792–16). The public hearing will be held in the Main IR Auditorium beginning at 2:00 p.m. in the Internal Revenue Service Building, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed amendments to the regulations, M. Pilar Puerto at (202) 317–5437; concerning submissions of comments, the hearing, or to be placed on the building access list to attend the hearing, Regina Johnson, at (202) 317–6901; concerning cost methodology, Eva Williams, at (202) 803–9728 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed regulations that would amend §§ 300.1 and 300.2 of the User Fee Regulations (26 CFR part 300), which provide for a user fee applicable to installment agreements under section 6159 of the Internal Revenue Code (Code).

Section 6159 authorizes the IRS to enter into an agreement with any taxpayer for the payment of tax in installments to the extent the IRS determines that entering into the installment agreement will facilitate the full or partial collection of the tax. Section 301.6159–1(a). Installment agreements are voluntary, and taxpayers may request an installment agreement in person, by completing the appropriate forms and mailing them to the IRS, online, or over the telephone. Before entering into an installment agreement, the IRS may examine the taxpayer's financial position to determine whether such an agreement is appropriate. See Internal Revenue Manual (IRM) 5.14. If the IRS accepts the installment agreement, the IRS must process the payments made by the taxpayer and monitor the taxpayer's compliance with the terms of the agreement. The terms of an agreement generally require the taxpayer to pay the minimum monthly payment on time, file all required tax returns on time, and pay all taxes in-full and on time. See Form 433–D, Installment Agreement. In addition, section 6159(d) requires that the IRS review partial payment installment agreements at least once every two years.

Under § 300.1, the IRS currently charges three rates for installment agreements. The user fee, in general, is $120 for an installment agreement. The user fee is reduced to $52 for a direct debit installment agreement, which is an agreement whereby the taxpayer authorizes the IRS to request the monthly electronic transfer of funds from the taxpayer's bank account to the IRS. The user fee is $43 notwithstanding the method of payment if the taxpayer is a low-income taxpayer, as defined below.

Under § 300.2, the IRS currently charges $50 for restructuring or reinstating an installment agreement that is in default. An installment agreement is deemed to be in default when a taxpayer fails to meet any of the conditions of the installment agreement. See IRM 5.14. Currently, there is no exception to this fee for low-income taxpayers.

Explanation of Provisions

A. Overview

To bring user fee rates for installment agreements in line with the full cost to the IRS of providing these taxpayer specific services, the proposed regulations under §§ 300.1 and 300.2 would increase the user fee for the existing installment agreement types and introduce two new types of online installment agreements, each subject to a separate user fee. Five of these proposed user fee rates are based on the full cost of establishing and monitoring installment agreements. The sixth rate is for low-income taxpayers.

- Regular Installment Agreements—A taxpayer contacts the IRS in person, by phone, or by mail and sets up an agreement to make manual payments over a period of time either by mailing a check or electronically through the Electronic Federal Tax Payment System (EFTPS). The proposed fee for entering into a regular installment agreement is $225.
- Direct Debit Installment Agreements—A taxpayer contacts the IRS by phone or mail and sets up an agreement to make automatic payments over a period of time through a direct debit from a bank account. The proposed fee for entering into a direct debit installment agreement is $107.
- Online Payment Agreements—A taxpayer sets up an installment agreement through *http://www.irs.gov* and agrees to make manual payments over a period of time either by mailing a check or electronically through the EFTPS. The proposed fee for entering into an online payment agreement is $149.
- Direct Debit Online Payment Agreements—A taxpayer sets up an installment agreement through *http://www.irs.gov* and agrees to make automatic payments over a period of time through a direct debit from a bank account. The proposed fee for entering into a direct debit online payment agreement is $31.
- Restructured/Reinstated Installment Agreements—A taxpayer modifies a previously established installment agreement or reinstates an installment agreement on which the taxpayer has defaulted. The proposed fee for restructuring or reinstating an installment agreement is $89.
- Low-Income Rate—A rate that applies when a low-income taxpayer enters into any type of installment agreement, other than a direct debit online payment agreement, and when a low-income taxpayer restructures or reinstates any installment agreement. A low-income taxpayer is a taxpayer that

has income at or below 250 percent of the dollar criteria established by the poverty guidelines updated annually in the **Federal Register** by the U.S. Department of Health and Human Services. Section 300.1(b)(2). The proposed low-income rate is $43.

B. User Fee Authority

The Independent Offices Appropriations Act (IOAA) (31 U.S.C. 9701) authorizes each agency to promulgate regulations establishing the charge for services provided by the agency (user fees). The IOAA provides that these user fee regulations are subject to policies prescribed by the President and shall be as uniform as practicable. Those policies are currently set forth in the Office of Management and Budget (OMB) Circular A–25, 58 FR 38142 (July 15, 1993; OMB Circular).

The IOAA states that the services provided by an agency should be self-sustaining to the extent possible. 31 U.S.C. 9701(a). The OMB Circular states that agencies that provide services that confer special benefits on identifiable recipients beyond those accruing to the general public are to establish user fees that recover the full cost of providing those services. The OMB Circular requires that agencies identify all services that confer special benefits and determine whether user fees should be assessed for those services.

Agencies are to review user fees biennially and update them as necessary to reflect changes in the cost of providing the underlying services. During this biennial review, an agency must calculate the full cost of providing each service, taking into account all direct and indirect costs to any part of the U.S. government. The full cost of providing a service includes, but is not limited to, salaries, retirement benefits, rents, utilities, travel, and management costs, as well as an appropriate allocation of overhead and other support costs associated with providing the service.

An agency should set the user fee at an amount that recovers the full cost of providing the service unless the agency requests, and the OMB grants, an exception to the full cost requirement. The OMB may grant exceptions only where the cost of collecting the fees would represent an unduly large part of the fee for the activity or any other condition exists that, in the opinion of the agency head, justifies an exception. When the OMB grants an exception, the agency does not collect the full cost of providing the service and therefore must fund the remaining cost of providing the service from other available funding sources. By doing so, the agency subsidizes the cost of the service to the recipients of reduced-fee services even though the service confers a special benefit on those recipients who should otherwise be required to pay the full costs of receiving that benefit as provided for by the IOAA and the OMB Circular.

C. Installment Agreement User Fee

The installment agreement program confers a special benefit on identifiable recipients beyond those accruing to the general public. Specifically, a taxpayer that is granted an installment agreement is allowed to pay an outstanding tax obligation over time without being subjected to IRS levy related to these taxes during this term of repayment. See section 6331(k)(2) of the Code and § 301.6159–1(f). Section 6331(k)(2) generally prohibits the IRS from levying to collect taxes while a request to enter into an installment agreement is pending with the IRS, for 30 days after the rejection of a proposed installment agreement, and for 30 days immediately following the termination of an installment agreement. If, prior to the expiration of the 30-day period following the rejection or termination of an installment agreement, the taxpayer appeals the rejection or termination decision, no levy may be made while the rejection or termination is being considered by Appeals. Because of these special benefits the IOAA and the OMB Circular authorize the IRS to charge a user fee for an installment agreement that reflects the full cost of providing the service of the installment agreement program to the taxpayer.

The installment agreement user fees were last changed in 2014. As required by the IOAA and the OMB Circular, the IRS completed its 2015 biennial review of the installment agreement program and determined that the full cost of a regular installment agreement is $225, and the full cost of a direct debit installment agreement is $107. The IRS determined that the full cost of a regular online payment agreement is $149, and the full cost for a direct debit online payment agreement is $31. The IRS determined that the full cost of restructuring or reinstating an installment agreement is $89.

The proposed regulations adopt the full cost amounts as the new user fees for the various types of installment agreements. Historically, the IRS charged a user fee that recovered less than the full cost of an installment agreement to make the service more accessible to a broader range of taxpayers. However, in light of constraints on IRS resources for tax administration, the Treasury Department and the IRS have determined that it is necessary to recoup the full costs of the installment agreement program. The IRS will continue its practice of providing services subject to user fees at less than full cost where there is a compelling tax administration reason to do so. Therefore, these proposed regulations do not increase the reduced user fee for offers submitted by low-income taxpayers and introduce a reduced fee for requests by low-income taxpayers to restructure or reinstate defaulted installment agreements.

The proposed fees reflect the IRS's determination to continue to provide a wide variety of installment agreement options to taxpayers and, as required by the OMB Circular, to determine the full cost for each option. Since the enactment of the installment agreement program, the IRS has periodically developed new ways for taxpayers to enter into and pay for installment agreements, such as through online payment agreements and direct debit online payment agreements. These new installment agreement types have not had their own separate user fee, but instead have been included in the existing user fee structure. In recent years, taxpayers' use of the online installment agreement options have increased, justifying a separate fee structure for the online installment agreement options.

Consistent with introducing these new fees, the most recent full cost analysis of the installment agreement program has been refined to more precisely account for the costs associated with administering the various types of installment agreements available to taxpayers. Requesting installment agreements in person or over the phone and receiving payment through means other than direct debit is more costly for the IRS to administer, and the proposed user fees reflect these costs. Similarly, this recent analysis has resulted in the availability of reduced user fees to taxpayers for those options that cost less for the IRS to administer. By offering a range of installment agreement options at a range of fees, the IRS is assisting taxpayers in coming into compliance with their tax payment obligations, which benefits tax administration and provides an enhanced service to taxpayers.

D. Calculation of User Fees Generally

User fee calculations begin by first determining the full cost for the service. The IRS follows the guidance provided by the OMB Circular to compute the full cost of the service, which includes all indirect and direct costs to any part of

the U.S. government including but not limited to direct and indirect personnel costs, physical overhead, rents, utilities, travel, and management costs. The IRS's cost methodology is described below.

Once the total amount of direct and indirect costs associated with a service is determined, the IRS follows the guidance in the OMB Circular to determine the costs associated with providing the service to each recipient, which represents the average per unit cost of that service. This average per unit cost is the amount of the user fee that will recover the full cost of the service.

The IRS follows generally accepted accounting principles (GAAP), as established by the Federal Accounting Standards Advisory Board (FASAB) in calculating the full cost of providing services. The FASAB Handbook of Accounting Standards and Other Pronouncements, as amended, which is available at *http://files.fasab.gov/pdffiles/2015_fasab_handbook.pdf*, includes the Statement of Federal Financial Accounting Standards No. 4: Managerial Cost Accounting Concepts and Standards for the Federal Government (SFFAS No.4). SFFAS No. 4 establishes internal costing standards under GAAP to accurately measure and manage the full cost of federal programs. The methodology described below is in accordance with SFFAS No. 4.

1. Cost Center Allocation

The IRS determines the cost of its services and the activities involved in producing them through a cost accounting system that tracks costs to organizational units. The lowest organizational unit in the IRS's cost accounting system is called a cost center. Cost centers are usually separate offices that are distinguished by subject-matter area of responsibility or geographic region. All costs of operating a cost center are recorded in the IRS's cost accounting system and allocated to that cost center. The costs allocated to a cost center are the direct costs for the cost center's activities as well as all indirect costs, including overhead, associated with that cost center. Each cost is recorded in only one cost center.

2. Determining the Per Unit Cost

To establish the per unit cost, the total cost of providing the service is divided by the volume of services provided. The volume of services provided includes both services for which a fee is charged as well as subsidized services. The subsidized services are those where OMB has approved an exception to the full cost requirement, for example, to charge a reduced fee to low-income taxpayers. The volume of subsidized services is included in the total volume of services provided to ensure that the IRS, and not those who are paying full cost, subsidizes the cost of the reduced-full cost services.

3. Cost Estimation of Direct Labor and Benefits

Not all cost centers are fully devoted to only one service for which the IRS charges a user fee. Some cost centers work on a number of different services. In these cases, the IRS estimates the cost incurred in those cost centers attributable to the service for which a user fee is being calculated by measuring the time required to accomplish activities related to the service, and estimating the average time required to accomplish these activities. The average time required to accomplish these activities is multiplied by the relevant organizational unit's average labor and benefits cost per unit of time to determine the labor and benefits cost incurred to provide the service. To determine the full cost, the IRS then adds an appropriate overhead charge as discussed below.

4. Calculating Overhead

Overhead is an indirect cost of operating an organization that cannot be immediately associated with an activity that the organization performs. Overhead includes costs of resources that are jointly or commonly consumed by one or more organizational unit's activities but are not specifically identifiable to a single activity.

These costs can include:

- General management and administrative services of sustaining and support organizations.
- Facilities management and ground maintenance services (security, rent, utilities, and building maintenance).
- Procurement and contracting services.
- Financial management and accounting services.
- Information technology services.
- Services to acquire and operate property, plants and equipment.
- Publication, reproduction, and graphics and video services.
- Research, analytical, and statistical services.
- Human resources/personnel services.
- Library and legal services.

To calculate the overhead allocable to a service, the IRS first calculates the Corporate Overhead rate and then multiplies the Corporate Overhead rate by the direct labor and benefits costs determined as discussed above. The IRS calculates the Corporate Overhead rate annually based on cost elements underlying the Statement of Net Cost included in the IRS Annual Financial Statements, which are audited by the Government Accountability Office. The Corporate Overhead rate is the ratio of the sum of the IRS's indirect labor and benefits costs from the supporting and sustaining organizational units—those that do not interact directly with taxpayers—and all non-labor costs to the IRS's labor and benefits costs of its organizational units that interact directly with taxpayers.

The Corporate Overhead rate of 65.85 percent for costs reviewed during FY 2015 was calculated based on FY 2014 costs as follows:

Indirect Labor and Benefits Costs	$1,693,339,843
Non-Labor Costs	+ $2,832,262,970
Total Indirect Costs	$4,525,602,813
Direct Labor and Benefits Costs	+ $6,872,934,473
Corporate Overhead Rate	*65.85%*

E. Calculation of Installment Agreement User Fee

The full cost analysis considers the common components of each of the five installment agreement types as well as each type's unique cost drivers. The costs for each type of installment agreement are broadly categorized into two groups: (1) Costs incurred by the IRS to establish the installment agreements and (2) costs incurred by the IRS to maintain and monitor the installment agreements.

The upfront costs for establishing installment agreements requested in person, in writing, or over the phone are significantly higher than those for online payment agreements. For that reason, the upfront costs for establishing installment agreements requested in person, in writing, or over the phone are determined separately and allocated only to installment agreements requested in person, in writing, or over the phone. In contrast, the only upfront costs to establish online payment agreements through *http://www.irs.gov* are the costs of the online payment agreement system such as annual maintenance and system enhancements, which are only allocated to online payment agreements.

After installment agreements are established, costs to maintain and monitor them, including routine notices to the taxpayers, vary significantly based on the type of installment agreement. Direct debit installment agreements and direct debit online

payment agreements have lower maintenance and monitoring costs because they do not require as much support on an ongoing basis as installment agreements not paid via direct debit. Payments under direct debit installment agreements and direct debit online payment agreements are automatically debited from the taxpayer's bank account. Because payments for direct debit installment agreements and direct debit online payment agreements are automatically debited from taxpayers' accounts without requiring taxpayers to initiate each payment, the IRS does not send monthly payment notices and in general sends fewer notices related to these agreements compared to installment agreements not paid via direct debit. Correspondingly, direct debit installment agreements and direct debit online payment agreements require less IRS time responding to taxpayer inquiries resulting from these notices than do installment agreements not paid via direct debit.

1. Establishing Installment Agreements

The IRS allocates costs attributed to establishing installment agreements based on whether the installment agreement is a non-online installment agreement or an online payment agreement.

a. Non-Online Installment Agreements

For non-online installment agreements, the IRS identified the activities conducted across various organizations to establish agreements, obtained the time spent on the activities through various time tracking systems, obtained the labor and benefits rates for employees from the financial system for FY 2013 and 2014 who spent time establishing agreements, and averaged those costs to create an annualized average cost. The average labor and benefits costs to establish non-online installment agreements is $110,143,952, calculated as follows:

Collection Field Function	$53,268,552
Compliance Services Collection Operations	19,989,943
Automated Collection System	19,377,987
Customer Service Toll-Free	6,183,764
Appeals Staff Labor and Benefits	8,624,615
Field Assistance	1,894,976
Examination	804,115
Average Labor and Benefits Costs to Establish Non-Online Installment Agreements	110,143,952

Because the non-labor costs for notices and telecommunication, which includes the costs of paper, postage and phone service, related to installment agreements can be identified, the IRS considered them to be direct costs for the installment agreement program. Accordingly, the IRS modified the calculation of the Corporate Overhead rate to exclude these notices and telecommunication costs from the total indirect costs in the calculation of the Corporate Overhead rate used for purposes of allocating Corporate Overhead to the installment agreement program (adjusted Corporate Overhead). The adjusted Corporate Overhead rate used for the entire installment agreement program is 60.89 percent, calculated as follows:

Indirect Labor and Benefits Costs	$1,693,339,843
Non-Labor Costs	+ 2,832,262,970
Non-Labor Costs for Notices and Telecommunication	(211,959,052)
Adjusted Total Indirect Costs	4,313,643,761

Direct Labor and Benefits Costs	$6,872,934,473
Non-Labor Costs for Notices and Telecommunication	+ 211,959,052
Adjusted Direct Labor and Benefits Costs	7,084,893,526
Adjusted Total Indirect Costs	4,313,643,761
Adjusted Direct Labor and Benefits Costs	+ 7,084,893,526
Adjusted Corporate Overhead Rate	*60.89%*

The IRS applied the adjusted Corporate Overhead rate to the labor and benefits costs to calculate the total labor and benefits cost for establishing non-online installment agreements as follows:

Labor and Benefits Costs to Establish Non-Online Installment Agreements	$110,143,952
Adjusted Corporate Overhead Rate (60.89%)	67,066,653
Total Labor and Benefits and Adjusted Overhead Costs to Establish Non-Online Installment Agreements	177,210,605

There are also non-labor costs attributed to establishing non-online installment agreements. Because these costs are non-labor, the IRS does not allocate any overhead to determine the total costs. The total non-labor costs for establishing non-online installment agreements are $636,046, calculated as follows:

Telecommunications	$145,169
Automated Collection System	274,664
Customer Service Toll-Free	216,213
Total Non-Labor Costs to Establish Non-Online Installment Agreements	636,046

The total costs for establishing non-online installment agreements are $177,846,650, calculated as follows:

Total Labor and Benefits and Adjusted Overhead Costs to Establish Non-Online Installment Agreements	$177,210,605
Total Non-Labor Costs to Establish Non-Online Installment Agreements	636,046
Total Costs to Establish Non-Online Installment Agreements	177,846,650

To determine the unit cost to establish non-online installment agreements, the IRS divided the total cost by the average volume of non-online installment agreements. The IRS determined the volume of non-online installment agreements by averaging the volumes of new agreements entered into in FY 2013 and FY 2014. The unit cost was calculated as follows:

Total Costs to Establish Non-Online Installment Agreements	$177,846,650
Average Annual Volume	2,175,142
Unit Cost to Establish Non-Online Installment Agreements	$81.76

b. Online Installment Agreements

For online payment agreements, the only cost to establish those agreements is the cost for the online payment agreement system that allows taxpayers to set up the agreements. In FY 2014, the IRS performed a substantial enhancement to this system at a cost of $4,200,000. The IRS amortizes system enhancements over a six year period; therefore, for FY 2014 through FY 2020 the annual amortized system cost for online payment agreements is $700,000. In addition to the annual amortized cost, the IRS incurs $200,000 in annual system maintenance costs for this system. The total annual cost for the online payment agreement system is $900,000. The use of online payment

agreements is trending upward and the IRS expects this upward trend to continue as more taxpayers utilize the IRS's online systems. To reflect the IRS's expectation of increased use of online systems, the IRS adjusted upward the average volume of online payment agreements received in FY 2013 and FY 2014 consistent with that expectation. The total cost to establish online payment agreements is $6, calculated as follows:

Amortized System Upgrade	$700,000
Annual System Maintenance Cost	$200,000
Average Yearly System Cost	$900,000
Average Annual Volume	150,000
Unit Cost to Establish Online Payment Agreement	$6

2. Maintaining and Monitoring Installment Agreements

The costs for maintaining and monitoring installment agreements consist of the costs of monitoring and telecommunications labor and benefits, an allocation of overhead to these labor costs, and notice and telecommunication non-labor costs.

The IRS identified the activities conducted across various business units to monitor installment agreements, obtained the time spent on the activities through various time tracking systems, obtained the labor and benefits rates for these personnel from the financial system for FY 2013 and 2014, and determined the average annual cost for monitoring installment agreements.

The IRS allocated the costs attributed to maintaining and monitoring installment agreements based on whether the agreement is a direct debit agreement (Direct Debit Installment Agreement or Direct Debit Online Payment Agreement), a non-direct debit agreement (Regular Agreement or Online Payment Agreement), or a Restructured/Reinstated Installment Agreement. The following sections describe the costs allocated to various types of installment agreements for maintaining and monitoring.

The IRS continuously monitors all installment agreements for accounts not meeting the terms of the agreement, for returned payments, and various other circumstances that result in a need to contact the taxpayer. When these circumstances arise, the IRS reviews the account and sends a notice to the taxpayer, as needed, to resolve the condition. The IRS maintains a system that measures the hours of correspondence labor by type of notice sent to taxpayers.

Generally, the IRS uses the costs for two years and averages those costs to determine the cost of an activity. However, for this component of cost, the IRS used existing data for the hours spent in FY 2014 on correspondence labor related to monitoring installment agreements and calculated total labor and benefits for those hours. The IRS does not believe including an additional year of data would result in a significant difference in the result. In the future, the IRS intends to use the average cost of two years to calculate this cost component. The total annual cost of correspondence for monitoring agreements labor and benefits is $5,807,847.

The IRS divided the total annual labor and benefits cost of correspondence for monitoring agreements by the total agreements in inventory at the end of FY 2014. The total inventory was 3,973,208, resulting in annual labor and benefits cost per agreement of $1.46. The IRS converted the annual cost of correspondence for monitoring agreements labor and benefits to a per-agreement cost by dividing the annual cost per installment agreement by 12 months to calculate the monthly cost per installment agreement. The IRS then multiplied the monthly cost per installment agreement by 40.31 months, the average term of installment agreements (in months), to calculate the unit cost over the life of the installment agreement.

Total Annual Cost of Correspondence for Monitoring Agreements Labor and Benefits	$5,807,847
Total Agreements in Inventory at End of FY 2014	3,973,208
Annual Labor and Benefits Cost per Agreement	$1.46
Monthly Cost Per Agreement (Annual Labor and Benefits Cost per Agreement divided by 12 months)	$0.12
Average Term of Installment Agreement (in months)	40.31
Unit Cost of Correspondence for Monitoring Agreements Labor and Benefits Over the Life of Installment Agreement	$4.91

There is not a significant difference in the cost of monitoring regular and direct debit installment agreements; therefore, each type of agreement is allocated the same ratio of monitoring costs. Restructured/reinstated installment agreements are not allocated any monitoring costs because monitoring costs for restructured/reinstated agreements are recovered in the original user fee. The unit cost of correspondence for monitoring agreements labor and benefits per installment agreement is shown below:

	Regular agreement	Direct debit installment agreement	Restructured/reinstated installment agreement
Unit Cost of Correspondence for Monitoring Agreements Labor and Benefits Over the Life of Installment Agreement	$4.91	$4.91	$0

The IRS maintains a system that calculates the number of seconds spent on the phone by type of call. To determine the telecommunications labor and benefits costs to maintain and monitor installment agreements, IRS first analyzed the time spent on phone calls related to monitoring and maintaining installment agreements, rather than establishing one. The total seconds are converted into hours and hourly salary and benefits rates are applied.

The average labor and benefits costs for responding to installment agreement questions are $58,917,275 for FY 2013 and FY 2014. These costs are accumulated by type of installment agreement. To determine the annual unit cost per type of agreement, the IRS used the total volume of the corresponding installment agreements in inventory at the end of FY 2014 as the baseline for the number of installment agreements that generate telecommunications costs of responding to questions. The IRS divided the average labor and benefits costs separated by type of agreement by the total agreements in inventory at the end of FY 2014 for each type of agreement. The IRS converted the annual cost of correspondence for telecommunications labor and benefits to a per-agreement cost as follows:

	Non-direct debit installment agreement	Direct debit installment agreement	Restructured/ reinstated agreement
Average Telecommunications Labor and Benefits Costs	$55,872,940	$2,014,736	$1,029,598
Volume of Installment Agreements in Inventory at end of FY 2014 by Type	3,084,844	888,364	1,082,303
Annual Unit Cost Per Installment Agreement	$18.11	$2.27	$0.95
Monthly Cost Per Installment Agreement 4 (Annual Unit Cost Per Installment Agreement divided by 12 months)	$1.51	$0.19	$0.08
Average Term of Installment Agreement (in months)	40.31	40.31	40.31
Unit Cost for Telecommunications Labor and Benefits Over the Life of the Installment Agreement	$60.84	$7.62	$3.20

Next, the IRS determined the appropriate allocation of overhead for installment agreements. As noted above, the IRS adjusted the Corporate Overhead Rate for the installment agreement program down to 60.89 percent. The IRS applied this adjusted Corporate Overhead rate to the total labor and benefits costs for monitoring and telecommunications calculated above. The total labor unit cost including the adjusted Corporate Overhead allocated to each type installment agreement is as follows:

	Non-direct debit installment agreement	Direct debit installment agreement	Restructured/ reinstated installment agreement
Unit Cost of Correspondence for Monitoring Agreements Labor and Benefits Over the Life of Installment Agreement	$4.91	$4.91	$0
Unit Cost for Telecommunications Labor and Benefits Over the Life of the Installment Agreement	60.84	7.62	3.20
Subtotal	65.75	12.53	3.20
Adjusted Corporate Overhead (60.89%)	40.03	7.63	1.95
Maintain and Monitor Labor and Benefits Unit Cost	105.78	20.16	5.15

The final element of the cost analysis for maintaining and monitoring installment agreements is the cost of non-labor notice and telecommunications. The IRS maintains a system for tracking notices and telecommunication costs. Each type of notice has a known number of pages, postage, and telecommunication costs responding to taxpayer inquiries related to the notices. The average annual non-labor cost for all notices and telecommunication related to installment agreements is $36,219,659. The IRS divided the total average notice and telecommunication non-labor cost by the total volume of agreements in inventory at the end of FY 2014 to determine the annual notice and telecommunication non-labor cost per installment agreement. The IRS converted the annual cost of notice and telecommunications to a per-agreement cost as follows:

	Regular installment agreement	Direct debit installment agreement	Restructured/ reinstated agreement
Average Annual Non-Labor Cost of All Notices	$33,005,331	$1,190,147	$608,206
Average Annual Non-Labor Cost of Telecommunication	$1,342,810	$48,421	$24,745
Total Average Notice and Telecommunication Non-Labor Costs	$34,348,141	$1,238,568	$632,950
Total Volume of Agreements in Inventory at end of FY 2014	3,084,844	888,364	1,082,303
Annual Notice and Telecommunication Non-Labor Cost Per Installment Agreement	$11.13	$1.39	$0.58
Monthly Notice and Telecommunication Non-Labor Cost Per Installment Agreement (Annual Notice and Telecommunication Non-Labor Cost divided by 12 months)	$0.93	$0.12	$0.05
Average Term of Installment Agreement (in months)	40.31	40.31	40.31
Unit Cost for Notice and Telecommunication Non-Labor Over the Life of the Installment Agreement	$37.40	$4.68	$1.96

The unit costs for maintaining and monitoring an installment agreement based on the total cost of maintaining and monitoring all installment agreements are as follows:

	Non-direct debit installment agreement	Direct debit installment agreement	Restructured/ reinstated installment agreement
Maintain and Monitor Labor Unit Costs	$105.78	$20.16	$5.15

	Non-direct debit installment agreement	Direct debit installment agreement	Restructured/ reinstated installment agreement
Maintain and Monitor Non-Labor Unit Cost	37.40	4.68	1.96
Total Maintain and Monitor Unit Cost	143.18	24.84	7.11

3. Per Unit Full Cost of Each Type of Installment Agreement

The per unit full cost and rates per each type of installment agreement are as follows:

	Regular agreement	Direct debit installment agreement	Restructured/ reinstated installment agreement	Direct debit online payment agreements	Online payment agreements
Unit Cost to Establish	$81.76	$81.76	$81.76	$6.00	$6.00
Unit Cost to Maintain and Monitor	143.18	24.84	7.11	24.84	143.18
Per Unit Full Cost	224.94	106.60	88.87	30.84	149.18
Rate	225	107	89	31	149

4. Low Income Installment Agreement User Fee

The proposed regulations maintain the low-income taxpayer user fee of $43 for regular installment agreements and direct debit installment agreements and extend the low-income taxpayer user fee of $43 to restructured/reinstated installment agreements and online payment agreements. When the IRS first instituted the $43 user fee for low-income taxpayers, it determined that this amount would not unduly burden or disproportionately dissuade low-income taxpayers from seeking installment agreements. Historically, approximately one-third of all installment agreement requests have come from low-income taxpayers, a percentage that has remained relatively consistent since the introduction of the $43 low-income taxpayer rate. In light of this, the IRS has determined to maintain the existing $43 user fee for low-income taxpayers and to extend this reduced user fee to restructured/reinstated installment agreements and online payment agreements requested by low-income taxpayers. Because the full cost of direct debit online payment agreements of $31 is less than the low-income taxpayer user fee, all taxpayers will be charged the same $31 user fee for direct debit online payment agreements.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the information that follows. The economic impact of these regulations on any small entity would result from the entity being required to pay a fee prescribed by these regulations in order to obtain a particular service. The dollar amount of the fee is not, however, substantial enough to have a significant economic impact on any entity subject to the fee. Low-income taxpayers and taxpayers entering into direct debit online payment agreements will be charged a lower fee, which lessens the economic impact of these regulations. Accordingly, a regulatory flexibility analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed amendments to the regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. All comments will be available at *www.regulations.gov* or upon request.

A public hearing has been scheduled for October 19, 2016, beginning at 2:00 p.m. in the Main IR Auditorium of the Internal Revenue Service Building, 1111 Constitution Avenue NW., Washington, DC 20224. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit written comments or electronic comments by October 6, 2016 and submit an outline of the topics to be discussed and the amount of time to be devoted to each topic (a signed original and 8 copies) by October 6, 2016. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Maria Del Pilar Puerto of the Office of Associate Chief Counsel (Procedure and Administration). Other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 300

Reporting and recordkeeping requirements, User fees.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 300 is proposed to be amended as follows:

PART 300—USER FEES

■ **Paragraph 1.** The authority citation for part 300 continues to read as follows:

Authority: 31 U.S.C. 9701.

■ **Par. 2.** In § 300.1, paragraphs (b) and (d) are revised to read as follows:

§ 300.1 Installment agreement fee.

* * * * *

(b) *Fee.* The fee for entering into an installment agreement before January 1, 2017, is $120. The fee for entering into an installment agreement on or after January 1, 2017, is $225. A reduced fee applies in the following situations:

(1) For installment agreements entered into before January 1, 2017, the fee is $52 when the taxpayer pays by way of a direct debit from the taxpayer's bank account. The fee is $107 when the taxpayer pays by way of a direct debit from the taxpayer's bank account for installment agreements entered into on or after January 1, 2017;

(2) For online payment agreements entered into before January 1, 2017, the fee is $120, except that the fee is $52 when the taxpayer pays by way of a direct debit from the taxpayer's bank account. The fee is $149 for entering into online payment agreements on or after January 1, 2017, except that the fee is $31 when the taxpayer pays by way of a direct debit from the taxpayer's bank account; and

(3) Notwithstanding the type of installment agreement and method of payment, the fee is $43 if the taxpayer is a low-income taxpayer, that is, an individual who falls at or below 250 percent of the dollar criteria established by the poverty guidelines updated annually in the **Federal Register** by the U.S. Department of Health and Human Services under authority of section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (95 Stat. 357, 511), or such other measure that is adopted by the Secretary, except that the fee is $31 when the taxpayer pays by way of a direct debit from the taxpayer's bank account with respect to online payment agreements entered into on or after January 1, 2017;

* * * * *

(d) *Effective/applicability date.* This section is applicable beginning January 1, 2017.

■ **Par. 3.** In § 300.2, paragraphs (b) and (d) are revised to read as follows:

§ 300.2 Restructuring or reinstatement of installment agreement fee.

* * * * *

(b) *Fee.* The fee for restructuring or reinstating an installment agreement before January 1, 2017, is $50. The fee for restructuring or reinstating an installment agreement on or after January 1, 2017, is $89. If the taxpayer is a low-income taxpayer, that is, an individual who falls at or below 250 percent of the dollar criteria established by the poverty guidelines updated annually in the **Federal Register** by the U.S. Department of Health and Human Services under authority of section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (95 Stat. 357, 511), or such other measure that is adopted by the Secretary, then the fee for restructuring or reinstating an installment agreement on or after January 1, 2017 is $43.

* * * * *

(d) *Effective/applicability date.* This section is applicable beginning January 1, 2017.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2016–19836 Filed 8–19–16; 8:45 am]

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DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

[NPS–SER–CAHA–21373; PPSECAHAS0, PPMPSPD1Z.YM0000]

RIN 1024–AE33

Special Regulations; Areas of the National Park System, Cape Hatteras National Seashore—Off-Road Vehicle Management

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: The National Park Service (NPS) proposes to amend its special regulation for off-road vehicle (ORV) use at Cape Hatteras National Seashore, North Carolina, to revise the times that certain beaches open to ORV use in the morning, extend the dates that certain seasonal ORV routes are open in the fall and spring, and modify the size and location of vehicle-free areas.

Consideration of changes to this special regulation was required by section 3057 of the National Defense Authorization Act for Fiscal Year 2015.

The NPS also proposes to amend this special regulation to allow the Cape Hatteras National Seashore to issue ORV permits that would be valid for different lengths of time than currently exist, and to replace an ORV route designation on Ocracoke Island with a park road to allow vehicle access and pedestrian use of a soundside area without the requirement for an ORV permit.

DATES: Comments must be received by October 21, 2016.

ADDRESSES: You may submit comments, identified by the Regulation Identifier Number (RIN) 1024–AE33, by any of the following methods:

- *Electronically:* Federal eRulemaking Portal*: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Hardcopy:* Mail or hand-deliver to: Superintendent, Cape Hatteras National Seashore, 1401 National Park Drive, Manteo, North Carolina 27954.

For additional information see Public Participation under **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: Superintendent, Cape Hatteras National Seashore, 1401 National Park Drive, Manteo, North Carolina 27954. Phone 252–475–9032.

SUPPLEMENTARY INFORMATION:

Background

Description of Cape Hatteras National Seashore

Situated along the Outer Banks of North Carolina, Cape Hatteras National Seashore (Seashore or park) was authorized by Congress in 1937 and established in 1953 as the nation's first national seashore. Consisting of more than thirty thousand acres distributed along approximately 67 miles of shoreline, the Seashore is part of a dynamic barrier island system.

The Seashore contains important wildlife habitat created by dynamic environmental processes. Several species listed under the Endangered Species Act, including the piping plover, rufa subspecies of the red knot, and five species of sea turtles, are found within the park. The Seashore also serves as a popular recreation destination where users participate in a variety of activities.

Authority and Jurisdiction To Promulgate Regulations

In the NPS Organic Act (54 U.S.C. 100101), Congress granted the NPS broad authority to regulate the use of

areas under its jurisdiction. The Organic Act authorizes the Secretary of the Interior (Secretary), acting through the NPS, to ''prescribe such regulations as the Secretary considers necessary or proper for the use and management of [National Park] System units.'' 54 U.S.C. 100751(a).

Off-Road Motor Vehicle Regulation

Executive Order 11644, Use of Off-Road Vehicles on the Public Lands, was issued in 1972 in response to the widespread and rapidly increasing off-road driving on public lands ''often for legitimate purposes but also in frequent conflict with wise land and resource management practices, environmental values, and other types of recreational activity.'' Executive Order 11644 was amended by Executive Order 11989 in 1977, and together they are jointly referred to in this rule as the ''E.O.'' The E.O. requires Federal agencies that allow motorized vehicle use in off-road areas to designate specific areas and routes on public lands where the use of motorized vehicles may be permitted. The regulations must also require that the designation of such areas and trails shall be in accordance with the following:

(1) Areas and trails shall be located to minimize damage to soil, watershed, vegetation, or other resources of the public lands.

(2) Areas and trails shall be located to minimize harassment of wildlife or significant disruption of wildlife habitats.

(3) Areas and trails shall be located to minimize conflicts between off-road vehicle use and other existing or proposed recreational uses of the same or neighboring public lands, and to ensure the compatibility of such uses with existing conditions in populated areas, taking into account noise and other factors.

(4) Areas and trails shall not be located in officially designated Wilderness Areas or Primitive Areas. Areas and trails shall be located in areas of the National Park System, Natural Areas, or National Wildlife Refuges and Game Ranges only if the respective agency head determines that off-road vehicle use in such locations will not adversely affect their natural, aesthetic, or scenic values.

The NPS regulation at 36 CFR 4.10(b) implements the E.O. and requires that routes and areas designated for ORV use be promulgated as special regulations and that the designation of routes and areas must comply with 36 CFR 1.5 and E.O. 11644. It also states that ORV routes and areas may be designated only in national recreation areas, national seashores, national lakeshores, and national preserves. This proposed rule is consistent with these authorities and with Section 8.2.3.1 (Motorized Off-road Vehicle Use) of NPS Management Policies 2006, available at: *http://www.nps.gov/policy/mp/policies.html.*

Recent ORV Management at Cape Hatteras National Seashore

In 2010, the NPS completed the Off-Road Vehicle Management Plan and Environmental Impact Statement (ORV FEIS) for ORV use at the Seashore to guide the management and use of off-road vehicles at the Seashore. As a part of the selected alternative, certain elements of the ORV FEIS were implemented through rulemaking. The Final Rule for ORV management at the Seashore was published in the **Federal Register** on January 23, 2012 (77 FR 3123) (2012 Final Rule).

On December 19, 2014, the President signed the National Defense Authorization Act for Fiscal Year 2015 (2014 Act). Section 3057 of the 2014 Act requires that the Secretary of the Interior consider three specific changes to the 2012 Final Rule regarding:

- Morning opening times of beaches that are closed to ORV use at night,
- Extending the dates for seasonal ORV routes, and
- The size and location of vehicle-free areas (VFAs).

On February 17, 2016, the NPS published the *Consideration of Modifications to the Final Rule for Off-Road Vehicle Management Environmental Assessment* (EA). The EA evaluated:

- The times that beach routes open to ORV use in the mornings,
- Extending the dates that seasonal ORV routes would be open in the fall and spring, and
- Modifying the size and location of VFAs.

The EA also considered:

- Issuing ORV permits for different lengths of time,
- Revising some ORV route designations, and
- Providing access improvements for soundside locations on Ocracoke Island.

The EA, which contains a full description of the purpose and need for taking action, scoping, the alternatives considered, maps and the environmental impacts associated with the project may be viewed on the NPS planning Web site at *http://parkplanning.nps.gov/caha-orv-ea* under the ''Document List'' link. Public comments on the EA were accepted until March 18, 2016. The NPS reviewed and considered the comments received on the EA when drafting this proposed rule. After the comment period closes on this proposed rule, the NPS will review the comments received on the proposed rule, complete the NEPA process, and publish a final rule.

The Proposed Rule

This proposed rule, pursuant to § 4.10(b), would implement the NPS preferred alternative (Alternative 2) in the EA.

This proposed rule would amend the special regulation for ORV use at the Seashore as it relates to:

- The morning opening times of beaches that are closed to ORV use at night,
- The dates that seasonal ORV routes are open in the fall and spring, and
- The size and location of VFAs.

The proposed rule would also allow the Seashore to issue ORV permits that would be valid for different lengths of time than currently exist, and would revise the status of some ORV routes to allow vehicular access without requiring an ORV permit. This proposed rule also includes some changes made for clarification, such as updating ramp numbers to reflect current conditions. Although the preferred alternative in the EA proposed additional changes to Seashore access, only those described below require a modification to the existing special regulation.

Beach Opening Times

As stated in the preferred alternative in the EA, most ORV routes would continue to open to ORV use at 7:00 a.m. Certain ''priority'' beach routes could be opened to ORV use earlier than 7:00 a.m., though no earlier than 6:00 a.m. The NPS proposed this change so that ORV users could access the more popular beaches earlier than 7:00 a.m. NPS resource staff would patrol these ''priority'' beaches before opening so that park resources would be protected even while earlier access is allowed. The NPS is proposing to amend the special regulation at 36 CFR 7.58(c)(12) to state that the priority beaches would open no earlier than 6:00 a.m. Instead of establishing an opening time in the special regulation, beach opening times would be published annually in the Superintendent's Compendium. The proposed rule also slightly edits some of this language for clarity. Moving the beach opening times from the regulation to the Compendium would give the Superintendent some flexibility based on changing conditions at the Seashore and the ability of park staff to patrol and complete resource management inventories on beaches before they are opened to vehicle use.

Dates for Use of Seasonal ORV Routes

The proposed rule would extend the dates for ORV use of seasonally designated routes in front of the villages of Rodanthe, Waves, Salvo, Avon, Frisco, and Hatteras and the Ocracoke Campground by two weeks in the fall and two weeks in the spring, making these seasonal routes open to ORV use from October 15 through April 14. This extension is proposed in areas and at times of the year which would not result in measureable impacts to sensitive wildlife, visitor experience, safety, or workload complexity of park staff.

Size and Location of VFAs

The proposed rule would modify the size and location of VFAs and improve access in some locations. Ramps 2.5 and 59.5 would not be constructed. Ramp 2 would be restored to ORV use, extending the existing ORV route 0.5 miles to the north and providing ORV access to the route from either ramp 4 or ramp 2. Ramp 59 would continue to be open to ORV use, extending the existing year-round ORV route approximately 0.5 miles. The seasonal ORV route at ramp 34 would be extended 1 mile to the north and the seasonal ORV route at ramp 23 would be extended 1.5 miles to the south. The NPS proposes making changes to these particular VFAs because it would slightly increase ORV access on each of the islands without measurably impacting visitor experience, safety, sensitive wildlife species, or workload complexity of park staff.

Permit Durations

The NPS is proposing to remove the specific times established for the duration of ORV permits from the special regulation at § 7.58(c)(2)(iv), and instead control the duration of the permits through the Superintendent's Compendium. As described in the preferred alternative in the EA, existing annual ORV permits would change from being valid for the calendar year of issuance to being valid for one year from the date of issuance. Also, the existing 7-day ORV permit would be replaced by a 10-day ORV permit. Also, changing to a 10-day ORV permit from a 7-day ORV permit could allow many ORV users to access the beaches over two weekends, depending upon when they arrive at the Seashore.

Any future substantive changes to the duration of ORV permits would require the appropriate NEPA compliance.

The NPS intends to continue to recover the costs of administering the ORV permit program under 54 U.S.C. 103104. This requirement will remain in the proposed rule.

Access Improvements—Ocracoke Island

The existing ORV route designation along Devil Shoals Road (also referred to as Dump Station Road) would be removed. No ORV permit would be required to access this location as it would be designated a park road instead of an ORV route. This is an existing dirt road located across North Carolina State Highway 12 from the Ocracoke campground that has been maintained as part of the park's road network. This road meets NPS road design standards as a Class II connector road that provides normal passenger vehicle access to park areas of scenic and recreational interest with a surface type of dirt/gravel. The NPS proposed these changes to allow for limited vehicular soundside access on Ocracoke Island without the requirement to purchase an ORV permit. Unlike the other islands at the Seashore, there is currently no vehicular access to the soundside of Ocracoke Island available without an ORV permit.

Access Improvements—Hatteras Island

The NPS proposes to extend the existing Cape Point bypass route south of ramp 44 by 0.4 miles to the north so that it would join with ramp 44. The NPS is also proposing to extend the existing bypass route by approximately 600 feet to the south. Although this southern extension was not originally part of the preferred alternative in the EA, impacts associated with this proposed 600-foot extension would be similar in nature to those disclosed in the EA for the 0.4-mile extension to the north. As concluded in the EA, impacts associated with the bypass route extension would be negligible at most and would have no impact to wetlands. The NPS proposes extending this existing bypass to provide additional ORV access near Cape Point when the ORV route along the beach is closed for safety or resource protection.

Other Updates

Several changes to the language in the existing rule are proposed for clarification or to reflect existing conditions. Ramp 25.5 is renamed ''ramp 25''; ramp 32.5 is renamed ''ramp 32''; ramp 47.5 is renamed ''ramp 48''; the soundside ORV route at Little Kinnakeet would be changed to begin just west of the Kinnakeet lifesaving structures; and additional details are added to further clarify where existing routes terminate (*e.g.* the routes adjacent to ramps 63, 48, and 32 do not end exactly at the ramp).

Maps

The proposed changes to routes and ramps are depicted on the maps in the EA (pages 35—41) and are available for review at *http://parkplanning.nps.gov/caha-orv-ea.*

Compliance With Other Laws, Executive Orders, and Department Policy

Use of Off-Road Vehicles on the Public Lands (Executive Order 11644)

As discussed previously, the E.O. applies to ORV use on federal public lands that is not authorized under a valid lease, permit, contract, or license. Section 3(4) of E.O. 11644 provides that ORV ''areas and trails shall be located in areas of the National Park system, Natural Areas, or National Wildlife Refuges and Game Ranges only if the respective agency head determines that off-road vehicle use in such locations will not adversely affect their natural, aesthetic, or scenic values.'' Since the E.O. clearly was not intended to prohibit all ORV use everywhere in these units, the term ''adversely affect'' does not have the same meaning as the somewhat similar terms ''adverse impact'' or ''adverse effect'' commonly used in the National Environmental Policy Act of 1969 (NEPA). Under NEPA, a procedural statute that provides for the study of environmental impacts, the term ''adverse effect'' refers to any effect, no matter how minor or negligible.

Section 3(4) of the E.O., by contrast, does not prescribe procedures or any particular means of analysis. It concerns substantive management decisions, and must instead be read in the context of the authorities applicable to such decisions. The Seashore is an area of the National Park System. Therefore, the NPS interprets the E.O. term ''adversely affect'' consistent with its NPS Management Policies 2006. These policies require the NPS to allow only ''appropriate uses'' of parks and to avoid ''unacceptable impacts'' to park resources or values. The NPS has evaluated this proposed rule and confirmed that it would comply with these policies.

Specifically, this rule would not impede the attainment of the Seashore's desired future conditions for natural and cultural resources as identified in the ORV FEIS. The NPS has determined this rule would not unreasonably interfere with the atmosphere of peace and tranquility, or the natural soundscape maintained in natural locations within the Seashore. Therefore, within the context of the E.O., ORV use on the ORV routes

amended by this rule (which are also subject to safety and resource closures and other species management measures that would be implemented under the proposed rule) would not adversely affect the natural, aesthetic, or scenic values of the Seashore.

Section 8(a) of the E.O. requires NPS to monitor the effects of the use of off-road vehicles on lands under its jurisdiction. On the basis of the information gathered, NPS shall from time to time amend or rescind designations of areas or other actions taken pursuant to the E.O. as necessary to further the policy of the E.O. The existing ORV FEIS and Record of Decision identify monitoring and resource protection procedures, and desired future conditions to provide for the ongoing and future evaluation of impacts of ORV use on protected resources. The Park Superintendent would have authority under this rule and under 36 CFR 1.5 to close portions of the Seashore as needed to protect park resources and values, and public health and safety.

Regulatory Planning and Review (Executive Orders 12866 and 13563)

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

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. It directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (RFA)

This rule will not have a significant economic effect on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). This certification is based on information contained in a report entitled, *''Benefit-Cost and Regulatory Flexibility Analyses: Special Regulations of Off-Road Motor Vehicles at Cape Hatteras National Seashore'',* available for public review at: *http://parkplanning.nps.gov/caha-orv-ea.* According to that report, no entities, small or large, are directly regulated by the proposed rule, which regulates visitors' use of ORVs. The courts have held that the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates them. Therefore, agencies must assess the impacts on directly regulated entities, but are not required to analyze in a regulatory flexibility analysis the indirect effects from rules on small entities.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2) of the SBREFA. This rule:

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

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

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

Unfunded Mandates Reform Act (UMRA)

This rule does not impose an unfunded mandate on state, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on state, local, or tribal governments or the private sector. The designated ORV routes are located entirely within the Seashore, and will not result in direct expenditure by State, local, or tribal governments. This rule addresses public use of NPS lands, and imposes no requirements on other agencies or governments. Therefore, a statement containing the information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required.

Takings (Executive Order 12630)

This rule does not effect a taking of private property or otherwise have taking implications under Executive Order 12630. Access to private property located within or adjacent to the Seashore will not be affected, and this rule does not regulate uses of private property. Therefore, a takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This rule only affects use of NPS-administered lands and imposes no requirements on other agencies or governments. A federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

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

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

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

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

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the criteria in Executive Order 13175 and under the Department's tribal consultation policy and have determined that tribal consultation is not required because the rule will have no substantial direct effect on federally recognized Indian tribes.

Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.)

This rule does not contain any new collection of information that requires approval by Office of Management and Budget (OMB) under the PRA of 1995. OMB has approved the information collection requirements associated with NPS Special Park Use Permits and has assigned OMB Control Number 1024–0026 (expires 08/31/2016). An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (NEPA)

In accordance with NEPA, the NPS prepared an Environmental Assessment (EA), which was released for public comment on February 17, 2016, for 30 days. A full description of the alternatives that were considered, the environmental impacts associated with

the project, public involvement, and other supporting documentation, can be found online at *http://parkplanning.nps.gov/caha-orv-ea.* The NPS considered public comments made on the EA in drafting this proposed rule. The NPS will evaluate substantive comments received on the proposed rule when developing the decision and the Final Rule.

Effects on the Energy Supply (Executive Order 13211)

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

Clarity of This Rule

We are required by Executive Orders 12866 and 12988, and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Public Participation

All submissions received must include the agency name and Regulatory Identifier Number (RIN) for this rulemaking, 1024–AE33. All comments received through the Federal eRulemaking portal at *http://www.regulations.gov* will be available without change. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment including your personal identifying information may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information, we cannot guarantee that we will be able to do so. To view comments received through the Federal eRulemaking portal, go to *http://www.regulations.gov* and enter 1024–AE33 in the search box.

Comments submitted through *http://www.regulations.gov* or submitted by mail must be entered or postmarked before midnight (Eastern Daylight Time) October 21, 2016 Comments submitted by hand delivery must be received by the close of business hours (5 p.m. Eastern Daylight Time) October 21, 2016.

Comments will not be accepted by fax, email, or in any way other than those specified above, and bulk comments in any format (hard copy or electronic) submitted on behalf of others will not be accepted. If you commented on the EA, your comments have already been considered in drafting the proposed rule. Comments should focus on this proposed rule; comments that relate solely to the EA will be untimely and will not be considered.

Drafting Information

The primary authors of this regulation were Russel J. Wilson, Chief Regulations, Jurisdiction and Special Park Uses, National Park Service; and, A.J. North, Regulations Coordinator, National Park Service.

List of Subjects in 36 CFR Part 7

District of Columbia, National Parks, Reporting and recordkeeping requirements.

In consideration of the foregoing, the National Park Service proposes to amend 36 CFR part 7 as follows:

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

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

Authority: 54 U.S.C. 100101, 100751, 320102; Sec. 7.96 also issued under DC Code 10–137 and DC Code 50–2201.07.

■ 2. In § 7.58, revise paragraphs (c)(2)(iv), (c)(9) and (c)(12)(i) to read as follows:

§ 7.58 Cape Hatteras National Seashore.

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(c) * * *

(2) * * *

(iv) ORV permits are valid for the dates specified on the permit. The public will be notified of any proposed changes to ORV permit durations through one or more of the methods listed in § 1.7(a) of this chapter.

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(9) *ORV routes.* The following tables indicate designated ORV routes. The following ramps are designated for off-road use to provide access to ocean beaches: 2, 4, 23, 25, 27, 30, 32, 34, 38, 43, 44, 48, 49, 55, 59, 63, 67, 68, 70, and 72. Designated ORV routes and ramps are subject to resource, safety, seasonal, and other closures implemented under § 7.58(c)(10).

(i) Soundside ORV access ramps are described in the table below. For a village beach to be open to ORV use during the winter season, it must be at least 20 meters (66 feet) wide from the toe of the dune seaward to mean high tide line.

(ii) Maps showing designated routes and ramps are available in the Office of the Superintendent and on the Seashore Web site.

Bodie Island—Designated Routes

Year Round	Ramp 2 to 0.2 miles south of ramp 4.
Seasonal: Open September 15 through March 14.	0.2 miles south of ramp 4 to the eastern confluence of the Atlantic Ocean and Oregon Inlet.

Hatteras Island—Designated Routes

Year Round	1.5 miles south of ramp 23 to ramp 27.
	Ramp 30 to approximately 0.3 miles south of ramp 32.
	The following soundside ORV access routes from NC Highway 12 to Pamlico Sound between the villages of Salvo and Avon: Soundside ramps 46, 48, 52, 53, 54. The soundside ORV access at Little Kinnakeet would start just to the west of the Kinnakeet lifesaving structures and would continue to the sound.
	Ramp 38 to 1.5 miles south of ramp 38.
	The following soundside ORV access routes from NC Highway 12 to Pamlico Sound between the villages of Avon and Buxton: Soundside ramps 57, 58, 59, and 60.
	0.4 miles north of ramp 43 to Cape Point to 0.3 miles west of ''the hook.''

	Bypass which extends due south from the opening at ramp 44, running continuously behind the dunes until the bypass connects with the beach. Interdunal route (''Inside Road'') from intersection with Lighthouse Road (i.e. ramp 44) to ramp 49, with one spur route from the interdunal route to ramp 48. Just east of Ramp 48 to east Frisco boundary. A soundside ORV access route from Museum Drive to Pamlico Sound near Coast Guard Station Hatteras Inlet. Pole Road from Museum Drive to Spur Road to Pamlico Sound, with one spur route, commonly known as Cable Crossing, to Pamlico Sound and four spur routes to the ORV route below. Ramp 55 southwest along the ocean beach for 1.6 miles, ending at the intersection with the route commonly known as Bone Road.
Seasonal: Open to ORV use October 15 through April 14.	0.1 mile south of Rodanthe Pier to 1.5 mile south of ramp 23. 1.0 mile north of ramp 34 to ramp 38 (Avon). East Frisco boundary to west Frisco boundary (Frisco village beach). East Hatteras boundary to ramp 55 (Hatteras village beach).
Ocracoke Island—Designated Routes	
Year Round	Ramp 59 to just southwest of ramp 63. Routes from NC Highway 12 to Pamlico Sound located north of the Pony Pens, commonly known as Prong Road, Barrow Pit Road, and Scrag Cedar Road. 1.0 mile northeast of ramp 67 to 0.5 mile northeast of ramp 68. 0.4 miles northeast of ramp 70 to Ocracoke inlet. From ramp 72 to a pedestrian trail to Pamlico Sound, commonly known as Shirley's Lane.
Seasonal: October 15 through April 14.	0.5 mile northeast of ramp 68 to ramp 68 (Ocracoke Campground area).
Seasonal: September 15 through March 14.	A route 0.6 mile south of ramp 72 from the beach route to a pedestrian trail to Pamlico Sound. A route at the north end of South Point spit from the beach route to Pamlico Sound.

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(12) *Night-Driving Restrictions/Hours of ORV Operation.*

(i) Hours of operation and night-driving restrictions are listed in the following table:

Hours Of Operation/Night Driving Restrictions	
November 16–April 30	All designated ORV routes are open 24 hours a day.
May 1–September 14	Designated ORV routes in sea turtle nesting habitat (ocean intertidal zone, ocean backshore, dunes) are closed at 9 p.m. and open no earlier than 6:00 a.m. The Seashore will publish exact opening times on an annual basis.
September 15–November 15	Designated ORV routes in sea turtle nesting habitat (ocean intertidal zone, ocean backshore, dunes) are closed at 9 p.m. and open no earlier than 6:00 a.m., but the Superintendent may open designated ORV routes, or portions of the routes, 24 hours a day if no turtle nests remain. The Seashore will publish exact opening times on an annual basis.

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Dated: August 4, 2016.

Michael Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2016–19844 Filed 8–19–16; 8:45 am]

BILLING CODE 4310–EJ–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2015–0642; FRL–9950–90–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Minor New Source Review Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve the state implementation plan (SIP) revision submitted by the Commonwealth of Virginia on July 15, 2013 pertaining to preconstruction permitting requirements under Virginia's minor New Source Review (NSR) program. In the Rules and Regulations section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. Additionally, a more detailed description of the state submittal and EPA's evaluation is included in a technical support document (TSD) prepared in support of this rulemaking action. A copy of the TSD is available, upon request, from the EPA Regional Office listed in the **ADDRESSES** section of this document or is also available electronically within the Docket for this rulemaking action at *www.regulations.gov*. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by September 21, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2015–0642 at *http://www.regulations.gov*, or via email to *campbell.dave@epa.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from

Regulations.gov. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: David Talley, (215) 814–2117, or by email at *talley.david@epa.gov.*

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the Rules and Regulations section of this **Federal Register** publication.

Dated: August 9, 2016.

Shawn M. Garvin,

Regional Administrator, Region III.

[FR Doc. 2016–19768 Filed 8–19–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2016–0285; A–1–FRL–9951–07–Region 1]

Air Plan Approval; New Hampshire; Rules for Reducing Particulate Emissions

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of New Hampshire on March 31, 2011 and on July 23, 2013. These SIP revisions establish particulate matter (PM) and visible emissions (VE) standards for the following sources: foundries, smelters, and investment casting operations; hot mix asphalt plants; and sand and gravel sources, non-metallic mineral processing plants, and cement and concrete sources. In addition, EPA is proposing to approve a part of a SIP revision submitted by New Hampshire on March 12, 2003 that establishes procedures for testing opacity of emissions (*i.e.,* VE). This action is being taken under the Clean Air Act.

DATES: Written comments must be received on or before September 21, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2016–0285 at *http://www.regulations.gov,* or via email to *Arnold.Anne@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Alison C. Simcox, Air Quality Planning Unit, Air Programs Branch (Mail Code OEP05–02), U.S. Environmental Protection Agency, Region 1, 5 Post Office Square, Suite 100, Boston, Massachusetts 02109–3912; (617) 918–1684; *simcox.alison@epa.gov.*

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

Organization of this document. The following outline is provided to aid in locating information in this preamble.

I. Background and Purpose

On March 31, 2011, New Hampshire Department of Environmental Services (NH DES) submitted a State Implementation Plan (SIP) revision, which included a regulation entitled ''Sand and Gravel Sources; Non-Metallic Mineral Processing Plants; Cement and Concrete Sources'' (New Hampshire Code of Administrative Rules Chapter (Env-A 2800)).

On July 23, 2013, NH DES submitted SIP revisions which included the following three regulations: ''Particulate Matter and Visible Emissions Standards'' (Env-A 2100); ''Ferrous and Non-Ferrous Foundries, Smelters, and Investment Casting Operations'' (Env-A 2400); and ''Hot Mix Asphalt Plants'' (Env-A 2700).

The four submitted regulations (Env-A 2100, 2400, 2700, and 2800) state that opacity shall be determined in accordance with test methods established in Env-A 807. On March 12, 2003, the NH DES submitted Env-A 800, ''Testing and Monitoring Procedures,'' which included Part Env-A 807. On November 5, 2012, EPA approved Env-A 800 as submitted in March 2003 and revised on July 9, 2007. Although the March 2003 submittal included Env-A 807, the July 2007 submittal did not. The November 2012 approval did not take action with regard to Env-A 807. See 77 FR 66388. Therefore, Env-A 807 submitted on March 12, 2003 is still pending before EPA.

Two of the submitted regulations (Env-A 2100 and 2400) included affirmative defense provisions for malfunction, which is defined as a sudden and unavoidable breakdown of process or control equipment. The New Hampshire regulations were submitted to EPA after EPA issued a start-up, shut-down, and malfunction (SSM) SIP Call proposal in February 2013 (78 FR 12460), which would have allowed narrowly drawn affirmative defense provisions in SIPs for malfunction. However, following issuance of our SIP Call proposal, a federal court ruled that the Clean Air Act precludes authority of the EPA to create affirmative defense provisions. EPA, therefore, believes that it cannot approve affirmative defense provisions in SIP submissions, even narrowly tailored ones for periods of malfunction (*See NRDC* v *EPA,* 749 F.3d 1055 (D.C. Circuit 2014)). As a result of the court decision, we issued a supplemental notice of proposed rulemaking (SNPR) on September 17, 2014 (79 FR 55920) that rescinded our

previous February 2013 proposal to allow narrowly tailored affirmative defense provisions for malfunction to be included in SIPs. Therefore, on April 13, 2016, NH DES sent a letter to EPA withdrawing the affirmative defense provisions in Chapter Env-A 2100 and 2400 (*i.e.,* 2103.03, and 2405).

After reviewing NH DES's SIP submittals for Env-A 807, 2100, 2400, 2700, 2800 and the letter withdrawing the affirmative defense provisions in Env-A 2100 and 2400, EPA is proposing to approve all of the SIP revisions without the withdrawn portions, and is soliciting public comments on the issues discussed in this notice or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to this proposed rule by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

II. EPA's Evaluation of New Hampshire's SIP Revisions

On March 12, 2003, NH DES submitted NH Code of Administrative Rules Chapter Env-A 807 for approval into the New Hampshire SIP. Env-A 807 establishes procedures for testing opacity of emissions (*i.e.,* visible emissions) from stationary sources, and from small boilers and emergency generators. Env-A 807 also establishes testing requirements for diesel engines in motor vehicles as well as procedures for determining opacity from fugitive emissions. Env-A 807 is not currently part of the federally-approved New Hampshire SIP. Four regulations that we are proposing to approve herein (Env-A 2100, 2400, 2700, and 2800) rely on use of test methods given in Env-A 807. Based on a review of Env-A 807, EPA has determined that the test procedures are appropriate and is proposing to approve Env-A 807 into the New Hampshire SIP.

On March 31, 2011, NH DES submitted Env-A 2800 (Sand and Gravel Sources; Non-Metallic Mineral Processing Plants; Cement and Concrete Sources) for approval into the New Hampshire SIP. This rule is not currently part of the federally-approved New Hampshire SIP.

Env-A 2800 sets standards for VE and PM emissions and fugitive-dust requirements for sand and gravel sources, non-metallic mineral processing plants, and cement and concrete sources. In addition, it establishes permit-by-notification (PBN) requirements for non-metallic mineral processing plants to replace the General State Permit (GSP) option. For all sources subject to Env-A 2800, visible fugitive emissions or visible stack emissions must not exceed 20-percent opacity for any continuous 6-minute period, and all sources are required to control emissions of dust from vehicular movement within plant property boundaries. This rule will benefit public health and the environment by controlling PM emissions and visible emissions from a variety of sources. Therefore, EPA is proposing to approve Env-A 2800 into the New Hampshire SIP.

On July 23, 2013, NH DES submitted Env-A 2100 (Particulate Matter and Visible Emissions Standards), Env-A 2400 (Ferrous and Non-Ferrous Foundries, Smelters, and Investment Casting Operations), and Env-A 2700 (Hot Mix Asphalt Plants) for approval into the New Hampshire SIP.

Env-A 2100 establishes emission standards for existing and new stationary sources or devices that emit particulate matter to the ambient air through a stack or through an exhaust and ventilation system. This rule is not currently part of the federally-approved New Hampshire SIP. Depending on the process weight rate (0.025 to 1,000 tons per hour (tph)), the PM emission standard in Env-A 2100 for ''new devices'' ranges from 0.36 to 77.6 pounds per hour (lbs/hr), and for ''existing devices'' from 0.43 to 93.11 lbs/hr. In addition, Env-A 2100 sets allowable visible emissions for stationary sources or devices at 20 percent opacity for any continuous 6-minute period. This rule will benefit public health and the environment by controlling PM emissions from certain stationary sources. Therefore, EPA is proposing to approve Env-A 2100 into the New Hampshire SIP.

Env-A 2400 establishes emission standards for ferrous and non-ferrous foundries, smelters, and investment casting operations. This rule is not currently part of the federally-approved New Hampshire SIP. For existing foundries (installed before or on May 12, 1971) and new ferrous foundries (installed after May 12, 1971), PM emission standards in Env-A 2400 are the same as those given for existing and new sources and devices in Env-A 2100. The standards are the same for non-ferrous foundries, smelters, and investment casting operations. However, for these non-ferrous facilities and operations, ''existing'' is defined as before or on February 18, 1972, and ''new'' is defined as after February 18, 1972. In addition, for any ferrous foundry installed or modified after June 15, 1974, PM emissions must not exceed 50 milligrams per dry standard cubic meter (mg/dscm) or 0.022 grains/dscf. For all facilities covered under Env-A 2400, allowable visible emissions are set at 20 percent opacity for any continuous 6-minute period. This rule will benefit public health and the environment by controlling PM emissions from foundries, smelters, and investment casting operations. Therefore, EPA is proposing to approve Env-A 2400 into the New Hampshire SIP.

Env-A 2700 establishes emission standards for hot mix asphalt plants. The PM emission standard is set at 90 mg/dscm or 0.04 grains/dscf, which is the same standard as in the federal Standards of Performance for Hot Mix Asphalt Facilities (40 FR 46259). In addition, visible fugitive emissions or visible stack emissions must not exceed an average of 20 percent opacity for any continuous 6-minute period. On August 22, 2012, EPA approved one provision of Env-A 2700, which was part of a SIP revision submitted by New Hampshire on January 28, 2005. See 77 FR 50651. This provision, Env-A 2703.02(a), states that ''The owner or operator of a hot mix asphalt plant shall not cause or allow visible fugitive emissions or visible stack emissions to exceed an average of 20 percent opacity for any continuous 6-minute period.'' NH DES withdrew the remaining parts of the January 2005 SIP submittal on July 23, 2013, when it submitted the version of Env-A 2700 that is addressed herein. In the July 23, 2013 submission, SIP-approved Env-A 2703.02(a) has been renumbered Env-A 2702.02(a). This rule will benefit public health and the environment by reducing emissions from hot mix asphalt plants. Also, by approving the July 23, 2013 submission of Env-A 2700 in its entirety, the existing provision limiting visible emissions will be retained in the New Hampshire SIP, thus meeting the requirements of section 110(l) of the CAA. Therefore, EPA is proposing to approve Env-A 2700 into the New Hampshire SIP.

EPA's review of the SIP submittals indicate that all concerns that EPA has expressed to NH DES about these state regulations have been adequately addressed. Concerns on the July 23, 2013 submittals were all in regard to affirmative defense provisions for malfunctions contained in Env-A 2100 and 2400. To address our concerns, NH DES submitted a letter withdrawing these provisions from Env-A 2100 and 2400. See letter to EPA dated July 8, 2013, available in the docket for today's action. The other regulations that we are proposing to approve herein (Env-A 807, 2700, and 2800) do not, even as a matter of state law, contain exceptions

for SSM periods or affirmative defense provisions.

III. Proposed Action

EPA is proposing to approve, and incorporate into the New Hampshire SIP, four regulations and part of one regulation, except for affirmative defense provisions in two of the regulations which NH DES has withdrawn. The four regulations include one regulation submitted by the State of New Hampshire on March 31, 2011, Sand and Gravel Sources; Non-Metallic Mineral Processing Plants; Cement and Concrete Sources (Env-A 2800), effective October 1, 2010; and three regulations submitted on July 23, 2013, Particulate Matter and Visible Emissions Standards (Env-A 2100), effective April 23, 2013; Ferrous and Non-Ferrous Foundries, Smelters, and Investment Casting Operations (Env-A 2400), effective April 23, 2013; and Hot Mix Asphalt Plants (Env-A 2700), effective February 16, 2013. As noted earlier, the affirmative defense provisions, which NH DES has withdrawn from its SIP submittals, are not included in this proposed approval action and are contained in state law only in Env-A 2103.03 and 2405. EPA is also proposing to approve Env-A 807 (''Testing for Opacity of Emissions''), effective October 31, 2002.

EPA is soliciting public comments on the issues discussed in this proposal or on other relevant matters. These comments will be considered before EPA takes final action. Interested parties may participate in the Federal rulemaking procedure by submitting comments to this proposed rule by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

IV. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the New Hampshire Code of Administrative Rules stated in section III above. The EPA has made, and will continue to make, these documents generally available electronically through *http://www.regulations.gov* and/or in hard copy at the appropriate EPA office.

V. Statutory and Executive Order Reviews

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

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

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

List of Subjects in 40 CFR Part 52

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

Dated: August 9, 2016.

H. Curtis Spalding,

Regional Administrator, EPA New England.

[FR Doc. 2016–19869 Filed 8–19–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 9

[Docket ID FEMA–2015–0006]

Guidance for Implementing the Federal Flood Risk Management Standard

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) is accepting comments on the proposed guidance for implementing the Federal Flood Risk Management Standard (FFRMS).

DATES: Comments must be received by October 21, 2016.

ADDRESSES: Comments must be identified by Docket ID: FEMA–2015–0006 and may be submitted by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Regulatory Affairs Division, Office of the Chief Counsel, Federal Emergency Management Agency, Room 8NE–1604, 500 C Street SW., Washington, DC 20472–3100.

The proposed guidance may be found at *http://www.regulations.gov*, using Docket ID FEMA–2015–0006. Members of the public without internet access may request a copy of the policy from using the information in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

FOR FURTHER INFORMATION CONTACT: Kristin Fontenot, Director, Office of Environmental Planning and Historic Preservation, Federal Insurance and Mitigation Administration, DHS/FEMA, 400 C Street SW., Suite 313,

Washington, DC 20472–3020, 202–646–2741.

SUPPLEMENTARY INFORMATION: FEMA is separately publishing in this issue of the **Federal Register** a notice of proposed rulemaking that proposes revisions to 44 CFR part 9, Floodplain Management and Protection of Wetlands. As proposed, the notice of proposed rulemaking would revise 44 CFR part 9 to implement the Federal Flood Risk Management Standard (FFRMS). FEMA is proposing to issue a policy supplementary to the proposed changes to 44 CFR part 9, to provide further guidance on how FEMA intends to implement the FFRMS.

If finalized as proposed, the policy would provide specific guidelines to implement the FFRMS for FEMA Federally Funded Projects, which are actions involving the use of FEMA funds for new construction, substantial improvement, or to address substantial damage to a structure or facility. The policy would select the use of the FFRMS-Freeboard Value Approach to establish the elevation and FFRMS floodplain for FEMA Federally Funded Projects that are non-critical actions. For FEMA Federally Funded Projects that are critical actions, the policy would select the use of the FFRMS-Freeboard Value Approach to establish the minimum FFRMS elevation and floodplain for critical actions. The policy would allow optional use of the FFRMS-Climate-Informed Science Approach to establish the elevation and FFRMS floodplain for critical actions, but only if the elevation established under the FFRMS-Climate-Informed Science Approach is higher than the elevation established under the FFRMS-Freeboard Value Approach. The policy would also encourage early coordination when multiple Federal agencies are jointly engaged in an action to ensure a consistent approach to determine which floodplain determination is applied.

Authority: Executive Order 11988, Floodplain Management, as amended and implementing regulations at 44 CFR part 9.

Dated: August 15, 2016.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–19809 Filed 8–19–16; 8:45 am]

BILLING CODE 9111–66–P

FEDERAL MARITIME COMMISSION

46 CFR Parts 530 and 531

[Docket No. 16–05]

RIN 3072–AC53

Amendments to Regulations Governing Service Contracts and NVOCC Service Arrangements

AGENCY: Federal Maritime Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Federal Maritime Commission (FMC or Commission) proposes to amend its rules governing Service Contracts and NVOCC Service Arrangements. The proposed rule is intended to update, modernize, and reduce the regulatory burden.

DATES: Submit comments on or before September 23, 2016. In compliance with the Paperwork Reduction Act, the Commission is also seeking comment on revisions to an information collection. See the Paperwork Reduction Act section under Regulatory Analyses and Notices below. Please submit all comments relating to the revised information collection to the Commission and to the Office of Management and Budget (OMB) at the address listed in the **ADDRESSES** section on or before October 24, 2016. Comments to OMB are most useful if submitted within 30 days of publication.

ADDRESSES: You may submit comments by the following methods:

- *Email: secretary@fmc.gov.* Include in the subject line: ''Docket 16–05, [Commentor/Company name].'' Comments should be attached to the email as a Microsoft Word or text-searchable PDF document. Only non-confidential and public versions of confidential comments should be submitted by email.
- *Mail:* Karen V. Gregory, Secretary, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573–0001.

Docket: For access to the docket to read background documents or comments received, go to the Commission's Electronic Reading Room at: *http://www.fmc.gov/16–05.*

Confidential Information: The Commission will provide confidential treatment for identified confidential information to the extent allowed by law. If your comments contain confidential information, you must submit the following:

- A transmittal letter requesting confidential treatment that identifies the specific information in the comments for which protection is sought and demonstrates that the information is a trade secret or other confidential research, development, or commercial information.
- A confidential copy of your comments, consisting of the complete filing with a cover page marked ''Confidential-Restricted,'' and the confidential material clearly marked on each page. You should submit the confidential copy to the Commission by mail.
- A public version of your comments with the confidential information excluded. The public version must state ''Public Version—confidential materials excluded'' on the cover page and on each affected page, and must clearly indicate any information withheld. You may submit the public version to the Commission by email or mail.

FOR FURTHER INFORMATION CONTACT: For questions regarding submitting comments or the treatment of confidential information, contact Karen V. Gregory, Secretary. *Phone:* (202) 523–5725. *Email: secretary@fmc.gov.* For technical questions, contact Florence A. Carr, Director, Bureau of Trade Analysis. *Phone:* (202) 523–5796. *Email: tradeanalysis@fmc.gov.* For legal questions, contact Tyler J. Wood, General Counsel. *Phone:* (202) 523–5740. *Email: generalcounsel@fmc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 1984, Congress passed the Shipping Act of 1984 (the Shipping Act or the Act). 46 U.S.C. 40101 *et seq.,* which introduced the concept of carriage under service contracts with the Federal Maritime Commission (Commission or FMC). The pricing of liner services via negotiated contracts, rather than exclusively by public tariffs, was a change that had profound effects on the liner industry. FMC regulations require all ocean freight rates, surcharges, and accessorial charges in liner trades to be published in ocean common carrier tariffs or agreed to in service contracts filed with the Commission. Contemporaneous with the filing of service contracts, carriers are also required to make available to the public a concise statement of essential terms in tariff format.

In 1998, Congress passed the Ocean Shipping Reform Act (OSRA), amending the Shipping Act of 1984 relating to service contracts. To facilitate compliance and minimize the filing burdens on the oceanborne commerce of the United States, service contracts and amendments effective after April 30, 1999, are required by FMC regulations to be filed with the Commission in

electronic format. This eliminated the regulatory burden of filing in paper format, thereby saving ocean carriers both time and money. In addition, OSRA reduced the essential terms that had to be made publicly available.[1] Service contracts and amendments continue to be filed into the Commission's electronic filing system, SERVCON.

In 2005, the Commission issued a rule exempting non-vessel-operating common carriers (NVOCCs) from certain tariff publication requirements of the Shipping Act, pursuant to section 16 of the Shipping Act, 46 U.S.C. 40103. 69 FR 75850 (Dec. 20, 2004) (final rule). Under the exemption, NVOCCs are relieved from certain Shipping Act tariff requirements, provided that the carriage in question is performed pursuant to an NVOCC Service Arrangement (NSA) filed with the Commission and the essential terms are published in the NVOCC's tariff. 46 CFR 531.1, 531.5, and 531.9.

On February 29, 2016, the Commission issued an Advance Notice of Proposed Rulemaking (ANPR) to elicit public comment regarding its regulations in Part 530, Service Contracts, and Part 531, NVOCC Service Arrangements. In drafting the ANPR, President Obama's Executive Order 13563 served as guidance for the Commission in seeking ways in which the regulations should be modified, expanded, or streamlined in order to make the regulations more effective, reduce the regulatory burden, encourage public participation, make use of technology, and consider flexible approaches, keeping in mind the FMC's mission, strategic goals, and regulatory responsibilities.

Eleven sets of comments were filed in response to the ANPR, which may be found on the Commission's Web site through the link to the FMC's Electronic Reading Room, above. Comments were received from Ascend Performance Materials; CEVA Freight LLC as agents for and on behalf of Pyramid Lines; Crowley Latin American Services, LLC, and Crowley Caribbean Service, LLC (Crowley); Global Maritime Transportation Services, Inc. (GMTS); Global Shippers Association; the National Customs Brokers and Forwarders Association of America, Inc. (NCBFAA); Oceaneering International Inc.; Shintech Inc.; UPS Ocean Freight Services, Inc., UPS Europe SPRL, UPS Asia Group Pte. Ltd. and UPS Supply Chain Solutions, Inc. (collectively, UPS); Unitcargo Container Line, Inc., and the World Shipping Council (WSC). Earlier, comments submitted in response to the Commission's Plan for Retrospective Review of Existing Rules pertaining to the subject rulemaking were filed by the NCBFAA and a group of major ocean carriers.[2] Those comments are also posted to the Commission's Web site under Docket No. 16–05. The comments received thus far represent a broad swath of industry stakeholders, including vessel-operating common carriers (VOCCs), a major trade association, a tariff publishing and contract management firm, licensed NVOCCs and freight forwarders, registered foreign based NVOCCs, beneficial cargo owners (BCOs) and a shippers' association.

II. Discussion

Below, on a section-by-section basis, is a discussion of issues on which the Commission requested public comment regarding the regulations governing service contracts and NSAs in 46 CFR parts 530 and 531, respectively.

Part 530—Service Contracts

Subpart A—General Provisions

§ 530.3 Definitions

§ 530.3 Affiliate

The Commission proposes adding a definition of affiliate in this section to provide clarity as well as consistency throughout the Commission's rules. FMC regulations currently define the term *affiliate* in the NVOCC Service Arrangements rules at § 531.3(b) as two or more entities which are under common ownership or control by reason of being parent and subsidiary or entities associated with, under common control with, or otherwise related to each other through common stock ownership or common directors or officers.[3]

Comments received from the WSC, and separately from Crowley, as a member of the WSC, have no objection to the Commission's proposal to adopt with respect to service contracts, the foregoing definition of *affiliate* used in the NSA regulations. The WSC further asks that the Commission clarify that the adoption of the definition ''does not preclude more specific definitions of that term in service contracts or tariffs, so long as those more specific definitions fall within the scope of the Commission's definition.'' As one example, the WSC opines that it would not foresee the Commission objecting to the inclusion in a service contract of a minimum level of common ownership between two shipper entities asking to be considered affiliates. The Commission does not presently object to an individual carrier narrowing the proposed definition of affiliate in its service contracts as described in the WSC's example.

UPS objects to adding the definition of affiliate to this Part and, instead, states that ''the opposite course—removing the corporate ownership and control restriction for both VOCC Service Contracts and NVOCC NSAs—would be far more beneficial to commerce and competitiveness in the logistics industries.'' UPS further states that ''there is no apparent benefit to anyone from restricting shipper 'affiliates' in NSAs to entities under common ownership and control.'' UPS notes that VOCC service contracts are not subject to the same corporate ownership restrictions for affiliates as NVOCCs under NSAs, which allows VOCCS to include as affiliates in their contracts various partners in the supply chain, such as buyers and suppliers, while NVOCCs may not. UPS believes that there should be an ''equal playing field'' between NVOCCs and VOCCs with respect to affiliates and suggests that removing the corporate ownership restriction rather than applying it to both NVOCCs and VOCCs would be the better approach.

GMTS has several concerns regarding the proposed definition of affiliate that were not addressed in the ANPR, namely: (1) whether existing contracts that do not comply will be grandfathered in, and if so, whether there would be limitations on extending those contracts' termination dates; (2) whether, if the Commission determines to add the proposed definition of affiliate, it would also consider adding the definition of shippers' association; and (3) asks how the Commission will address currently effective service contracts between a VOCC and multiple NVOCCs that are not affiliated under the

[1] Prior to OSRA, contract rates were published in the essential terms tariff publication, thereby allowing similarly situated shippers to request and obtain similar terms. In enacting OSRA, Congress limited the essential terms publication to the following terms: The origin and destination port ranges, the commodities, the minimum volume or portion, and the duration.

[2] The commenting carriers consisted of thirty ocean carriers participating in the following agreements active at that time: the fourteen members of the Transpacific Stabilization Agreement; ten members of the Westbound Transpacific Stabilization Agreement; the six members of the Central America Discussion Agreement; the eleven members of the West Coast of South America Discussion Agreement; the five members of the Venezuela Discussion Agreement; three members of the ABC Discussion Agreement; the six members of the United States Australasia Discussion Agreement; and the three members of the Australia and New Zealand-United States Discussion Agreement.

[3] This definition also currently exists in the rules governing NVOCC Negotiated Rate Arrangements (NRAs). See § 532.3(e).

proposed definition and are not part of an association.

While UPS, an NVOCC and freight forwarder, cites a perceived VOCC advantage gained by not having shipper affiliates restricted to common ownership or control in service contracts, in contrast, the WSC, which is comprised of ocean carriers representing approximately 90% of global liner vessel capacity, does not object to adding the proposed definition of affiliate to service contract regulations, noting that ''the proposed definition is consistent with definitions that are often included in service contracts (either directly or through incorporation of proposed tariff definitions).'' The advantage that VOCCs have over NVOCCs as a result of this inconsistent requirement seems unclear, given WSC's position and further request for clarification that any imposition of a minimum ownership percentage by a VOCC with respect to an affiliate in a service contract would not conflict with the proposed definition, should it be added.

Over the years, Commission staff has been contacted regularly by VOCCs with issues and questions stemming from a lack of clarity regarding appropriate criteria for affiliates participating in service contracts. Regulated entities have noted the existence of the definition of affiliate in both the NSA rules at § 531.3(b) and the NRA rules at § 532.3(e), along with the omission of the identical definition in the service contract regulations, and have expressed confusion with this disparate treatment. This rulemaking seeks to address this dissimilarity, as the consistent application of regulatory requirements contributes to a more efficient regulatory process and therefore, absent evidence of harm to shippers or an undue regulatory burden on carriers, is in the Commission's interest.

While the Commission believes that the consistent application of common ownership or control criteria in determining whether two companies are affiliated lends validity to the concept of affiliation with respect to a shipper's status under a service contract or NSA, it does not propose to include a specific minimum ownership percentage in the definition of affiliate. The proposed definition in this section is broad enough to allow individual VOCCs the ability to stipulate a minimum ownership percentage at the service contract or tariff level, and ensures consistency with the definition in the Commission's rules governing NSAs in Part 531 and NRAs in Part 532.

Similarly, another government agency, the Securities and Exchange Commission, 17 CFR 230.405, defines an affiliate, of, or person affiliated with, a specified person, as a person that directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, the person specified.

§ 530.3(i) Effective Date

FMC regulations require that a service contract or amendment cannot become effective prior to its filing with the Commission. In the ANPR, the Commission sought comment on whether it should amend the definition of effective date with respect to service contract amendments to allow the effective date of amendments to be prior to the filing date of the amendment.

In its comments, WSC stated that this change would ''remove a regulatory obstacle to the timely implementation of commercial terms to which the shipper and the carrier have agreed.'' WSC notes that, not only are there over 500,000 service contract amendments filed annually, but filing activity surges during peak periods, and the current requirement delays implementation of agreed upon-terms. The WSC urges the Commission to move promptly toward finalizing a rule to implement this change. Crowley, which endorses the WSC comments, also states that it enthusiastically supports the Commission allowing service contract amendments to be filed up to 30 days after the terms of the amendment are agreed upon with the shipper.

Shintech Inc., a beneficial cargo owner (BCO), supports the proposed change to allow service contract amendments to be effective upon agreement of the parties with the filing occurring up to 30 days later. If finalized, Shintech states that this proposed rule change ''would provide our industry with much needed modifications to a system that no longer reflects the practical needs of maritime commerce.'' Two other BCOs, Ascend Performance Materials and Oceaneering International Inc. also support a 30-day grace period for filing service contract amendments, as does Global Shippers Association. CEVA, an agent for registered foreign NVOCC Pyramid Lines, supports allowing up to 30 days after agreement of the parties for amendments to both service contracts and NSAs to be filed with the Commission.

Unitcargo Container Line, Inc., a licensed NVOCC, ''applauds'' the Commission's efforts to review and simplify its regulations relating to service contracts and NSAs. Unitcargo believes that the proposed changes to the regulations relating to the periods of time within which ocean carriers and NVOCCs may file amendments and corrections to service contracts and NSAs, would undoubtedly reduce the associated regulatory burdens and lauds those changes for ''making it possible for ocean carriers and NVOCCs to keep pace with the often turbulent ocean shipping marketplace.''

UPS commended the Commission ''for examining possible approaches to increase efficiency in the industry.'' UPS believes that the Commission should allow service contracts, NSAs, and amendments to be filed and the corresponding essential terms to be published ''within a reasonable time after the effective date, rather than in advance.'' UPS explains that ''[i]n many instances, shippers approach carriers with potential business opportunities that involve complex arrangements, including transactions covering multiple levels of a supply chain.'' UPS emphasizes that ''[i]t is critical to the shippers and carriers to be able to implement these arrangements rapidly, in order to assist the U.S. exporter or supply chain manager to meet competitive conditions or avoid port congestion.'' UPS states that the requested regulatory relief ''will facilitate transactions and encourage compliance, rather than incentivizing participants to try to structure transactions to avoid regulation.''

In its comments, the NCBFAA supports the Commission's proposal to ease the service contract amendment filing requirements to allow filing up to 30 days after agreement and requests that the Commission provide that same regulatory relief to NSAs. NCBFAA, however, also believes that the relief discussed in the ANPR is not expansive enough to provide meaningful relief to NVOCCs and urges the Commission to completely eliminate its NSA essential terms publication and filing requirements.

GMTS expressed that the current requirement that a service contract amendment must be filed with the Commission on or before its effective date ''ensures that the checks and balances of the full compliance of the tariffs, contract and amendments are determined prior to their submission.'' GMTS further states that ''[s]hould the proposed change to amendments be permitted, it could be possible that sizeable shipments of cargo are moved prior to the determination of the amendment being fully compliant.'' As an example, GMTS highlights the VOCC's need to verify that an NVOCC shipper and its affiliates are in good standing with Commission requirements, and observes that, should

the VOCC only verify their status at the time of filing the amendment, the delay between implementation and filing could result in a non-compliant amendment with an NVOCC whose license has been revoked.

The majority of commenters to the ANPR favored the Commission introducing regulatory flexibility by allowing up to 30 days for filing after an amendment to a service contract has been agreed to by the carrier and shipper. Some commenters also advocated extending that relief to original service contract filings and NSA amendments as well. The Commission is considering the potential impact of a 30-day delay in receiving service contract amendments after their implementation, in light of its investigative needs and oversight responsibilities and seeks to balance those against any regulatory burden that might be imposed by the requirement.

The existing regulations protect the shipper's interests by demonstrating the agreement of the parties prior to the movement of the cargo. Shippers have expressed confidence in this process knowing that both the shipper and carrier will honor the commitment of their service contract filed with the FMC. The Commission notes a distinction between an original service contract filing and an amendment to a contract. An original service contract is a comprehensive agreement between the parties that encompasses the commodities that are to be shipped, the origins and destinations between which cargo is to move, the rates for the transportation of that cargo, as well as terms and conditions governing the transportation of goods for the shipper. Amendments to service contracts, on the other hand, are more limited in scope, generally adding new commodities and/or rates. Numerous commenters support more flexibility in filing service contract amendments, which they contend will not diminish the effectiveness of the Commission's oversight of service contracts.

In considering the impact on all parties, the Commission is seeking comments on its proposal to allow the filing of sequential service contract amendments in the SERVCON system within 30 days of the effective date of the agreement reached between the shipper and carrier. The Commission is not proposing to allow a 30-day delay for filing of original service contracts however, given their nature and the Commission's belief that doing so would diminish its oversight abilities. Further, the Commission is seeking comment on GMTS' concerns regarding the impact of a 30-day delay in filing service contract amendments on compliance with § 530.6 and § 515.27. At this time, the Commission does not believe that these concerns outweigh the benefits of the proposed 30-day filing period. Finally, the Commission is proposing to amend certain definitions that require updating to reflect the current bureau and office names, more specifically those in § 530.3(d) and (o).

§ 530.5 Duty To File

The Commission sought comment in the ANPR on amending its regulations to ensure that carriers are aware of the availability of the automated ''web services'' process for filing service contracts and amendments. In response to an industry request, the Commission developed an automated web services process in 2006, which allows service contracts, NSAs and their amendments to be filed directly from a carrier's contract management system into SERVCON, thereby reducing the regulatory burden associated with manual processing. ''Pushing'' the unique data already entered in the filer's contract management system directly to the SERVCON system eliminates the time, expense and opportunity for data entry errors involved in manually logging into SERVCON and filing service contracts and NSAs.

The Commission has encouraged the use of web services by ocean carriers throughout the years, and the pace of new carriers implementing its use has recently increased. While it was previously estimated, based on carrier and tariff publisher projections of web services implementation, that the vast majority of service contracts and amendments would be filed using web services by April 1, 2016, due to delays in software programming and other issues, only 35% are presently using this option.

The Commission received one comment regarding web services. Global Maritime Transportation Services, Inc., which files service contracts on behalf of multiple carriers, has no objection to the Commission making carriers aware of the availability of the automated web services process. However, it questions whether amending the regulations is necessary given that the percentage of filings by April 2016 through this option is anticipated to be over 90%. GMTS also questions whether it is the Commission's intent to make filing using web services mandatory.

The Commission does not propose to make the web services option mandatory, as it is a technology that is more advantageous to high volume filers who use automated contract management systems. Given the gradual pace of adoption of web services, highlighting it in the Commission's rules would provide a public benefit. Accordingly, the Commission proposes to add regulatory language which makes filers aware of the option to use web services when filing service contracts, NSAs and amendments.

§ 530.6 Certification of Shipper Status

This section sets forth the requirement that shippers entering into service contracts certify their status and requires VOCCs to obtain proof of an NVOCC's compliance with tariff and financial responsibility requirements. Carriers regularly use the FMC Web site, *www.fmc.gov,* to verify whether or not an NVOCC contract holder or affiliate is in good standing. Many carriers employ more rigid standards in certifying NVOCC status by requiring copies of the NVOCC's bond as well as the title pages of its published tariffs. In addition, many VOCCs include the NVOCC's 6-digit FMC Organization Number in the service contract, which indicates that the VOCC sought to ensure compliance with the requirements of § 530.6.

Commission staff is regularly asked by carriers about the FMC's electronic systems' capability to automatically verify compliance with § 530.6 by determining the current status of an NVOCC party named in a service contract or amendment. While the Commission's SERVCON system does not currently have this capability, the Commission may be able to add such functionality in the future.

The Commission asked for comment in the ANPR on whether the Commission should move forward in requiring filings to include the 6-digit FMC Organization Number for NVOCCs who are a contract holder or affiliate in a service contract by one of two options, namely:

(1) Adding a data field in the Commission's electronic filing system (SERVCON) in order to enter the 6-digit FMC Organization Number when an NVOCC is party to a contract; or

(2) requiring that service contracts be formatted to contain metadata that includes the 6-digit FMC Organization Number for each NVOCC that is a contract holder or affiliate in a service contract.

The Commission pointed out in the ANPR that simply including an NVOCC party's FMC Organization Number in the body of a service contract would not allow the FMC's SERVCON system to verify NVOCC status. Only adding a data field to the SERVCON filing process wherein filers would enter the NVOCC party's Organization Number or the approach of adopting a standard

service contract format to include metadata that includes the NVOCC party's Organization Number would allow the FMC to perform an automated verification of status.

With respect to the first option, a new data field in SERVCON would require a VOCC to enter the NVOCC's 6-digit FMC Organization Number when an NVOCC is a contract holder or affiliate. If multiple NVOCCs are parties to a service contract, each NVOCC's respective Organization Number would be required to be entered into this field. The Commission may be able to enhance SERVCON to automatically determine at the time a contract or amendment is uploaded for filing, whether the NVOCC is in good standing with the Commission. Upon development, a message would be transmitted to the filer notifying it if any of the NVOCC parties are not in good standing. The development of such an automated process could potentially save carriers a substantial amount of time currently spent manually verifying an NVOCC's status.

Under the second option, a standard service contract format would have to be adopted by all ocean carriers, allowing ''metadata'' to be incorporated into the service contract format to include the 6-digit FMC Organization Number of all NVOCC parties.[4] This option would require a substantial amount of Commission information technology resources to develop and implement, including resources that would need to be allocated to SERVCON system programming. With the required programming implemented, however, it is likely that this technology could be leveraged to identify during the filing process service contracts or amendments not in compliance with § 530.6. If a service contract is not compliant, an alert could be sent to the carrier filing the contract or amendment.

The Commission received comments from Crowley, WSC and GMTS on this issue. Crowley supports ''modifications to the SERVCON system that facilitate verification of a service contract signatory's NVOCC status by inputting the signatory's FMC-assigned, six-digit Organization Number.'' Crowley opposes, however, ''any requirement to imbed the Org. No. in the service contract metadata, or any change to SERVCON that would require service contract filers to input an Org. No. but did not provide immediate and definitive feedback on the status of the contract signatory.'' GMTS supports the options put forth by the Commission in the ANPR but asks for clarification regarding how a rejection would be handled, whether a multiple NVOCC contract is voided if only one NVOCC lacks legal status, and asks if the FMC could provide a daily list of non-compliant parties. The WSC requests more detailed information as to how the proposed SERVCON changes would work before fully endorsing the Commission's proposal on verifying a NVOCC contracting party. WSC is concerned that the Commission's proposal might be too cumbersome, outweighing any advantage to be gained. They advise for example, ''if a VOCC could simply add the Organization Number of an NVOCC service contract party into a specified field in SERVCON, and the system would then generate either a 'green light' or 'red light' response, then such a system would have the potential to simplify compliance and reduce costs.'' WSC would not, on the other hand, support a reconfiguring of SERVCON requiring a uniform structuring of service contracts in order to pull ''metadata'' to verify NVOCC status.

It is not the Commission's intent for verification of NVOCC status through technological enhancements of the SERVCON system to result in rejection of service contracts. If implemented, it is contemplated that the new technology would simply provide carriers with timely information on which they could act to achieve greater compliance in a less burdensome manner. *See* 46 CFR 530.6(d) (regarding carrier reliance). The system could allow filers to receive a message during the filing process identifying any NVOCC shipper or affiliate that is not in good standing with the Commission's licensing, registration or financial responsibility requirements. The Commission notes that comments regarding standardization of service contract format to include metadata indicate that such an approach would be considered by filers to be so cumbersome as to outweigh the potential benefits. The Commission, therefore, proposes to add an additional field in its SERVCON filing system which requires the input of an NVOCC's six-digit Organization Number when they are the contract holder or affiliate. If there are multiple NVOCC parties to a service contract, the filer would be required to input the six-digit Organization Number of all NVOCCs.

The Commission contemplates that, upon completion of necessary SERVCON programming, this data would be corroborated against FMC's database systems and return a message to the filing party if the NVOCC is not in good standing. Completing this process would satisfy the due diligence requirements in § 530.6.

Subpart B—Filing Requirements

§ 530.8 Service Contracts

In the comments submitted by thirty ocean common carriers in response to the Commission's Plan for Retrospective Review of Existing Rules, a number of the carriers cite the filing of service contract amendments as the largest administrative burden for both carriers and their customers. Many ocean carriers believe that the service contract effective date requirement is overly burdensome and restrictive given current commercial practices, particularly with respect to amendments to contracts. The carriers maintain that filing amendments within 30 days would enable shippers and carriers to apply agreed-upon terms immediately and thus do business without disrupting or delaying that business. Of note, the proposed change in the definition of effective date would only affect the filing date of the amendment, as the parties must still agree to the rates and/or contract terms prior to receipt of the cargo. Comments regarding whether the Commission should allow filing of service contract amendments up to 30 days after agreement by the parties have been summarized previously under the discussion of § 530.3(i), Effective date.

This section relates to the implementation in the SERVCON system of the method whereby carriers could file service contract amendments up to 30 days after agreement, should the Commission take that action. To facilitate this discussion, the Commission sought comment in the ANPR on whether it should revise its regulations to allow: (1) A service contract amendment to be filed individually and sequentially within 30 days of its effectiveness; or (2) any number of service contract amendments to be consolidated into a single document, but filed within 30 days of the effective date of the earliest of all amendments contained in the document.

A more detailed explanation of the manner in which service contract amendments are presently filed into the FMC's SERVCON system may be useful to evaluate the two approaches.

[4] ''Metadata is structured information that describes, explains, locates, or otherwise makes it easier to retrieve, use, or manage an information resource. Metadata is often called data about data or information about information.'' National Information Standards Organization (NIST), *Understanding Metadata,* NIST Press (2004), available at: *http://www.niso.org/publications/press/UnderstandingMetadata.pdf (last visited June 17, 2016).*

Currently, SERVCON is designed to process the filing of the initial service contract as Amendment ''0,'' with subsequent amendments to the contract numbered sequentially, beginning with Amendment No. ''1.'' Each amendment requires that the filer enter the corresponding effective date of that amendment. If the Commission determines to allow amendments to be filed up to 30 days after agreement and the existing filing process is maintained involving the sequential filing of amendments starting with Amendment No. 1, then little, if any, programming changes may be required in SERVCON. With that approach, the only difference from the present process would be that the effective date entered could be up to 30 days prior to the filing date.

The alternative approach on which the Commission requested comments was the possibility of consolidating multiple service contract amendments into a single document. This was considered because the carriers also proposed aggregating several contract changes in a single amendment in what, in effect, could be a monthly filing. In a monthly filing of this type, it would still be necessary for carriers to specify the effective date of each amendment to the contract. Adding to this complexity, we note that the rate may change more than once in a monthly period. The SERVCON system is not presently capable of processing multiple amendments consolidated into a single document, *e.g.,* Amendment Nos. 2 through 10, with multiple effective dates. Thus, this approach would require a substantial amount of reprogramming to enable the system to capture both the effective dates and amendment numbers. Further, based on input from the Commission's Office of Information Technology, carriers would still need to manually input the effective date of each amendment into SERVCON. Therefore, absent the requisite reprogramming, this process could possibly result in more, rather than less, of a filing burden. Consolidating several service contract amendments may also prevent carriers from using the Commission's web services technology in accordance with § 530.5, thereby offsetting the advantages of this technology, which does not require manual input and is intended to streamline processes and reduce the burden of filing.

In this regard, the WSC commented:

On the issue of whether the Commission should allow multiple service contract amendments to be filed in a single document, such a process would provide the greatest relief and would potentially be the most efficient. Based on the discussion in the ANPRM, however, it appears that there may be substantial SERVCON re-programming requirements associated with such functionality. Absent such re-programming, the Commission has suggested that filing multiple amendments in a single document may require substantial manual data input by carriers.

The WSC added that ''the primary focus should be on providing a 30-day period in which to file service contract amendments.'' WSC clarified that, while it would be ''ideal'' to accommodate multiple amendments in a single document, ''if creating the ability to file multiple amendments in a single document would require a cumbersome manual process, then such a process would not be attractive.''

Crowley commented, ''[w]hen an amendment makes multiple changes that were effective on different dates, Crowley envisions that the amendment itself would reflect the effective date of each change, thereby avoiding any need to alter the Commission's SERVCON filing system.'' ''However,'' Crowley adds that it ''would be open to alternative filing approaches, provided that any approach eventually adopted minimizes the burden on the industry.''

GMTS suggests ''a more effective administration of the contract process'' and encourages a ''rule making by the FMC that would specifically allow for electronic acceptance of an amendment, as is the case with NRA's.'' GMTS also expresses concern ''that by allowing filings to take place after the effective date it undermines the public record process and obscures activity.'' GMTS adds that it is ''also concerned that relaxing this requirement does not address issues, which would come to light especially if the FMC adopts the suggestion of including the NVOCC registration number into the filing of contracts.''

The Commission notes that it would require significant programming time and considerable expense to update the SERVCON system to allow for multiple amendments to be filed in a single document at one time. Another suggestion of noting disparate effective dates within the service contract amendment alongside each change does not facilitate Commission review of contract amendments and could lead to confusion in ascertaining effective dates of changes. Therefore, the Commission proposes maintaining its existing requirement requiring sequential amendments to service contracts with a single effective date for all changes within that amendment, but also proposes allowing for those amendments to be filed up to 30 days after they have been concluded by the carrier and shipper.

§ 530.10 Amendment, Correction, Cancellation, and Electronic Transmission Errors

The carriers' comments discussed in the ANPR noted that the current service contract correction procedures are outdated, and they maintained that these procedures are ''ill suited'' to the manner in which service contracts are employed today. The carriers requested a number of revisions to these requirements. The ANPR sought comment regarding service contract correction requests, corrected transmissions, and a proposed ''conforming amendment.'' An item by item discussion follows.

Electronic Transmission Errors

The carriers' request that the Commission allow a 30-day grace period in which a carrier would not be required to file a service contract correction request (seeking retroactive effectiveness to correct a clerical or administrative error) or a formal amendment to the contract (effective upon filing or in the future). Rather, carriers would be permitted to submit a new type of filing, designated as a ''conforming amendment'' or similar special designation in order to retroactively correct a ''typographical or clerical error''.

The Commission questions whether this process would, in effect, replace the service contract correction process in § 530.10(c) within the first 30 days after filing. That process provides a means for carriers to correct a clerical or administrative error within 45 days of filing by submitting, among other things, an affidavit and other documentation used for verification purposes that establishes the nature of the error and the parties' intent. The carriers' suggested procedure would seem to eliminate the requirement for such documentation for a correction filed within 30 days of the contract's filing

In this regard, a service contract or amendment can currently be corrected through a Corrected Transmission. Pursuant to § 530.10(d), *Electronic transmission errors,* carriers may file a ''Corrected Transmission'' (CT) within forty-eight (48) hours of filing a service contract or amendment into SERVCON, but only to correct a purely technical data transmission error or a data conversion error that occurred during uploading. A CT may not be used to make changes to rates, terms or conditions.

While the vast majority of service contracts are uploaded into the Commission's electronic filing system, SERVCON, without encountering any problems, staff has noted that, when errors do occur, many times carriers do not discover the error until after the initial 48-hour period has passed. Most of these mistakes are attributable to data entry errors on the SERVCON upload screen (*e.g.,* the incorrect amendment or service contract number is entered, an incorrect effective date is typed, or the wrong contract or amendment is attached for uploading). Staff verifies that these are indeed purely clerical data errors that do not make changes to rates, terms, or conditions prior to accepting the CT filings. While incorporation of web services filing would reduce the occurrence of many of the technical and data transmission errors leading to a Corrected Transmission, the Commission is seeking comments on whether the current 48-hour period in which to file a CT after filing the original contract or amendment should be extended to thirty (30) days to afford carriers with a more realistic time frame to correct purely technical data transmission errors.

In its comments, GMTS supports extending the time period in which to submit a Corrected Transmission for an electronic transmission error from 48 hours to 30 days. WSC and Crowley agree that the 30-day period for a CT is more realistic, and believe that extending the filing period would ''enhance the accuracy of filed service contract information without affecting regulatory purposes.''

As a Corrected Transmission is limited only to correcting a purely technical data transmission error or a data conversion error that occurred during uploading in SERVCON, and may not be used to make changes to rates, terms or conditions, the Commission proposes extending the time frame in which to file a Corrected Transmission from 48 hours to 30 days.

Extend Filing Period for Correction Requests to 180 Days

The Commission requested comment regarding whether it should extend the time period for filing a service contract correction request from forty-five (45) to one-hundred eighty (180) days after the contract's filing. The Commission is aware that an error in a service contract may not be discovered until after cargo has moved, been invoiced on the bill of lading, and, the shipper notes that the rate assessed is not the agreed upon rate. Given long transit times due to carriers' global pendulum services and slow steaming, in many cases this type of error is not discovered until well after 45 days has transpired. In other cases, shippers engage in audits of bills of lading thtat identify errors in the service contract that do not match the rates offered. These audits may be well after the 45-day period. To provide needed flexibility in this process, the Commission has considered whether a longer time period in which to file is appropriate.

Comments filed by WSC, Crowley and GMTS all support extending the time in which to file a service contract correction request from 45 days to 180 days. WSC noted that ''the nature of some services, in conjunction with the time involved in the issuance of an invoice by a carrier and the review of that invoice by a shipper (the process through which errors are likely to be discovered) makes the existing 45-day period inadequate in many circumstances.'' WSC also believes that the Commission's regulations ''should support the parties' interests in having their commercial agreements implemented, and allowing additional time to discover and correct mistakes would further that purpose and reduce disputes.'' No comments were filed objecting to this requested change.

The Commission recognizes that the discovery of a mistake made in a service contract which is contrary to the agreement of the parties may not necessarily occur within a short time after the cargo has moved. In addition, auditing of freight bills by shippers can be delayed as well. Commission staff is occasionally contacted by carriers who wish to correct a service contract error which was not discovered until the present 45-day time limit for correction requests has expired. In such cases, no regulatory remedy exists and the parties must make a commercial accommodation in the service contract to address the problem. Given the foregoing, including the lack of objections to this request, the Commission proposes extending the time period in which to file a service contract correction request from 45 days to 180 days.

Extend the Service Contract Correction Procedure To Include Unfiled Contracts and Amendments

The ANPR requested comment on various aspects of the requests posed in the ocean carriers' comments. The ocean carriers requested that the Commission allow the correction process to also be utilized for unfiled service contracts and service contract amendments. The Shipping Act requires that service contracts be filed with the Commission. 46 U.S.C. 40502. Shippers have expressed to the Commission that they believe a filed contract provides them with assurance that the rates and terms of the service contract will be adhered to by both the shipper and carrier.

GMTS was the only party to comment on this issue. It supports extending the service contract correction process to include unfiled service contracts and amendments, provided that the affidavit process is maintained ''in order to establish a verifiable error was clerical or systems but not intentional.''

The Commission has an interest in granting flexibility in the regulatory process where public benefits outweigh the costs. The changes proposed regarding the extension of time for electronic transmission errors and for filing service contract correction requests should provide needed flexibility. However, extension of the service contract correction process to address a carrier's failure to file a service contract or amendment with the Commission would undermine the statutory filing requirement and shippers' reliance on that requirement. The Commission, therefore, does not propose extending the service contract correction process to include unfiled service contracts and amendments.

Eliminate Carrier Affidavit and Significantly Reduce Filing Fee

The ANPR sought comment on the carriers' request to the Commission to eliminate the affidavit requirement for service contract correction requests and also significantly reduce the filing fee. The filing fee reflects time expended by Commission staff to research and verify information provided in the correction request and to conduct its analysis.

The Commission is not proposing any changes to the affidavit requirement but is considering reducing the fee as part of its rulemaking under FMC Docket No. 16–06, Update of Existing and Addition of New User Fees, in which a Notice of Proposed Rulemaking (NPRM) was issued on May 27, 2016. 81 FR 33637. The affidavit requirement is a critical component in establishing and verifying the facts surrounding an error, while streamlining Commission staff's review and analysis of the correction request. In the only comment filed concerning this matter, GMTS supports reducing the filing fee on the condition that the Commission maintain the affidavit requirement.

The Commission estimated in the User Fee NPRM that it could reduce the filing fee from $315 to $95 by streamlining its internal processes, provided that the affidavit requirement is not eliminated. If the affidavit

requirement were eliminated, staff time researching and verifying information would increase, and thus, the filing fee would need to be increased commensurate with the additional time required for processing and analysis.

Subpart C—Publication of Essential Terms

§ 530.12 Publication

During discussions with stakeholders held prior to the initiation of this rulemaking, several advised the Commission that essential terms publications were no longer accessed by the public or useful. However, other stakeholders indicated that they do rely on them for various purposes, such as during a grievance proceeding.

GMTS was the only commenter to respond to the ANPR regarding the essential terms publication requirement. GMTS does not support any changes to the current essential terms requirements. GMTS suggests that the essential terms publication provides critical volume and commodity information and fills both a commercial and compliance need without which there would be a diminution of the public record.

The Commission does not propose modifying its rules regarding the publication of essential terms.

Subpart D—Exceptions and Implementation

§ 530.13 Exceptions and Exemptions

§ 530.13(a) Statutory Exceptions

Commission rules in this section identify the commodities that are exempt from the tariff publication and service contract filing requirements of the Shipping Act. See 46 U.S.C. 40501(a)(1) and 40502(b)(1). Commodities that are presently exempt pursuant to the Act are bulk cargo, forest products, recycled metal scrap, new assembled motor vehicles, and waste paper or paper waste.

In response to the ANPR, WSC reiterated its support of the comments submitted previously by the ocean common carriers that recommended the FMC expand the list of exempt commodities pursuant to the Commission's exemption authority contained in Section 16 of the Act, 46 U.S.C. 40103. As WSC explains, ''the basis for this proposal is that the commodities for which exempt status is requested may be moved in bulk or by tramp vessels, and that the exemption would provide flexibility that would increase competition for those cargoes.'' WSC supports the carriers' proposal to add the following commodities to the list of exempt commodities: Grain, soybeans, meal, flour, corn products, cotton, resins, coffee, animal feed, seeds, food additives, clay, hay, hides and plastic scrap.

In addition to the commodities identified by the WSC, Crowley requests the exemption of fruits, vegetables and other agricultural products as well. Crowley asserts that these commodities are, similar to the existing exempt commodities, ''subject to transport by bulk or reefer operators that, in many cases, are not subject to FMC regulation.'' Crowley claims that U.S. importers and exporters would benefit should the Commission exempt these agricultural commodities.

GMTS, a tariff and contract management firm that files service contracts in SERVCON for numerous VOCC clients, stated that they are ''concerned that the introduction of additional commodities to the exempt commodity list would make it difficult if not impossible to produce a relevant index on these commodities.'' In their experience, GMTS asserts, some of the commodities proposed for inclusion in the exempt commodities list tend to be seasonal, are contracted on an annual basis with limited changes, and therefore, do not involve a large number of contract amendments. GMTS stated that they reviewed hundreds of VOCC service contracts in their filing system that included the new commodities proposed for exemption, and found that contracts comprising shipments of a single commodity, such as seed or soybean alone, had very few contract amendments. GMTS is concerned with the potential ''expansion of the exempted commodity list and its impact on reliant analysis should these commodities be removed from the reporting process.''

The Commission has a number of concerns regarding expansion of the list of exempt commodities. Of note, two of the highest paying commodities in terms of freight rates in the U.S. export trade are among those proposed for exemption by WSC and the ocean carriers, namely, refrigerated cargoes and cattle hides. Exporters of currently exempt commodities have expressed frustration to the Commission regarding the ocean carrier practice of offering exempt commodity tariff rates with periods of limited duration, in some cases for only thirty to sixty days, rather than for the longer periods that are customary in service contracts. Further, exempt commodity tariffs are not published and do not provide shippers with thirty days' notice prior to implementation of rate increases. Whereas service contracts allow shippers to negotiate rates and terms with carriers to tailor services and terms to the shipper's specific needs, many exporters advise that exempt commodities are not afforded this opportunity.

Given the potential disadvantage to shippers in negotiating with ocean carriers for transportation of exempt commodities, and the lack of shipper support for exempting additional commodities, the Commission does not propose exercising its exemption authority to add new commodities to the list of those exempted from the FMC's tariff publication and service contract filing requirements.

The Commission is proposing, however, to amend § 530.13(b)(2), to reflect the change in name of the relevant Department of Defense entity from Military Transportation Management Command to Surface Deployment and Distribution Command.

§ 530.14 Implementation

If the Commission adopts the proposal to allow up to 30 days for filing service contract amendments after agreement of the parties, corresponding changes would be made to § 530.14. Refer to the discussion under § 530.3(i), Effective date.

Part 531—NVOCC Service Arrangements

Subpart A—General Provisions

§ 531.1 Purpose

In response to the ANPR, NCBFAA echoes its earlier comments regarding the Commission's Plan for Retrospective Review of Existing Rules and its petition for rulemaking in FMC Docket No. P2–15.[5] NCBFAA supports the Commission's consideration of regulatory changes focused on reducing unnecessary regulatory burdens and easing compliance by potentially allowing more time to process amendments to service contracts and NSAs, and to correct technical or substantive errors made in filings. NCBFAA believes that the current service contract and NSA filing requirements are ill suited to keeping pace with the ''dynamic nature of the ocean shipping marketplace in this post-OSRA environment'' and requests that any regulatory relief granted by the

[5] NCBFAA filed a petition for rulemaking on April 18, 2015. See Docket No. P2–15, *Petition of the National Customs Brokers and Forwarders Association of America, Inc. for Initiation of Rulemaking* (NCBFAA Petition). The Commission has accepted the NCBFAA Petition and will address the proposals presented therein during a subsequent rulemaking proceeding.

Commission to VOCCs with respect to their service contract requirements also be extended to the NVOCC NSA requirements.

NCBFAA argues that justification for relief to NVOCCs is even more compelling than that of VOCCs, given the challenges NVOCCs face reacting to the daily rate and surcharge changes being made by VOCCs that an NVOCC utilizes for transporting its clients' cargo. NCBFAA states that NSAs are significantly underutilized by NVOCCs and asserts that NSA filing statistics clearly indicate that NSAs have not been commercially accepted. However, those NVOCCs using NSAs face similar pressures as VOCCs to timely file. Thus, NCBFAA supports Commission efforts to ease NSA requirements with respect to the timing of amendment filings. The group does not believe, however, that such efforts are far reaching enough.

In fact, NCBFAA reminds the Commission that it has been ''urging the Commission to eliminate the NSA publication and filing requirements since their inception.'' While recognizing that VOCCs and NVOCCs are both common carriers, NCBFAA asserts that the Commission's introduction of NSA filing requirements was only to ''maintain the superficial parity in the way VOCCs and NVOCCs are regulated'' and claims that such parity ''is not warranted because VOCCs and NVOCCs are not similarly situated and their activities are quite different. NCBFAA emphasizes that NVOCCs do not enjoy antitrust immunity and therefore do not have ''collectively established boilerplate terms and conditions or consider, let alone follow, 'voluntary guidelines' relating to pricing or service conditions.'' NCBFAA advocates that, inasmuch as there are situations where NVOCCs and their customers would like to enter into more formal, long-term arrangements, which cannot be accomplished through NRAs, the industry would benefit by having the Commission reexamine the need for continuing the filing of NSAs and the publication of essential terms. NCBFAA further urges the Commission to allow NRAs, which unlike NSAs are not filed with the FMC, to include ''non-rate economic terms, including credit and payment terms, rate methodology, minimum quantities, forum selection and arbitration clauses.''

Unitcargo Container Line, Inc., an NVOCC, submitted comments paralleling those of NCBFAA inasmuch as they support changes to NSA regulations that would allow more time for filing NSA amendments. It also urges the Commission to completely eliminate the NSA filing and publication requirements and allow for the inclusion of non-economic terms in NRAs. Unitcargo states that it and its customers prefer using NRAs, noting that many of its shippers find NSAs ''unnecessarily formal and burdensome.''

UPS strongly opposes the position taken by NCBFAA, commenting that ''NCBFAA appears to suggest that the provisions in the Commission's regulations for NSAs filed with the Commission ought to be phased out in favor of exclusive use of unfiled NSAs.'' UPS maintains that NCBFAA's suggested approach ''would do damage to larger volume NVOCCs that have built their core service arrangements around the NSA format.'' UPS describes the distinctions between NSAs and NRAs, stating ''although the numbers of unfiled NRAs now in use are substantially larger than the number of NSAs filed annually, the NRAs are typically single-rate, single-lane, single-shipper arrangements, whereas NSAs often cover hundreds of rates on multiple global routes, as part of a multimodal master services arrangement for a shipper affiliate group, often covering continuing shipments over a period of time.'' UPS goes on to say that ''NVOCCs such as UPS make substantial percentages of their ongoing bookings utilizing NSAs, especially for large retailers, industrial shippers and government shippers.'' While UPS supports Commission initiatives that would introduce flexibility into the current NSA regulations, they further advocate that ''NSAs cannot simply be scrapped in favor of forcing NVOCCs that have developed complex competitive arrangements to revert to the use of NRAs that are not always suitable to meet the expectations of large-volume sophisticated shipper customers.''

CEVA Freight LLC, agents for Pyramid Lines, supports flexibility in filing amendments ''so that the regulatory process does not delay the implementation of commercial agreements.'' However, CEVA sees no reason why NSAs need to be filed with the Commission, advocating that the Commission can request an NSA from an NVOCC to fulfill FMC regulatory review needs. GMTS' comments do not support elimination of the filing of NSAs.

The Commission will be addressing the request to eliminate the NSA filing and publication requirements in a future rulemaking addressing NCBFAA's petition. Accordingly, the Commission takes no position at this time on the comments supporting such a change, and the Commission is moving forward with the proposed amendments to Part 531, described in detail below, in this rulemaking.

§ 531.3 Definitions

§ 531.3(k) Effective Date

The Commission's regulations presently require that an NSA or amendment be filed on or before the date it becomes effective. In response to filed VOCC comments, the Commission is proposing to allow the filing of service contract amendments pursuant to Part 530 to be delayed up to 30 days after an amendment is agreed to by the contract parties. In order to relieve the filing burden on NVOCCs as well, the Commission is proposing to similarly allow amendments to NSAs to be filed up to 30 days after an amendment is agreed to by the parties.

The NCBFAA comments stated, ''[j]ust as it is appropriate for the Commission to adopt the proposed changes in the service contract regulations, the agency should at least provide the same relief to NVOCCs with respect to NSAs.''

UPS commends the Commission for examining possible approaches to increase efficiency in the industry and favors greater flexibility in the NSA regulations. UPS supports the concept of allowing contracts and amendments to be filed and essential terms publication to be completed within a reasonable time after the effective date, rather than in advance.

CEVA Freight, LLC, as agents for Pyramid Lines, supports the Commission permitting NVOCCs the ''flexibility in filing amendments so that the regulatory process does not delay the implementation of commercial agreements.'' In addition, CEVA supports the Commission allowing NVOCCs to file multiple NSA amendments signed over a 30-day period in a single filing. GMTS does not support the filing of amendments to NSAs after the effective date of agreement of the parties.

The Commission invites further comments on these varying positions regarding up to the 30-day delay in filing NSA amendments. As discussed above, the Commission does not currently believe that GMTS' concerns outweigh the proposed 30-day filing period. With respect to CEVA's comment to allow multiple amendments to be included in a single filing, the Commission is tentatively rejecting this recommendation for the same reasons discussed above in the service contract section. It would require significant programming time and considerable expense to update the SERVCON system

to allow multiple amendments to be filed in a single document at one time, and, therefore, the Commission proposes maintaining its existing requirement that sequential amendments for NSAs be filed with a single effective date for all changes within that amendment. Those amendments could, however, be filed up to 30 days after they have gone into effect.

§ 531.5 Duty To File

The Commission proposes to add regulatory language under § 530.5 which makes service contract filers aware of the option to use web services when filing service contracts and their corresponding amendments. While no comments were received from NVOCCs regarding this matter, larger volume filers of NSAs may find it advantageous. The Commission wishes to avail NVOCCs of this option as well, and therefore, proposes to add similar regulatory language to this section to alert NSA filers of their ability to use web services to file NSAs and amendments, should they so choose.

Subpart B—Filing Requirements

§ 531.6 NVOCC Service Arrangements

Presently the Commission's regulations require that an NSA or amendment be filed on or before the date it becomes effective. As discussed above, the Commission is proposing to allow up to 30 days for filing NSA amendments after their effective date, and is proposing corresponding changes to § 531.6.

§ 531.6(d) Other Requirements

Pursuant to § 531.6(d)(4), an NVOCC may not knowingly and willfully enter into an NSA with another NVOCC that is not in compliance with the Commission's tariff and proof of financial responsibility requirements. As more fully discussed under § 530.6, above, the industry frequently refers to the Commission's Web site, *www.fmc.gov,* to verify whether or not an NVOCC contract holder or affiliate is compliant with these requirements.

The ANPR requested comment on different options that, upon development, would allow the FMC's SERVCON system to alert filers at the time of uploading service contracts, NSAs and amendments thereto, if an NVOCC contract signatory or affiliate is not in good standing. As discussed, the alert notifying the filer that an NVOCC is not in good standing is intended to leverage technology in order to assist filers with compliance and would not result in the rejection of a filing.

Given the comments discussed in § 530.6 above, the Commission proposes to add an additional field in its SERVCON filing system which requires the input of an NVOCC's six-digit Organization Number when they are the contract holder or affiliate. If there are multiple NVOCC parties to a service contract, the filer would be required to input the six-digit Organization Number of all NVOCCs.

§ 531.6(d)(5) Certification of Shipper Status

The NSA regulations do not include a requirement that the NSA shipper certify its status, which is a requirement for shippers under current service contract regulations in Part 530. The Commission sought comment on whether to make this requirement consistent and uniform for NVOCCs and VOCCs. No comments were filed that addressed certification of shipper status in NSAs. The Commission's interest in ensuring that all NVOCCs in the supply chain are FMC licensed or registered, and as a consequence hold an OTI bond, provides greater assurance that shippers will not be harmed by unfair or deceptive practices. Given the potential benefits, the Commission proposes to add a requirement that all NSA contract shippers and affiliates certify their shipper status.

§ 531.8 Amendment, Correction, Cancellation, and Electronic Transmission Errors

Under the Commission's regulations, VOCC service contracts and NVOCC service arrangements are agreements between a common carrier and a shipper for the carriage of cargo. Given these congruencies, the Commission is considering whether changes being proposed by the VOCCs to the correction procedures for service contracts should be handled in a similar manner for NSAs. A complete discussion of the changes requested with respect to service contract amendment, correction, cancellation, and electronic transmission errors is included in § 530.10 above.

To provide the same flexibility with regard to correcting errors in NVOCC NSAs as the Commission proposes for VOCCs service contract errors, the Commission proposes: (1) Extending the time period in which to file a Corrected Transmission to remedy an NSA electronic transmission error under § 531.8(c) from 48 hours to 30 days and; (2) extending the time period for filing an NSA correction request under § 531.8(b) from 45 to 180 days.

Subpart C—Publication of Essential Terms

§ 531.9 Publication

As noted previously, NCBFAA's comments requested that the Commission consider whether the NSA filing and the essential term tariff publication requirements are necessary, and requests the Commission eliminate those requirements. The other commenter on this matter, GMTS, does not support any changes to the current essential terms filing requirements.

The Commission will be addressing the request to eliminate the NSA publication requirements in a future rulemaking addressing NCBFAA's petition. Accordingly, the Commission takes no position at this time on the comments supporting such a change and is not proposing any changes to the NSA publication requirements as part of this rulemaking.

Subpart D—Exceptions and Implementation

§ 531.10 Excepted and Exempted Commodities

The Commission sought comment on whether to treat VOCC service contracts and NVOCC service arrangements, as well as the tariffs of both, in a similar fashion with respect to exempted commodities. No specific comments were filed addressing this issue related to NVOCCs. As the Commission is not proposing to exercise its exemption authority under Section 16 of the Shipping Act to exempt additional commodities for VOCCs, it does not propose to do so for NVOCCs under this section.

The Commission is proposing however, to amend § 531.10(b)(2), to reflect the change in name of the relevant Department of Defense entity from Military Transportation Management Command to Surface Deployment and Distribution Command.

§ 531.11 Implementation

Changes regarding the effective date of service contract amendments are being proposed by the Commission under Part 530. The Commission is proposing similar requirements for NSA amendments in Part 531 (NVOCC Service Arrangements).

III. Regulatory Notices and Analysis

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, provides that whenever an agency is required to publish a notice of proposed rulemaking under the Administrative Procedure Act (APA), 5

U.S.C. 553, the agency must prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the proposed rule on small entities, unless the head of the agency certifies the rulemaking, 5 U.S.C. 603, 605. Accordingly, the Chairman of the Federal Maritime Commission certifies that the proposed rule, if promulgated, will not have a significant impact on a substantial number of small entities. The regulated business entities that would be impacted by the rule are vessel operating common carriers (VOCCs) and non-vessel operating common carriers (NVOCCs) that enter into service contracts and NVOCC service arrangements (NSAs), respectively, with shippers of cargo. The Commission has determined that VOCCs generally do not qualify as small under the guidelines of the Small Business Administration (SBA), while the majority of NVOCCs do qualify as small under the SBA guidelines. The Commission concludes, however, that the proposed rule would not have a significant impact on NVOCCs. In this regard, the rule pertains to an NSA entered into between a NVOCC and a shipper, which is an optional pricing arrangement that benefits the shipping public and relieves NVOCCs from the burden of the statutory tariff filing requirements in 46 U.S.C. 40501. The only proposed change that would increase the burden on NVOCCs is the proposed requirement to include the organization number for NVOCC shippers. Although this requirement would increase the filing burden associated with NSAs, the additional burden would be minimal. Specifically, as discussed in more detail below, the Commission estimates that only 10% of NSA filings would be affected by this proposed requirement and inputting the NVOCC shipper's organization number would add less than a minute to the filing time for affected submissions. As a result, the total additional burden imposed across all NVOCCs would only be 5 hours of additional filing time annually.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) (PRA) requires an agency to seek and receive approval from the Office of Management and Budget (OMB) before collecting information from the public. 44 U.S.C. 3507. The agency must submit collections of information in proposed rules to OMB in conjunction with the publication of the notice of proposed rulemaking. 5 CFR 1320.11.

The information collection requirements in Part 530, Service Contracts, and Part 531, NVOCC Service Arrangements, are currently authorized under OMB Control Numbers 3072–0065 and 3072–0070, respectively. If approved, this rule would require a VOCC that files a service contract or amendment thereto into the FMC's SERVCON system to also enter the 6-digit FMC Organization Number of any NVOCC shipper party or affiliate. The same requirement is being proposed for NVOCC Service Arrangement filings. In compliance with the PRA, the Commission has submitted the proposed revised information collections to the Office of Management and Budget.

The Shipping Act prohibits common carriers from accepting cargo from, transporting cargo for, or entering into a service contract with an ocean transportation intermediary that does not have a tariff and a bond. See 46 U.S.C. 41104(11)–(12). While current rules recognize several options by which service contract filers verify shipper status, 46 CFR 530.6(b) and 515.27(a)–(d), common carriers typically obtain the NVOCC's Organization Number prior to contract filing, in the course of verifying whether an NVOCC maintains a current tariff and bond. Indeed, twenty major VOCCs already collect and include this information in their filings. Therefore, the Commission estimates that the average time needed to input and submit this additional data item when transmitting filings to be minimal, *i.e.,* less than one minute per filing.

Public burden for the collection of information associated with Part 530, Service Contracts, as revised, would encompass 103 likely respondents and an estimated 2,216,097 annual instances,[6] with an overall annual estimated burden of 89,775 total hours. The Commission estimates that approximately 45% of service contracts are entered into with NVOCC shippers, to which the proposed 6-digit organization number reporting requirement would apply. Consequently, of the 89,775 hours estimated annually for the Part 530 information collection, approximately 4,336 hours would be attributable to the new requirement proposed in this rulemaking.

Public burden for the collection of information pursuant to Part 531, NVOCC Service Arrangements, as revised, would comprise 79 likely respondents and an estimated 10,371 annual instances,[7] with an overall annual estimated burden of 839 total hours. The Commission estimates that approximately 10% of NSAs include NVOCC shippers, to which the proposed 6-digit organization number reporting requirement would apply. Of the 839 hours estimated annually for the Part 531 information collection, approximately 5 hours would be attributable to the new requirement proposed in this rulemaking.

Comments are invited on:

- Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility;
- Whether the Commission's estimate for the burden of the information collection is accurate;
- Ways to enhance the quality, utility, and clarity of the information to be collected;
- Ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Please submit any comments, identified by the docket number in the heading of this document, by any of the methods described in the **ADDRESSES** section of this document.

Regulation Identifier Number

The Commission assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda). The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda, available at *http://www.reginfo.gov/public/do/eAgendaMain.*

List of Subjects

46 CFR Part 530

Freight, Maritime carriers, Report and recordkeeping requirements.

46 CFR Part 531

Freight, Maritime carriers, Report and recordkeeping requirements.

[6] Annual instances include the filing of new service contracts and amendments, essential terms publication, notification/filing requirements, Form FMC–83, disclosure/third party, and record keeping/audit requirements. Of the total annual instances of 2,216,097, the number of service contracts and amendments combined is 642,309. Forty-five percent of those is 289,039.

[7] Annual instances include the filing of new NSAs and amendments, essential terms publication, notification/filing requirements, Form FMC–78, disclosure/third party, and record keeping/audit requirements. Of the total annual instances of 10,371, the number of NSAs and amendments combined is 3,249. Ten percent of those is 325.

For the reasons stated in the supplementary information, the Federal Maritime Commission proposes to amend 46 CFR parts 530 and 531 as follows:

PART 530—SERVICE CONTRACTS

■ 1. The authority citation for part 530 continues to read as:

Authority: 5 U.S.C. 553; 46 U.S.C. 305, 40301–41306, 40501–40503, 41307.

■ 2. Amend § 530.3 by:
■ a. Redesignating paragraph (s) as paragraph (u);
■ b. Redesignating paragraphs (b) through (r) as paragraphs (c) through (s), respectively;
■ c. Adding new paragraph (b); and
■ d. Revising newly redesignated paragraphs (e), (j), and (p).

The addition and revisions read as follows:

§ 530.3 Definitions.

* * * * *

(b) *Affiliate* means two or more entities which are under common ownership or control by reason of being parent and subsidiary or entities associated with, under common control with, or otherwise related to each other through common stock ownership or common directors or officers.

* * * * *

(e) *BTA* means the Commission's Bureau of Trade Analysis or its successor bureau.

* * * * *

(j) *Effective date* means the date upon which a service contract or amendment is scheduled to go into effect by the parties to the contract. For an original service contract, the effective date cannot be prior to the filing date with the Commission. For a service contract amendment, the effective date can be no more than thirty (30) calendar days prior to the filing date with the Commission. A service contract or amendment thereto becomes effective at 12:01 a.m. Eastern Standard Time on the beginning of the effective date.

* * * * *

(p) *OIT* means the Commission's Office of Information Technology or its successor office.

* * * * *

■ 3. Amend § 530.5 by revising paragraph (b) to read as follows:

§ 530.5 Duty to file.

* * * * *

(b) Filing may be accomplished by any duly agreed-upon agent, as the parties to the service contract may designate, and subject to conditions as the parties may agree. The parties, or their duly agreed-upon agent, may utilize web services to transmit filings into the Commission's service contract electronic filing system (SERVCON).

* * * * *

■ 4. Amend § 530.6 by revising paragraph (b) to read as follows:

§ 530.6 Certification of shipper status.

* * * * *

(b) *Proof of tariff and financial responsibility.* If the certification completed by the contract party under paragraph (a) of this section identifies the contract party or an affiliate or member of a shippers' association as an NVOCC, the ocean common carrier, conference or agreement shall obtain proof that such NVOCC has a published tariff and proof of financial responsibility as required under sections 8 (46 U.S.C. 40501–40503) and 19 (46 U.S.C. 40901–40904) of the Act before signing the service contract. An ocean common carrier, conference or agreement can obtain such proof by the same methods prescribed in § 515.27 of this chapter. Alternatively, for each NVOCC that is a shipper, an affiliate or a member of a shippers' association, its 6-digit FMC Organization Number must be entered at the time of filing into the corresponding SERVCON field, which shall serve as such proof.

* * * * *

■ 5. Amend § 530.8 by revising paragraph (a) and paragraph (d) introductory text to read as follows:

§ 530.8 Service contracts.

(a) Authorized persons shall file with BTA, in the manner set forth in appendix A of this part, a true and complete copy of:

(1) Every service contract before any cargo moves pursuant to that service contract; and

(2) Every amendment to a filed service contract no later than thirty (30) days after any cargo moves pursuant to that service contract amendment.

* * * * *

(d) *Other requirements.* Every service contract filed with BTA shall include, as set forth in appendix A to this part:

* * * * *

■ 6. Amend § 530.10 by revising paragraph (c) introductory text and the first sentence of paragraph (d) to read as follows:

§ 530.10 Amendment, correction, cancellation, and electronic transmission errors.

* * * * *

(c) *Corrections.* Requests shall be filed, in duplicate, with the Commission's Office of the Secretary within one-hundred eighty (180) days of the contract's filing with the Commission, accompanied by remittance of a $315 service fee and shall include:

* * * * *

(d) *Electronic transmission errors.* An authorized person who experiences a purely technical electronic transmission error or a data conversion error in transmitting a service contract filing or amendment thereto is permitted to file a Corrected Transmission (''CT'') of that filing within 30 days of the date and time of receipt recorded in SERVCON.

* * *

* * * * *

■ 7. Amend § 530.13 by revising paragraph (b)(2) to read as follows:

§ 530.13 Exceptions and exemptions.

* * * * *

(b) * * *

(2) *Department of Defense cargo.* Transportation of U.S. Department of Defense cargo moving in foreign commerce under terms and conditions negotiated and approved by the Surface Deployment and Distribution Command and published in a universal service contract. An exact copy of the universal service contract, including any amendments thereto, shall be filed with the Commission as soon as it becomes available.

* * * * *

■ 8. Amend § 530.14 by revising paragraph (a) to read as follows:

§ 530.14 Implementation.

(a) *Generally.* Performance under an original service contract may not begin before the day it is effective and filed with the Commission. Performance under a service contract amendment may not begin until the day it is effective, provided however that amendments must be filed no later than thirty (30) calendar days after effectiveness.

* * * * *

§ 530.15 [Amended]

■ 9. Amend § 530.15 by removing paragraph (b) and redesignating paragraphs (c) and (d) as paragraphs (b) and (c), respectively.

PART 531—NVOCC SERVICE ARRANGEMENTS

■ 10. The authority citation for part 531 continues to read as:

Authority: 46 U.S.C. 40103.

■ 11. Amend § 531.3 by revising paragraph (k) to read as follows.

§ 531.3 Definitions.

* * * * *

(k) *Effective date* means the date upon which an NSA or amendment is scheduled to go into effect by the parties to the contract. For an original NSA, the effective date cannot be prior to the filing date with the Commission. For an NSA amendment, the effective date can be no more than thirty (30) calendar days prior to the filing date with the Commission. An NSA or amendment thereto becomes effective at 12:01 a.m. Eastern Standard Time on the beginning of the effective date.

* * * * *

■ 12. Amend § 531.5 by revising paragraph (c) to read as follows.

§ 531.5 Duty to file.

* * * * *

(c) Filing may be accomplished by any duly agreed-upon agent, as the parties to the NSA may designate, and subject to conditions as the parties may agree. The parties, or their duly agreed-upon agent, may utilize web services to transmit filings into the Commission's electronic filing system (SERVCON).

* * * * *

■ 13. Amend § 531.6 by
■ a. Revising paragraphs (a) and (b)(9)(ii);
■ b. Redesignating paragraphs (b)(10) and (11) as (b)(11) and (12), respectively;
■ c. Adding a new paragraph (b)(10);
■ d. Redesignating paragraphs (d) through (g) as paragraphs (e) through (h), respectively;
■ e. Adding a new paragraph (d); and
■ f. Revising newly redesignated paragraphs (e)(1) and (g).

The additions and revisions to read as follows:

§ 531.6 NVOCC Service Arrangements

(a) Authorized persons shall file with BTA, in the manner set forth in appendix A of this part, a true and complete copy of:

(1) Every NSA before any cargo moves pursuant to that NSA; and

(2) Every amendment to a filed NSA no later than thirty (30) days after any cargo moves pursuant to that NSA amendment.

(b) * * *

(9) * * *

(ii) Certify that this information will be provided to the Commission upon request within ten (10) business days of such request. However, the requirements of this section do not apply to amendments to NSAs that have been filed in accordance with the requirements of this section unless the amendment adds new parties or affiliates;

(10) A certification of shipper status;

* * * * *

(d) *Certification of shipper status.* The NSA shipper party shall sign and certify on the signature page of the NSA its shipper status (*e.g.,* owner of the cargo, shippers' association, NVOCC, or specified other designation), and the status of every affiliate of such party or member of a shippers' association entitled to receive service under the NSA. For each NVOCC that is a shipper, an affiliate or a member of a shippers' association, its 6-digit FMC Organization Number must be entered at the time of filing into the corresponding SERVCON field.

(e) * * *

(1) For service pursuant to an NSA, no NVOCC may, either alone or in conjunction with any other person, directly or indirectly, provide service in the liner trade that is not in accordance with the rates, charges, classifications, rules and practices contained in an effective NSA.

* * * * *

(g) *Exception in case of malfunction of Commission electronic filing system.* (1) In the event that the Commission's electronic filing system is not functioning and cannot receive NSAs filings for twenty-four (24) continuous hours or more, affected parties will not be subject to the requirements of paragraph (a) of this section and § 531.11 that an NSA be filed before cargo is shipped under it.

(2) However, NSAs which go into effect before they are filed due to a malfunction of the Commission's electronic filing system pursuant to paragraph (g)(1) of this section, must be filed within twenty-four (24) hours of the Commission's electronic filing system's return to service.

(3) For an NSA that is effective without filing due to a malfunction of the Commission's filing system, failure to file that NSA within twenty-four (24) hours of the Commission's electronic filing system's return to service will be considered a violation of these regulations.

■ 14. Amend § 531.8 by revising paragraphs (b)(1) and (c) to read as follows:

§ 531.8 Amendment, correction, cancellation, and electronic transmission errors.

* * * * *

(b) * * *

(1) Requests shall be filed, in duplicate, with the Commission's Office of the Secretary within one-hundred eighty (180) days of the NSAs filing with the Commission, accompanied by remittance of a $276 service fee.

* * * * *

(c) *Electronic transmission errors.* An authorized person who experiences a purely technical electronic transmission error or a data conversion error in transmitting an NSA or an amendment thereto is permitted to file a Corrected Transmission (''CT'') of that filing within 30 days of the date and time of receipt recorded in SERVCON. This time-limited permission to correct an initial defective NSA filing is not to be used to make changes in the original NSA rates, terms or conditions that are otherwise provided for in paragraphs 531.6(b) of this section. The CT tab box in SERVCON must be checked at the time of resubmitting a previously filed NSA, and a description of the correction made must be stated at the beginning of the corrected NSA in a comment box. Failure to check the CT box and enter a description of the correction will result in the rejection of a file with the same name, since documents with duplicate file names or NSA and amendment numbers are not accepted by SERVCON.

* * * * *

■ 15. Amend § 531.10 by revising paragraph (b)(2) to read as follows.

§ 531.10 Excepted and exempted commodities.

* * * * *

(b) * * *

(2) *Department of Defense cargo.* Transportation of U.S. Department of Defense cargo moving in foreign commerce under terms and conditions approved by the Surface Deployment and Distribution Command and published in a universal service contract. An exact copy of the universal service contract, including any amendments thereto, shall be filed with the Commission as soon as it becomes available.

* * * * *

■ 16. Revise § 531.11 to read as follows.

§ 531.11 Implementation.

Generally. Performance under an original NSA may not begin before the day it is effective and filed with the Commission. Performance under an NSA amendment may not begin until the day it is effective, provided however that amendments must be filed no later than thirty (30) calendar days after effectiveness.

By the Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2016–19843 Filed 8–19–16; 8:45 am]

BILLING CODE 6730–01–P

AGENCY FOR INTERNATIONAL DEVELOPMENT

48 CFR Part 752

RIN 0412–AA81

Requirement for Nondiscrimination Against End-Users of Supplies or Services (''Beneficiaries'') Under USAID-Funded Contracts

AGENCY: U.S. Agency for International Development.

ACTION: Proposed rule.

SUMMARY: The Foreign Assistance Act of 1961, as amended (FAA), authorizes the U.S. Agency for International Development (USAID) to provide foreign assistance in the form of development and humanitarian assistance that reflect American ideals. To help emphasize USAID's intent and expectation of non-discrimination of beneficiaries in USAID-funded activities, USAID is proposing to amend its Agency for International Development Acquisition Regulation (AIDAR) to include a new clause entitled ''Nondiscrimination against End-Users of Supplies or Services.'' This proposed clause expressly states that USAID-funded contractors must not discriminate among end-users of supplies or services (referred to in this rule as beneficiaries and potential beneficiaries) in any way that is contrary to the scope of the activity as defined in the statements of work (SOWs).

DATES: To be considered, comments must be received no later than September 21, 2016.

ADDRESSES: Address all comments concerning this notice to Todd Larson, Senior Coordinator, U.S. Agency for International Development, Rm. 6.09–71 RRB, 1300 Pennsylvania Avenue NW., Washington, DC 20523. Submit comments, identified by title of the action and Regulatory Information Number (RIN) by any of the following methods:

1. Through the Federal eRulemaking Portal at *http://www.regulations.gov* by following the instructions for submitting comments.

2. *By Email:* Submit electronic comments to *tlarson@usaid.gov.* See **SUPPLEMENTARY INFORMATION** for file formats and other information about electronic filing.

3. *By Mail addressed to:* Todd Larson, U.S. Agency for International Development, Rm. 6.09–71 RRB, 1300 Pennsylvania Avenue NW., Washington, DC 20523.

FOR FURTHER INFORMATION CONTACT: Todd Larson Telephone: 202–712–4969 or Email: *tlarson@usaid.gov*

SUPPLEMENTARY INFORMATION:

I. Background

USAID seeks to improve the lives of people around the world by being inclusive in its development and humanitarian assistance efforts. In so doing, USAID recognizes that every person is instrumental in the transformation of their own societies, with the end result that each and every person is recognized and equally valued without regard to artificial and discriminatory distinctions. The inclusion, protection, and empowerment of all persons is critical because drawing on the full contributions of the entire population leads to more effective, comprehensive, and sustainable development results.

Nondiscrimination is the basic foundation of USAID's inclusive development approach; as such, all USAID programs seek to ensure access for all potential beneficiaries within the scope of the contract without discrimination. Contractors must adhere to this by implementing the activities as outlined in the contract SOWs. Nondiscrimination is a critical foundation for protecting and promoting the human rights of all persons. In addition, nondiscrimination ensures equitable access to USAID programs. Effective nondiscrimination practices support USAID's principles of inclusion and equal access and help to ensure that USAID programs empower and effectively reach women and girls; marginalized ethnic and religious populations; indigenous peoples; internally displaced persons; persons with disabilities; youth and the elderly; lesbian, gay, bisexual, transgender, and intersex individuals; and other socially marginalized individuals and peoples unique to the country or regional context.

In recent years, the Government has made multiple pronouncements of policy in many areas reflecting its emphasis on equity, fairness, and human dignity—effective nondiscrimination is a means toward achieving all of these. For example, in 2011, the White House issued E.O. 13563, ''Improving Regulation and Regulatory Review,'' to update all agencies on factors to consider when issuing rules; in addition to quantitative factors, it advised that the qualitative values of equity, fairness, and human dignity are important considerations. Additionally, a 2011 Presidential Memorandum, ''International Initiatives to Advance the Human Rights of Lesbian, Gay, Bisexual, and Transgender Persons,'' directs all agencies engaged abroad to advance nondiscrimination. This proposed rule addressing discrimination in the provision of supplies or services is consistent with the values that animate the above.

II. Discussion

This rulemaking would revise (48 CFR) AIDAR to add a new clause at 752.7038 entitled ''Nondiscrimination against End-Users of Supplies or Services.'' The clause, applicable to all solicitations, contracts, and subcontracts at any tier, prohibits contractors and subcontractors from discriminating against beneficiaries or potential beneficiaries (*i.e.,* those individuals intended to receive the benefits of the award, whether goods or services) on the basis of any characteristics not expressly stated in the award.

This proposed rule is published for public comment pursuant to the Office of Federal Procurement Policy Act (41 U.S.C. 1707).

The Administrative Procedure Act (APA) provides an exception for ''matter[s] relating to agency management or personnel or to public property, loans, grants, benefits, or contracts'' from the requirement of public notice and comment before a final rulemaking. 5 U.S.C. 553(a)(2). This rulemaking is directly related to contracts.

The Office of Federal Procurement Policy Act, 41 U.S.C. 1707, imposes a separate requirement for public comment prior to final rulemaking for any ''procurement policy, regulation, procedure, or form . . . if it (A) relates to the expenditure of appropriated funds; and (B)(i) has a significant effect beyond the internal operating procedures of the agency issuing [it]; or (ii) has a significant cost or administrative impact on contractors or offerors.'' This proposed rulemaking is related to procurement policy and will amend USAID's Acquisition Regulation (AIDAR).

Per subsection (b) of this statute, USAID is publishing this proposed rulemaking for a comment period of 30 days.

The purpose of this rulemaking is to ensure adherence to the intent and authorities in the FAA, and other statutes related to humanitarian assistance and international development. The stated intent of the FAA is to help people, without regard to irrelevant and discriminatory distinctions among them. This intent is reflected in many places in the statute. The first words of the Act set out that it seeks to promote United States

interests ''by assisting peoples of the world.'' Congress explained its intent thusly in FAA section 101: ''[T]he Congress reaffirms the traditional humanitarian ideals of the American people and renews its commitment to assist people in developing countries to eliminate hunger, poverty, illness, and ignorance.''

A survey of FAA provisions relevant to USAID awards reflects that they focus on development and humanitarian assistance needs and effectiveness toward meeting them. For example, FAA section 103, on agriculture, rural development, and nutrition, suggests assistance should focus on alleviating poverty. FAA section 104, on health-related assistance, suggests limited targeting of activities to the specialized health needs of children, infants, and mothers. FAA section 491, on international disaster assistance, contemplates ''prompt United States assistance to alleviate human suffering'' and emphasizes only that the implementing agency ''shall insure that the assistance provided by the United States shall, to the greatest extent possible, reach those most in need of relief and rehabilitation as a result of natural and manmade disaster.''

In some contexts, such as assistance for child survival, the foreign assistance authorities contemplate a focus on women and children, but that is a matter of programmatic need and effectiveness. There is no context where excluding individuals from assistance based on any of the types of discrimination proscribed by this clause, outside the scope of the award, would have a positive effect on implementing USAID's foreign assistance authorities.

The main effect of this clause is to ensure that USAID's policy and practice of non-discrimination in planning projects and activities is followed through to completion by the contractors that implement them. Its impact on contractors and offerors is to remind them to follow the terms and conditions of the contract, including the implementation of the SOW as designed, and to refrain from the types of discrimination described in the clause. In itself, the proposed clause serves as a reminder to contractors and offerors of USAID's long-standing, pre-existing expectations based on USAID's programmatic and planning priorities and authorities.

III. Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess the costs and benefits of the intended regulation. E.O. 13563 allows that in making this assessment, an agency ''may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.'' The estimated costs of this rulemaking do not exceed the threshold of economic significance (*i.e.,* an annual effect on the economy of $100 million or more). However, the proposed rule has been designated a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and therefore it has been reviewed by the Office of Management and Budget.

This rule provides a benefit by promoting non-discrimination, which itself promotes programmatic efficiency, with very little additional administrative burden for the affected entities, USAID contractors. It does not ask them to carry out activities beyond those in their contract SOWs and terms and conditions; it does not ask them to alter the manner in which they conduct the work as set out in their contracts. In fact, it reminds them to stay within those instructions. The only potential cost the Agency could identify for contractors and subcontractors is for minimal training, to the extent that contractors do not already proscribe discrimination as part of the normal conduct of their business.

USAID awards approximately 1,300 contracts/task orders annually. As a practical matter for these current contracts, even absent this clause, if for example a contract specified the provision of food parcels in a certain community, the contractor could not, on its own, decide that only certain members of that community should receive the food parcels or that certain members should be excluded.

Including this clause in all new contracts and subcontracts going forward provides an explicit reminder of USAID's expectation that its contractors not discriminate against any protected group or individual, and is particularly important in countries where stigma and discrimination toward certain groups is tolerated or officially endorsed by the government. The benefits of the rule would be to expressly reinforce notions of equity, fairness, and human dignity under Federal Government contracts.

Contractors responding to a solicitation (*e.g.* request for proposals (RFP) or invitation for bid (IFB)) would further be on notice not to include any discriminatory criteria in their response to a solicitation, absent specific programmatic justification in the SOW to do so.

IV. Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act of 1980, as amended, 5 U.S.C. 601–612, to ensure that Government regulations do not unnecessarily or disproportionately burden small entities. It requires a regulatory flexibility analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities.

In fiscal year 2015, 330 small businesses received USAID funds. In fiscal years 2011, 2012, 2013, and 2014 the 391, 384, 349, and 363 small businesses received USAID funds, respectively. The requirement this rule would impose on small businesses is no different than the requirement for other entities: Contracts or subcontracts awarded to them will include a provision reminding them not to discriminate. Beyond adding a brief reminder or discussion of this now explicit requirement to existing trainings on business ethics and conduct they provide to their staff, as already required by FAR 3.10, we do not estimate that this will impose a significant additional cost. As with all contractors, the employees of small businesses will be expected to be mindful of the principles of equity, fairness, and human dignity when performing the work under their contracts; as they have always been. The additional effort by small businesses (a matter of a few minutes of discussion) is so de minimis that we do not estimate that this will impose more than a negligible cost.

There are no reporting or recordkeeping requirements associated with this rule. The rule does not duplicate, overlap, or conflict with any other Federal rules. There is currently no other Federal rule addressing discrimination of recipients of supplies or services pursuant to a Federal Government contract. There were no significant alternatives identified that would meet the objective of the rule.

In light of the above analysis, the USAID Chief Acquisition Officer certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities.

V. Paperwork Reduction Act

This rule does not include a reporting or information collection requirement. Therefore, USAID has determined that this rule does not impose any new or revised reporting or disclosure requirements that would be considered collections of information requiring Office of Management and Budget approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 48 CFR Part 752

Government procurement.

For the reasons discussed in the preamble, USAID amends 48 CFR Chapter 7 as set forth below:

■ 1. The authority citation for 48 CFR Chapter 7 part 752 continues to read as follows:

Authority: Sec. 621, Pub. L. 87–195, 75 Stat. 445 (22 U.S.C. 2381), as amended; E.O. 12163, Sept. 29, 1979, 44 FR 56673; and 3 CFR 1979 Comp., p. 435.

SUBCHAPTER H—CLAUSES AND FORMS

PART 752—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 2. Add Section 752.7038 to read as follows:

§ 752.7038 Nondiscrimination against End-Users of Supplies or Services.

The following clause must be inserted in section I of all solicitations and resulting contracts.

Nondiscrimination Against End-Users of Supplies or Services (Date)

(a) USAID policy requires that the contractor not discriminate against any end-user of the contract supplies or services (*i.e.,* the beneficiaries of the supplies or services) in implementation of this award, such as, but not limited to, by withholding, adversely impacting, or denying equitable access to the supplies or services (benefits) provided through this contract on the basis of any factor not expressly stated in the award. This may include, for example, race, color, religion, sex (including gender identity, sexual orientation, and pregnancy), national origin, disability, age, genetic information, marital status, parental status, political affiliation, or veteran's status. Nothing in this clause is intended to limit the ability of a contractor to target activities toward the assistance needs of certain populations as defined in the contract.

(b) The Contractor must insert this clause, including this paragraph, in all subcontracts under this contract.

(End of clause)

Dated: August 8, 2016.

Sunil Xavier,

Acting Chief Acquisition Officer.

[FR Doc. 2016–19716 Filed 8–19–16; 8:45 am]

BILLING CODE 6116–01–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 269

[Docket No. FRA–2016–0023, Notice No. 3]

RIN 2130–AC60

Competitive Passenger Rail Service Pilot Program

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Proposed rule; notice of public hearing and extension of comment period.

SUMMARY: On June 22, 2016, FRA published a Notice of Proposed Rulemaking (NPRM) that would implement a pilot program for competitive selection of eligible petitioners in lieu of Amtrak to operate not more than three long-distance routes operated by Amtrak. FRA is announcing a public hearing to provide interested persons an opportunity to provide oral comments on the proposal. FRA is also announcing an extension of the comment period for this proceeding to allow time for interested parties to submit written comments in response to views or information provided at the public hearing.

DATES: A public hearing will be held on September 7, 2016, at 1:45 p.m. in Washington, DC. The comment period for the NPRM published on June 22, 2016, (81 FR 40624) is open through August 22, 2016. Comments in response to views or information provided at the public hearing must be received by October 7, 2016.

ADDRESSES: *Public Hearing.* The public hearing will be held at the U.S. Department of Transportation, 1200 New Jersey Avenue SE., Conference Center Room 7, Washington, DC 20590.

Comments. You may submit comments identified by Docket Number FRA–2016–0023 by any of the following methods:

- *Online:* Comments should be filed at the Federal eRulemaking Portal, *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Instructions: All submissions must include the agency name, docket name, and docket number or Regulatory Identification Number (RIN) for this rulemaking (RIN 2130–AC60). FRA will post all comments received without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading in the ''Supplementary Information'' section of this document for Privacy Act information about any submitted petitions, comments, or materials.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or to the U.S. Department of Transportation, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Brandon White, Office of Railroad Policy and Development, Federal Railroad Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 493–1327, *Brandon.White@dot.gov,* or Zeb Schorr, Office of Chief Counsel, Federal Railroad Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 493–6072.

SUPPLEMENTARY INFORMATION: Interested parties are invited to present oral statements and to offer information and views at the hearing. The hearing will be informal and will be conducted by a representative FRA designates under FRA's Rules of Practice (49 CFR 211.25). The hearing will be a non-adversarial proceeding. Therefore, there will be no cross examination of persons presenting statements or offering evidence. An FRA representative will make an opening statement outlining the scope of the hearing. After all initial statements are completed those persons wishing to make a brief rebuttal will be given the opportunity to do so in the same order the initial statements were made. FRA will announce additional procedures necessary to conduct the hearing, at the hearing. The purpose of this hearing is to receive oral comments in response to an NPRM for a competitive passenger rail service pilot program. FRA will add a transcript of the discussions to the public docket in this proceeding.

Public Participation Procedures. Any person wishing to make a statement at the hearing should notify Mr. White by telephone, email, or in writing, at least 5 working days before the date of the hearing and submit three copies of the

oral statement he or she intends to make at the proceeding. The notification should identify the party the person represents, the particular subject(s) the person plans to address, and the time requested. The notification should also provide the participant's mailing address and other contact information. FRA reserves the right to limit participation in the hearing of persons who fail to provide such notification. FRA also reserves the right to limit the duration of presentations if necessary to afford all persons with the opportunity to speak. For information on facilities or services for persons with disabilities, or to request special assistance at the hearing, contact FRA Program Analyst, Mr. Kenton Kilgore, by telephone, email, or in writing, at least at least 5 working days before the date of the hearing. Mr. Kilgore can be reached at Federal Railroad Administration, Office of Railroad Safety, Mail Stop 25, 1200 New Jersey Avenue SE., Washington, DC 20590; (202) 493–6286; or *Kenton.Kilgore@dot.gov.*

Extension of Comment Period. The comment period for the NPRM is currently open through August 22, 2016. To accommodate the public hearing and afford interested parties the opportunity to submit comments in response to views or information provided at the public hearing, FRA will extend the comment period. FRA must receive comments in response to views or information provided at the public hearing by October 7, 2016.

Privacy Act

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). See *http://www.regulations.gov/#!privacyNotice* for the privacy notice of *www.regulations.gov.* Interested parties may also review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Issued in Washington, DC, on August 16, 2016.

Jamie Rennert,

Office Director, Office of Program Delivery.

[FR Doc. 2016–19910 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Parts 28 and 29

[Docket No. FWS–HQ–NWRS–2012–0086; FXRS12610900000–167–FF09R24000]

RIN 1018–AX36

Management of Non-Federal Oil and Gas Rights

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; availability of Final Environmental Impact Statement.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), make available the final environmental impact statement (EIS) on regulations governing the exercise of non-Federal oil and gas rights outside of Alaska in order to improve our ability to protect refuge resources, visitors, and the general public's health and safety from potential impacts associated with non-Federal oil and gas operations located within refuges.

DATES: The Service will execute a Record of Decision no sooner than 30 days from the date of publication of the notice of availability of the FEIS by the Environmental Protection Agency.

ADDRESSES: Copies of the FEIS will be available for public review at *http://www.fws.gov/refuges/oil-and-gas/rulemaking.html* and at *www.regulations.gov* at Docket No. FWS–HQ–NWRS–2012–0086.

FOR FURTHER INFORMATION CONTACT: Scott Covington, U.S. Fish and Wildlife Service, Division of Natural Resources and Planning, MS: NWRS, 5275 Leesburg Pike, Falls Church, Virginia 22041; telephone 703–358–2427. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339. Further contact information can be found at *http://www.fws.gov/refuges/oil-and-gas/rulemaking.html.*

SUPPLEMENTARY INFORMATION: Under the authority of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) and the Department of the Interior regulations that implement NEPA (part 46 of title 43 of the Code of Federal Regulations) and the National Wildlife Refuge System Administration Act, as amended by the National Wildlife Refuge System Improvement Act (16 U.S.C. 668dd *et seq.*), we issue this supplementary document. The Environmental Protection Agency will publish similar notification of this action in the **Federal Register**.

Background

On February 24, 2014, we issued an advance notice of proposed rulemaking (ANPR) (79 FR 10080) to assist us in developing a proposed rule on managing activities associated with non-Federal oil and gas development on lands and waters of the National Wildlife Refuge System (NWRS). Non-Federal oil and gas development refers to oil and gas activities associated with any private, state, or tribally owned mineral interest where the surface estate is administered by the Service as part of the Refuge System. The ANPR had a 60-day comment period, ending April 25, 2014. On June 9, 2014, we reopened the comment period for another 30 days, ending July 9, 2014 (79 FR 32903). The ANPR requested the public to focus their comments on seven topics identified as major areas of concern: (1) Plans of Operations and Special Use Permits; (2) Operating Standards; (3) Financial Assurances; (4) Access Fees; (5) Noncompliance; (6) Existing Operations; and (7) Impacts from the Proposed Rulemaking.

We published a proposed rule on December 11, 2015 (80 FR 77200), to revise the regulations governing the exercise of non-Federal oil and gas rights located within NWRS units, and we announced the availability of a draft EIS. The comment period closed February 9, 2016. We now announce the availability of the FEIS.

The FEIS evaluates the impacts of three alternatives, including the following alternative elements:

- Requirement that oil operators proposing new oil and gas development (*e.g.,* drilling a well) obtain an operations permit.
- Requirement of financial assurance (bonding). Financial assurance would be equal to the reasonable estimated cost of site reclamation.
- Requirement that all operations, regardless of status, obtain a reclamation permit (including bonding) once that operation ceases to be economically productive.
- Improving enforcement authority by assimilating State oil and gas laws and regulations. Law enforcement staff would have authority to write citations for noncompliance with State regulations, primarily State regulations addressing surface impacts.

- Clarifying our authority to permit an operator access on NWRS units outside the boundary of an operator's mineral right.
- Clarifying the regulations to make it easier to identify an operator's information requirements and operating standards that apply to each type of operation.

Dated: July 29, 2016.

Michael J. Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2016–19519 Filed 8–19–16; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 81, No. 162
Monday, August 22, 2016

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

DEPARTMENT OF AGRICULTURE

Office of Tribal Relations, Council for Native American Farming and Ranching

AGENCY: Office of Tribal Relations, USDA.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a forthcoming meeting of The Council for Native American Farming and Ranching (CNAFR), a public advisory committee of the Office of Tribal Relations (OTR). Notice of the meetings are provided in accordance with section 10(a)(2) of the Federal Advisory Committee Act, as amended, (5 U.S.C. Appendix 2). This will be the fourth meeting held during fiscal year 2016 and will consist of, but not be limited to: Hearing public comments, update of USDA programs and activities, and discussion of committee priorities. This meeting will be open to the public.

DATES: The teleconference meeting will be held on September 1, 2016. The meeting will be open to the public with time set aside for public comment at approximately 1:30 p.m. to 2:30 p.m. The OTR will make the agenda available to the public via the OTR Web site *http://www.usda.gov/tribalrelations* no later than 10 business days before the meeting and at the meeting.

ADDRESSES: The meeting will be conducted using teleconference technology. This meeting will not be convened in person. Participants interested in joining this meeting may dial 1–877–369–5243 or 1–617–668–3633. Any modification to this number will be accessible online at *www.usda.gov/tribalrelations.*

Written Comments: Written comments may be submitted to: Josiah Griffin, Acting Designated Federal Officer, 1400 Independence Ave. SW., Whitten Bldg., 501–A, Washington, DC 20250; by Fax: (202) 720–1058; or by email: *Josiah.Griffin@osec.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Questions should be directed to the CNAFR Contact Person: Josiah Griffin, Acting Designated Federal Officer, 1400 Independence Ave. SW., Whitten Bldg., 501–A, Washington, DC 20250; by Fax: (202) 720–1058 or email: *Josiah.Griffin@osec.usda.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App. 2), USDA established an advisory council for Native American farmers and ranchers. The CNAFR is a discretionary advisory committee established under the authority of the Secretary of Agriculture, in furtherance of the *Keepseagle* v. *Vilsack* settlement agreement that was granted final approval by the District Court for the District of Columbia on April 28, 2011.

The CNAFR will operate under the provisions of the FACA and report to the Secretary of Agriculture. The purpose of the CNAFR is (1) to advise the Secretary of Agriculture on issues related to the participation of Native American farmers and ranchers in USDA loan and grant programs; (2) to transmit recommendations concerning any changes to USDA regulations or internal guidance or other measures that would eliminate barriers to program participation for Native American farmers and ranchers; (3) to examine methods of maximizing the number of new farming and ranching opportunities created by USDA loan and grant programs through enhanced extension and financial literacy services; (4) to examine methods of encouraging intergovernmental cooperation to mitigate the effects of land tenure and probate issues on the delivery of USDA programs; (5) to evaluate other methods of creating new farming or ranching opportunities for Native American producers; and (6) to address other related issues as deemed appropriate.

Interested persons may present views, orally or in writing, on issues relating to agenda topics before the CNAFR. Written submissions may be submitted to the contact person on or before August 29, 2016. Oral presentations from the public will be heard approximately 1:30 p.m. to 2:30 p.m. on September 1, 2016. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the issue they wish to present and the names and addresses of proposed participants by August 29, 2016. All oral presentations will be given three (3) to five (5) minutes depending on the number of participants.

The OTR will also make the agenda available to the public via the OTR Web site *http://www.usda.gov/tribalrelations* no later than 10 business days before the meeting and at the meeting. The minutes from the meeting will be posted on the OTR Web site. OTR welcomes the attendance of the public at the CNAFR meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Josiah Griffin, at least 5 business days in advance of the meeting.

Leslie Wheelock,

Director, Office of Tribal Relations.

[FR Doc. 2016–19929 Filed 8–19–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Forest Service

Black Hills National Forest Advisory Board

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Black Hills National Forest Advisory Board (Board) will meet in Rapid City, South Dakota. The Board is established consistent with the Federal Advisory Committee Act of 1972 (5 U.S.C. App. II), the Forest and Rangeland Renewable Resources Planning Act of 1974 (16 U.S.C. 1600 *et seq.*), the National Forest Management Act of 1976 (16 U.S.C. 1612), and the Federal Public Lands Recreation Enhancement Act (Pub. L. 108–447). Additional information concerning the Board, including the meeting summary/minutes, can be found by visiting the Board's Web site at: *http://www.fs.usda.gov/main/blackhills/workingtogether/advisorycommittees.*

DATES: The meeting will be held on Wednesday, September 21, 2016, at 1:00 p.m.

All meetings are subject to cancellation. For updated status of meeting prior to attendance, please

contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Mystic Ranger District, 8221 South Highway 16, Rapid City, South Dakota.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses, when provided, are placed in the record and available for public inspection and copying. The public may inspect comments received at the Black Hills National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Scott Jacobson, Board Coordinator, by phone at 605–440–1409 or by email at *sjjacobson@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide:

(1) Rushmore Connector Trail update;

(2) Proposed Land Exchange—Spearfish Canyon/Bismarck Lake;

(3) Teckla-Osage 230 kV Transmission Project update;

(4) Black Hills Resilient Landscapes Project update;

(5) BHNF Timber Program update (FY 16/FY 17);

(6) Forest Health Working Group update;

(7) Recreation Facilities Working Group update; and

(8) Non-motorized Trails/Over Snow Working Group update.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should submit a request in writing by September 12, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the Board may file written statements with the Board's staff before or after the meeting. Written comments and time requests for oral comments must be sent to Scott Jacobson, Black Hills National Forest Supervisor's Office, 1019 North Fifth Street, Custer, South Dakota 57730; by email to *sjjacobson@fs.fed.us,* or via facsimile to 605–673–9208.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: August 15, 2016.

Jim Zornes,

Acting Forest Supervisor.

[FR Doc. 2016–19932 Filed 8–19–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket No. NRCS–2016–006]

Notice of Meeting of the Agricultural Air Quality Task Force

AGENCY: Natural Resources Conservation Service (NRCS), USDA.

ACTION: Notice of meeting.

SUMMARY: The U.S. Department of Agriculture (USDA) Agricultural Air Quality Task Force (AAQTF) will meet for discussions on critical air quality issues relating to agriculture. Special emphasis will be placed on obtaining a greater understanding about the relationship between agricultural production and air quality. The meeting is open to the public. A draft agenda is included in this notice.

DATES: The meeting will convene at 8:00 a.m. PDT on Thursday and Friday September 8–9, 2016. A public comment period will be held on the morning of September 9, 2016. The meeting will end at approximately noon on September 9, 2016.

ADDRESSES: The meeting will be held at the Holiday Inn Sacramento—Capitol Plaza, 300 J Street, Sacramento, California 95814.

FOR FURTHER INFORMATION CONTACT: Questions and comments should be directed to Dr. Greg Johnson, Designated Federal Official, USDA, NRCS, 2901 East Gate City Boulevard, Suite 2100, Greensboro, North Carolina 27401; telephone: (336) 370–3352; fax: (336) 273–8132; email: *greg.johnson@por.usda.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2. Additional information concerning AAQTF, including revised agendas for the September 8–9, 2016, meeting that occurs after this **Federal Register** Notice is published, may be viewed at: *www.nrcs.usda.gov/wps/portal/nrcs/detail/national/air/taskforce.*

Procedural: This meeting is open to the public. On September 9, 2016, the public will have an opportunity to provide up to 5 minutes of input to the AAQTF.

Information on Services for Individuals With Disabilities: For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, please contact Greg Johnson (contact information listed above). USDA prohibits discrimination in its programs and activities on the basis of race, color, national origin, gender, religion, age, sexual orientation, or disability. Additionally, discrimination on the basis of political beliefs and marital or family status is also prohibited by statutes enforced by USDA. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternate means for communication of program information (Braille, large print, audio tape, etc.) should contact the USDA's Target Center at (202) 720–2000 (voice and TDD).

Signed August 12, 2016, in Washington, DC.

Jason A. Weller,

Chief.

Draft Agenda

AAQTF Meeting

September 8–9, 2016, Sacramento, California

A. Welcome Remarks and Introductions

B. USDA and California Air Resources Board Leadership Remarks

C. Particulate Matter Research

D. USDA Climate Change Building Blocks, Greenhouse Gas Mitigation, and U.S. Agriculture

E. Update on Agricultural Air Quality Regulatory Issues at the Environmental Protection Agency

F. Updates from USDA Agencies (Forest Service, NRCS, National Institute of Food and Agriculture, and Agricultural Research Service)

G. AAQTF Subcommittee Formation and Break-Out Sessions

H. Reactive Nitrogen Guest Speaker

I. Public Input (**Note:** Individual presentations will be limited to 5 minutes.)

* Please note that the timing of events in the agenda is subject to change to accommodate changing schedules of expected speakers and or extended discussions.

[FR Doc. 2016–19872 Filed 8–19–16; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket No. NRCS–2016–0004]

Notice of Proposed Changes to the National Handbook of Conservation Practices for the Natural Resources Conservation Service

AGENCY: Natural Resources Conservation Service (NRCS), U.S. Department of Agriculture (USDA).

ACTION: Notice of availability of proposed changes to NRCS' National Handbook of Conservation Practices for public review and comment.

SUMMARY: Notice is hereby given of the intention of NRCS to issue a series of revised conservation practice standards in the National Handbook of Conservation Practices. These standards include Anionic Polyacrylamide (PAM) Application (Code 450), Compost Facility (Code 317), Constructed Wetland (Code 656), Critical Area Planting (Code 342), Drainage Water Management (Code 554), Feed Management (Code 592), Field Border (Code 386), Filter Strip (Code 393), Irrigation Land Leveling (Code 464), Irrigation System, Surface and Subsurface (Code 443), Residue and Tillage Management, No Till (Code 329), Residue and Tillage Management, Reduced Till (Code 345), and Stream Habitat Improvement (Code 395). NRCS State Conservationists who choose to adopt these practices for use within their States will incorporate them into section IV of their respective electronic Field Office Technical Guide. These practices may be used in conservation systems that treat highly erodible land (HEL) or on land determined to be a wetland. Section 343 of the Federal Agriculture Improvement and Reform Act of 1996 requires NRCS to make available for public review and comment all proposed revisions to conservation practice standards used to carry out HEL and wetland provisions of the law.

DATES: *Effective Date:* This is effective August 22, 2016.

Comment Date: Submit comments on or before September 21, 2016. Final versions of these new or revised conservation practice standards will be adopted after the close of the 30-day period and after consideration of all comments.

ADDRESSES: Comments should be submitted, identified by Docket Number NRCS–2016–0004, using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail or hand-delivery:* Public Comments Processing, Attention: Regulatory and Agency Policy Team, Strategic Planning and Accountability, Natural Resources Conservation Service, 5601 Sunnyside Avenue, Building 1–1112D, Beltsville, Maryland 20705.

NRCS will post all comments on *http://www.regulations.gov.* In general, personal information provided with comments will be posted. If your comment includes your address, phone number, email, or other personal identifying information, your comments, including personal information, may be available to the public. You may ask in your comment that your personal identifying information be withheld from public view, but this cannot be guaranteed.

FOR FURTHER INFORMATION CONTACT: Terri Ruch, Acting National Environmental Engineer, Conservation Engineering Division, Natural Resources Conservation Service, 1400 Independence Avenue SW., South Building, Room 6133, Washington, DC 20250.

Electronic copies of the proposed revised standards are available through *http://www.regulations.gov* by accessing Docket No. NRCS–2016–0004. Alternatively, copies can be downloaded or printed from the following Web site: *http://go.usa.gov/TXye.* Requests for paper versions or inquiries may be directed to Emil Horvath, National Practice Standards Review Coordinator, Natural Resources Conservation Service, Central National Technology Support Center, 501 West Felix Street, Fort Worth, Texas 76115.

SUPPLEMENTARY INFORMATION: The amount of the proposed changes varies considerably for each of the conservation practice standards addressed in this notice. To fully understand the proposed changes, individuals are encouraged to compare these changes with each standard's current version as shown at: *http://www.nrcs.usda.gov/wps/portal/nrcs/detailfull/national/technical/cp/ncps/?cid=nrcs143_026849.* To aid in this comparison, the following are highlights of some of the proposed revisions to each standard.

Anionic PAM Application (Code 450): The revision adds a purpose to the standard, which is to ''improve soil surface infiltration rate and minimize soil crusting to allow for uniform plant growth on irrigated land.'' There was also criteria for this purpose added to the standard which sets the PAM application rate to not exceed 4 pounds per acre, as well as criteria for mixing and injecting PAM.

Compost Facility (Code 317): Revised language to improve readability and clarify intent of criteria. Criteria was revised to include facility siting and design language. Additional sections, ''Criteria for Mechanically Assisted Composting'' and ''Power Supply'' were added.

Constructed Wetland (Code 656): Revised language to improve readability and clarify intent of criteria. Additional conditions related to bioreactors and saturated buffers were added. Added criteria under the heading ''Additional Criteria Applicable to Constructed Wetlands for Water Quality Improvement'' to use the design procedure recognized by the regulatory and academic conservation partners, and to select a design hydraulic retention time that will achieve the intended water quality results. Added consideration to address odor concerns near populated areas.

Critical Area Planting (Code 342): Revised language to improve readability and clarify intent of criteria. The purpose of stabilizing areas being degraded by the concentration of salts or other chemicals was deleted and is covered in other conservation practice standards. Critical slope criteria to stabilize banks, shorelines, and other areas was changed from 2:1 slopes to 3:1 slopes.

Drainage Water Management (Code 554): The entire document was edited for clarity. Two purposes were removed: (1) Reduce wind erosion or particulate matter (dust) emissions and (2) provide seasonal wildlife habitat. Significant additions and clarifications were made to most of the ''General Criteria,'' particularly instructions under ''Control Elevation'' and ''Control Zone.'' Similarly, changes were made to ''Additional Criteria to Reduce Nutrient, Pathogen, and Pesticide Loading;'' and ''Additional Criteria to Improve Productivity, Health, and Vigor of Plants.'' The ''Considerations'' and ''Plans and Specifications'' sections were rewritten.

Feed Management (Code 592): Changes in format, stronger emphasis on feed management for pathogen control and odor and greenhouse gas mitigation, feed management by grouping of animals, as well as select wording changes are incorporated. The new version should be easier to use by NRCS field staff and easier to understand by producers.

Field Border (Code 386): Clarified the ''Purpose'' statements to better align with NRCS resource concerns. Minor

edits were made throughout the document for clarification purposes. Added the purpose: ''reduce excessive sediment in surface waters.''

Filter Strip (Code 393): Practice purposes were revised. Minor editing was made throughout the document to clarify criteria. The noxious or invasive plants language was removed since this is NRCS policy for all matters. Added criteria to remove phosphorus by harvesting above-ground biomass at least once each year.

Irrigation Land Leveling (Code 464): This standard was updated to be more readable and formatted according to current standards. A ''Design'' section was added to the standard to provide current reference information. The ''Operation and Maintenance'' section was expanded to include more detailed information to the operator to ensure the practice will last longer.

Irrigation System, Surface, and Subsurface (Code 443): Very few substantial changes. Clarifying words and grammatical corrections make up the majority of changes. A criteria was added in the ''Application Efficiency and Distribution Uniformity'' section that directs users to the current technical guidance.

Residue and Tillage Management, No Till (Code 329): Practice purposes edited to align with NRCS resource concerns. Added the purpose: ''reduce excessive sediment in surface waters.'' Made minor edits throughout the document to improve clarity. Removed the 2,000 pounds per acre of residue to increase plant available moisture as this is no longer needed for the erosion prediction tools in use at this time. The needed amount of residue now states 60 percent.

Residue and Tillage Management, Reduced Till (Code 345): Added the purpose: ''reduce sheet, rill, and wind erosion, and excessive sediment in surface waters.'' Made minor edits to improve clarity throughout the document. Added the criteria to document and determine the purpose to reduce sheet, rill, and wind erosion, and excessive sediment in surface waters.

Stream Habitat Improvement (Code 395): The definition and purpose are simplified to better focus on habitat. Language was added to better coordinate with other conservation practices. Application of the practice within a watershed context is now required as a specified criterion rather than as a consideration. Revised language as needed to improve readability and clarify intent of criteria.

Signed this 12th day of August 2016, in Washington, DC.

Jason A. Weller,

Chief, Natural Resources Conservation Service.

[FR Doc. 2016–19866 Filed 8–19–16; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

Submission for OMB Review; Comment Request

August 17, 2016.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by September 21, 2016 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Housing Service

Title: Form RD 410–8, Application Reference Letter (A Request for Credit Reference).

OMB Control Number: 0575–0091.

Summary of Collection: The Rural Housing Service (RHS), under Section 502 of Title V of the Housing Act of 1949, as amended, provides financial assistance to construct, improve, alter, repair, replace, or rehabilitate dwellings, which will provide modest, decent, safe, and sanitary housing to eligible individuals in rural areas. Form RD 410–8, *Applicant Reference Letter,* provides credit information and is used by RHS to obtain information about an applicant's credit history that might not appear on a credit report.

Need and Use of the Information: Using form RD–410–8, RHS will collect information to supplement or verify other debts when a credit report is limited and unavailable to determine the applicant's eligibility and creditworthiness for RHS loans and grants. It can be used to document an ability to handle credit effectively for applicants who have not used sources of credit that appear on a credit report. The form provides RHS with relevant information about the applicant's creditworthiness and is used to make better creditworthiness decisions.

For the form to retain the OMB number, this collection is for approval of the form itself. The burden for this form will be accounted for within the individual RD program collection packages using the form.

Description of Respondents: Business or other for-profit.

Number of Respondents: 1.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 1.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2016–19942 Filed 8–19–16; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF COMMERCE

Indirect Cost Rates for the Damage Assessment, Remediation, and Restoration Program for Fiscal Year 2015

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The National Oceanic and Atmospheric Administration's (NOAA's) Damage Assessment, Remediation, and Restoration Program (DARRP) is announcing new indirect cost rates on the recovery of indirect costs for its component organizations involved in natural resource damage assessment and restoration activities for fiscal year (FY) 2015. The indirect cost rates for this fiscal year and date of implementation are provided in this notice. More information on these rates and the DARRP policy can be found at the DARRP Web site at *www.darrp.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: For further information, contact LaTonya Burgess at 301–713–4248, ext. 211, by fax at 301–713–4389, or email at *LaTonya.Burgess@noaa.gov.*

SUPPLEMENTARY INFORMATION: The mission of the DARRP is to restore natural resource injuries caused by releases of hazardous substances or oil under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (42 U.S.C. 9601 *et seq.*) and the Oil Pollution Act of 1990 (OPA) (33 U.S.C. 2701 *et seq.*), and to support restoration of physical injuries to National Marine Sanctuary resources under the National Marine Sanctuaries Act (NMSA) (16 U.S.C. 1431 *et seq.*). The DARRP consists of three component organizations: The Office of Response and Restoration (ORR) within the National Ocean Service; the Restoration Center within the National Marine Fisheries Service; and the Office of the General Counsel Natural Resources Section (GCNRS). The DARRP conducts Natural Resource Damage Assessments (NRDAs) as a basis for recovering damages from responsible parties, and uses the funds recovered to restore injured natural resources.

Consistent with federal accounting requirements, the DARRP is required to account for and report the full costs of its programs and activities. Further, the DARRP is authorized by law to recover reasonable costs of damage assessment and restoration activities under CERCLA, OPA, and the NMSA. Within the constraints of these legal provisions and their regulatory applications, the DARRP has the discretion to develop indirect cost rates for its component organizations and formulate policies on the recovery of indirect cost rates subject to its requirements.

The DARRP's Indirect Cost Effort

In December 1998, the DARRP hired the public accounting firm Rubino & McGeehin, Chartered (R&M) to: Evaluate the DARRP cost accounting system and allocation practices; recommend the appropriate indirect cost allocation methodology; and determine the indirect cost rates for the three organizations that comprise the DARRP. A **Federal Register** notice on R&M's effort, their assessment of the DARRP's cost accounting system and practice, and their determination regarding the most appropriate indirect cost methodology and rates for FYs 1993 through 1999 was published on December 7, 2000 (65 FR 76611).

R&M continued its assessment of DARRP's indirect cost rate system and structure for FYs 2000 and 2001. A second federal notice specifying the DARRP indirect rates for FYs 2000 and 2001 was published on December 2, 2002 (67 FR 71537).

In October 2002, DARRP hired the accounting firm of Cotton and Company LLP (Cotton) to review and certify DARRP costs incurred on cases for purposes of cost recovery and to develop indirect rates for FY 2002 and subsequent years. As in the prior years, Cotton concluded that the cost accounting system and allocation practices of the DARRP component organizations are consistent with federal accounting requirements. Consistent with R&M's previous analyses, Cotton also determined that the most appropriate indirect allocation method continues to be the Direct Labor Cost Base for all three DARRP component organizations. The Direct Labor Cost Base is computed by allocating total indirect cost over the sum of direct labor dollars, plus the application of NOAA's leave surcharge and benefits rates to direct labor. Direct labor costs for contractors from ERT, Inc. (ERT), Freestone Environmental Services, Inc. (Freestone), and Genwest Systems, Inc. (Genwest) were included in the direct labor base because Cotton determined that these costs have the same relationship to the indirect cost pool as NOAA direct labor costs. ERT, Freestone, and Genwest provided on-site support to the DARRP in the areas of injury assessment, natural resource economics, restoration planning and implementation, and policy analysis. Subsequent federal notices have been published in the **Federal Register** as follows:

- FY 2002, published on October 6, 2003 (68 FR 57672)
- FY 2003, published on May 20, 2005 (70 FR 29280)
- FY 2004, published on March 16, 2006 (71 FR 13356)
- FY 2005, published on February 9, 2007 (72 FR 6221)
- FY 2006, published on June 3, 2008 (73 FR 31679)
- FY 2007 and FY 2008, published on November 16, 2009 (74 FR 58948)
- FY 2009 and FY 2010, published on October 20, 2011 (76 FR 65182)
- FY 2011, published on September 17, 2012 (77 FR 57074)
- FY 2012, published on August 29, 2013 (78 FR 53425)
- FY 2013, published on October 14, 2014 (79 FR 61617)
- FY 2014, published on December 17, 2015 (80 FR 78718)

Cotton's recent reports on these indirect rates can be found on the DARRP Web site at *www.darrp.noaa.gov.*

Cotton reaffirmed that the Direct Labor Cost Base is the most appropriate indirect allocation method for the development of the FY 2015 indirect cost rates.

The DARRP's Indirect Cost Rates and Policies

The DARRP will apply the indirect cost rates for FY 2015 as recommended by Cotton for each of the DARRP component organizations as provided in the following table:

DARRP Component organization	FY 2015 Indirect rate %
Office of Response and Restoration (ORR)	151.18
Restoration Center (RC)	60.91
General Counsel, Natural Resources Section (GCNRS)	32.75

These rates are based on the Direct Labor Cost Base allocation methodology.

The FY 2015 rates will be applied to all damage assessment and restoration case costs incurred between October 1, 2014 and September 30, 2015. DARRP will use the FY 2015 indirect cost rates for future fiscal years, beginning with FY 2016, until subsequent year-specific rates can be developed.

For cases that have settled and for cost claims paid prior to the effective date of the fiscal year in question, the DARRP will not re-open any resolved matters for the purpose of applying the revised rates in this policy for these fiscal years. For cases not settled and cost claims not paid prior to the effective date of the fiscal year in question, costs will be recalculated using the revised rates in this policy for these fiscal years. Where a responsible party has agreed to pay costs using previous year's indirect rates, but has not yet made the payment because the settlement documents are not finalized, the costs will not be recalculated.

Dated: August 5, 2016.

David Westerholm,

Director, Office of Response and Restoration.

[FR Doc. 2016–19953 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–25–2016]

Foreign-Trade Zone (FTZ) 133—Quad-Cities, Iowa/Illinois; Authorization of Production Activity; Deere & Company; Subzone 133D (Construction and Forestry Equipment); Davenport, Iowa

On April 15, 2016, Deere & Company submitted a notification of proposed production activity to the Foreign-Trade Zones (FTZ) Board for its facility within Subzone 133D, in Davenport, Iowa.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (81 FR 26200, May 2, 2016). The FTZ Board has determined that no further review of the activity is warranted at this time. The production activity described in the notification is authorized, subject to the FTZ Act and the Board's regulations, including Section 400.14.

Dated: August 15, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–20017 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–117–2016]

Foreign-Trade Zone 262—Southaven, Mississippi; Application for Subzone; ASICS America Corporation; Byhalia, Mississippi

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Northern Mississippi FTZ, Inc., grantee of FTZ 262, requesting subzone status for the facility of ASICS America Corporation, located in Byhalia, Mississippi. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on August 16, 2016.

The proposed subzone (49.665 acres) is located at 549 Wingo Road in Byhalia, Mississippi. The proposed subzone would be subject to the existing activation limit of FTZ 262. No authorization for production activity has been requested at this time.

In accordance with the Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is October 3, 2016. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to October 17, 2016.

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

For further information, contact Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: August 16, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–20013 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–54–2016]

Foreign-Trade Zone 124—Gramercy, Louisiana; Application for Expansion of Subzone 124D; LOOP LLC; Lafourche and St. James Parishes, Louisiana

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Port of South Louisiana, grantee of FTZ 124, requesting an expansion of Subzone 124D on behalf of LOOP LLC. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on August 16, 2016.

Subzone 124D was approved on June 1, 1995 (Board Order 748, 60 FR 30267, June 8, 1995) and expanded on March 29, 2002 (Board Order 1217, 67 FR 17048, April 9, 2002). The subzone currently consists of two sites located in Lafourche and St. James Parishes: *Site 1* (520.72 acres total and 37 miles of pipeline) includes the following parcels: *Parcel A* (10 acres)—Fourchon Booster Station, Highway 1, Fourchon; *Parcel B* (287 acres)—Clovelly Dome Storage Terminal, Clovelly; *Parcel D* (27 acres)—Operations Center, 224 E. 101 Place, Cut Office; *Parcel E* (103.5 acres)—Clovelly Tank Farm, South Lafourche Airport Road, Clovelly; *Parcel F* (80 acres)—Tank Farm adjacent to Parcel E, Clovelly; and, *Parcel G* (13.22 acres)—Small Boat Harbor, located on Bayou Lafourche, Port Fourchon; and, *Site 2* (124 acres and 55 miles of pipeline)—St. James Terminal, located on Bayou Lafourche, Port Fourchon.

The applicant is requesting authority to expand Site 1 of the subzone to include a new 16-acre parcel (Parcel H). The new parcel is located at 224 East 101 Place in Cut Off. No additional authorization for production activity has been requested at this time.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is October 3, 2016. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to October 17, 2016.

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

For further information, contact Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: August 16, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–20020 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–823]

Silicomanganese From India: Final Results No Shipment Determination of Antidumping Duty Administrative Review; 2014–2015

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

SUMMARY: On May 10, 2016, the Department of Commerce (the Department) published the *Preliminary Results* of the 2014–2015 administrative review (AR) of the antidumping duty (AD) order on silicomanganese from India. The period of review (POR) is May 1, 2014, through April 30, 2015. We received no comments from interested parties. Therefore, the Department continues to find that Universal Ferro and Allied Chemicals Ltd. (Universal) had no reviewable transactions of subject merchandise to the United States during the POR.

DATES: Effective August 22, 2016.

FOR FURTHER INFORMATION CONTACT: David Lindgren at (202) 482–3870; AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On May 10, 2016, the Department published the *Preliminary Results* of the AR of the AD order on silicomanganese from India.[1] We invited interested parties to comment on the *Preliminary Results.* No party provided comments. The Department has conducted this AR in accordance with section 751(a)(1) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products subject to the order are all forms, sizes and compositions of silicomanganese, except low-carbon silicomanganese, including silicomanganese briquettes, fines and slag. Silicomanganese is a ferroalloy composed principally of manganese, silicon and iron, and normally contains much smaller proportions of minor elements, such as carbon, phosphorous and sulfur. Silicomanganese is sometimes referred to as ferrosilicon manganese. Silicomanganese is used primarily in steel production as a source of both silicon and manganese. Silicomanganese generally contains by weight not less than 4 percent iron, more than 30 percent manganese, more than 8 percent silicon and not more than 3 percent phosphorous. Silicomanganese is properly classifiable under subheading 7202.30.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Some silicomanganese may also be classified under HTSUS subheading. This scope covers all silicomanganese, regardless of its tariff classification. Although the HTSUS subheadings are provided for convenience and U.S. Customs and Border Protection (CBP) purposes, our written description of the scope remains dispositive.

The low-carbon silicomanganese excluded from this scope is a ferroalloy with the following chemical specifications: minimum 55 percent manganese, minimum 27 percent silicon, minimum 4 percent iron, maximum 0.10 percent phosphorus, maximum 0.10 percent carbon and maximum 0.05 percent sulfur. Low-carbon silicomanganese is used in the manufacture of stainless steel and special carbon steel grades, such as motor lamination grade steel, requiring a very low carbon content. It is sometimes referred to as ferromanganese-silicon. Low-carbon silicomanganese is classifiable under HTSUS subheading 7202.99.8040.

Final Determination of No Shipments

As explained above, in the *Preliminary Results,* the Department found that Universal did not have reviewable entries during the POR. Also in the *Preliminary Results,* the Department stated that it is not appropriate to rescind the review with respect to Universal, but rather complete the review with respect to Universal and issue appropriate instructions to CBP based on the final results.[2]

After issuing the *Preliminary Results,* the Department received no comments from interested parties, and has not received any information that would cause it to alter its preliminary determination. Therefore, for these final results, the Department continues to find that Universal did not have any reviewable entries during the POR. As the Department received no comments or new information for consideration in these final results, the Department has not prepared an Issues and Decision Memorandum for this AR.

Assessment

The Department has determined, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.[3] The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review. Additionally, because the Department determined that Universal had no shipments of subject merchandise during the POR, any suspended entries that entered under Universal's AD case number (*i.e.,* at that exporter's rate) will be liquidated at the all-other rate if there is no rate for the intermediate company(ies) involved in the transaction.[4]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this AR for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For Universal, which claimed no shipments, the cash deposit rate will remain unchanged from the rate assigned to Universal in the most recently completed segment of this proceeding; (2) for previously reviewed or investigated companies, the cash deposit rate will continue to be the company-specific rate published in the most recently completed segment of this proceeding in which that manufacturer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the manufacturer of subject merchandise; and, (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous segment of this proceeding, the cash deposit rate will be the all-others rate of 17.74 percent, as established in the investigation.[5] These deposit

[1] *See Silicomanganese From India: Preliminary Results of Antidumping Duty Administrative Review; 2014–2015,* 81 FR 28826 (May 10, 2016) (*Preliminary Results*).

[2] *See Preliminary Results,* 81 FR at 28826.

[3] *See* 19 CFR 351.212(b).

[4] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[5] *See Silicomanganese from India: Notice of Final Determination of Sales at Less Than Fair Value and Final Negative Critical Circumstances Determination,* 67 FR 15531 (April 2, 2002), as corrected in *Notice of Amended Final Determination of Sales at Less than Fair Value and Antidumping Duty Orders: Silicomanganese from India, Kazakhstan, and Venezuela,* 67 FR 36149 (May 23, 2002).

requirements, when imposed, shall remain in effect until further notice.

Notifications

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

In accordance with 19 CFR 351.305(a)(3), this notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

These final results of this AR and notice are published in accordance with sections 751(a)(l) and 777(i)(l) of the Act and 19 CFR 351.213(h).

Dated: August 15, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–20009 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–036]

Certain Biaxial Integral Geogrid Products From the People's Republic of China: Affirmative Preliminary Determination of Sales at Less Than Fair Value, Affirmative Determination of Critical Circumstances, in Part, and Postponement of Final Determination

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

SUMMARY: The Department of Commerce (''Department'') preliminarily determines that certain biaxial integral geogrid products (''geogrids'') from the People's Republic of China (''PRC'') are being, or are likely to be, sold in the United States at less than fair value (''LTFV''). The period of investigation (''POI'') is July 1, 2015, through December 31, 2015. The estimated weighted-average dumping margins are shown in the ''Preliminary Determination'' section of this notice. Interested parties are invited to comment on this preliminary determination.

DATES: Effective August 22, 2016.

FOR FURTHER INFORMATION CONTACT: Susan Pulongbarit or Julia Hancock, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4031 or (202) 482–1394, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the notice of initiation of this investigation on February 16, 2016.[1] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum, which is dated concurrently with this determination and hereby adopted by this notice.[2] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is geogrids from the PRC. For a full description of the scope of this investigation, *see* the ''Scope of the Investigation,'' in Appendix I.

Scope Comments

In accordance with the preamble to the Department's regulations,[3] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[4] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice,* as well as additional language proposed by the Department. For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Decision Memorandum.[5] The Department is preliminarily modifying the scope language as it appeared in the Initiation Notice to clarify the definition of the term ''molecular orientation'' as it relates to geogrids covered by the scope of this investigation. *See* ''Scope of the Investigation,'' in Appendix I, which includes the additional clarifying language.

Methodology

The Department is conducting this investigation in accordance with section 731 of the Tariff Act of 1930, as amended (''the Act''). We calculated export prices in accordance with section 772(a) of the Act. Because the PRC is a non-market economy within the meaning of section 771(18) of the Act, we calculated normal value (''NV'') in accordance with section 773(c) of the Act. For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.

Preliminary Affirmative Determination of Critical Circumstances, in Part

On May 2, 2016, Petitioner timely filed an amendment to the Petition, pursuant to section 733(e)(1) of the Act and 19 CFR 351.206(c)(2)(i), alleging that critical circumstances exist with respect to imports of the merchandise under consideration.[6] We preliminarily

[1] *See Certain Biaxial Integral Geogrid Products From the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 81 FR 7755 (February 16, 2016) (''*Initiation Notice''*).

[2] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance ''Decision Memorandum for the Preliminary Determination in the Antidumping Duty Investigation of Certain Biaxial Integral Geogrid Products from the People's Republic of China,'' dated concurrently with and hereby adopted by this notice (''Preliminary Decision Memorandum'').

[3] *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27323 (May 19, 1997).

[4] *See Initiation Notice,* 80 FR at 37229.

[5] *See* Preliminary Decision Memorandum.

[6] *See* Letter from Petitioner, ''Amendment to Petition for the Imposition of Antidumping and Countervailing Duties: Biaxial Integral Geogrid Products from the People's Republic of China'' (May 2, 2016) (''CC Allegation'').

determine that critical circumstances exist for Taian Modern [7] and the PRC-wide entity. However, for BOSTD,[8] we preliminarily determine that critical circumstances do not exist. For a full description of the methodology and results of our analysis, *see* the Preliminary Decision Memorandum.

Combination Rates

In the *Initiation Notice,* the Department stated that it would calculate combination rates for the respondents that are eligible for a separate rate in this investigation. Policy Bulletin 05.1 describes this practice.[9]

Preliminary Determination

The Department preliminarily determines that the following weighted-average dumping margins exist:

Exporter	Producer	Weighted-average dumping margin (percent)
BOSTD Geosynthetics Qingdao Ltd	BOSTD Geosynthetics Qingdao Ltd	00.00
Taian Modern Plastic Co., Ltd	Taian Modern Plastic Co., Ltd	38.92
PRC-Wide Entity		66.74

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, we will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of geogrids from the PRC as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register** except for those produced and exported by BOSTD. Because the estimated preliminary weighted-average dumping margin for BOSTD is zero, we are not directing CBP to suspend liquidation of entries of the merchandise it produced and exported.

Section 733(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the later of (a) the date which is 90 days before the date on which the suspension of liquidation was first ordered, or (b) the date on which notice of initiation of the investigation was published. We preliminarily find that critical circumstances exist for imports of geogrids from the PRC produced or exported by Taian Modern and the PRC-wide entity. Accordingly, for Taian Modern and the PRC-wide entity, in accordance with section 733(e)(2)(A) of the Act, the suspension of liquidation shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of this notice.

Pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), the Department will instruct CBP to require a cash deposit [10] equal to the weighted-average amount by which the NV exceeds U.S. price as follows: (1) The cash deposit rate for the exporter/producer combination listed in the table above will be the rate identified for that combination in the table; (2) for all combinations of PRC exporters/producers of merchandise under consideration that have not received their own separate rate above, the cash-deposit rate will be the cash deposit rate established for the PRC-wide entity, 66.74 percent; and (3) for all non-PRC exporters of the merchandise under consideration which have not received their own separate rate above, the cash-deposit rate will be the cash deposit rate applicable to the PRC exporter/producer combination that supplied that non-PRC exporter. These suspension of liquidation instructions will remain in effect until further notice.

We normally adjust antidumping duty cash deposit rates by the amount of export subsidies, where appropriate. In the companion CVD investigation, we preliminarily found that Taian Modern did not receive export subsidies. Therefore, no offset to Taian Modern's cash deposit rates for export subsidies is necessary.[11] With respect to BOSTD, because it is receiving a zero margin, there is no cash deposit rate for BOSTD and therefore no need to make an offset to its' cash deposit rate.[12] For the PRC-wide entity, which received an adverse facts available rate based on information contained in the Petition, as an extension of the adverse inference found necessary pursuant to section 776(b) of the Act, the Department has adjusted the PRC-wide entity's AD cash deposit rate by the lowest export subsidy rate determined for any party in the companion CVD proceeding.[13] Here, that rate is zero and thus, no adjustment is necessary for the PRC-wide rate.[14] [15]

Pursuant to section 777A(f) of the Act, we normally adjust preliminary cash deposit rates for estimated domestic subsidy pass-through, where appropriate. However, in this case there

[7] Taian Modem Plastic Co., Ltd. (''Taian Modern'').

[8] BOSTD Geosynthetics Qingdao Ltd. (''BOSTD'').

[9] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy Bulletin 05.1), available on the Department's Web site at *http://enforcement.trade.gov/policy/bull05-1.pdf.*

[10] *See Modification of Regulations Regarding the Practice of Accepting Bonds During the Provisional Measures Period in Antidumping and Countervailing Duty Investigations,* 76 FR 61042 (October 3, 2011).

[11] *See Countervailing Duty Investigation of Certain Biaxial Integral Geogrid Products From the People's Republic of China: Preliminary Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 81 FR 4292 (June 24, 2016) and accompanying Preliminary Decision Memorandum (''*Geogrids CVD Preliminary Determination*'') (unchanged in *Certain Biaxial Integral Geogrid Products From the People's Republic of China: Amended Preliminary Results of Countervailing Duty Investigation,* 81 FR 48384 (July 25, 2016) (''*Geogrids Amended CVD Preliminary Determination*'')).

[12] *See Aluminum Extrusions From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Rescission, in Part; 2013–2014,* 80 FR 32347 (June 8, 2015) unchanged at *Aluminum Extrusions From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2013–2014,* 80 FR 75060 (December 1, 2015).

[13] *See, e.g., Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value; Preliminary Affirmative Determination of Critical Circumstances; In Part and Postponement of Final Determination,* 80 FR 4250 (January 27, 2015), and accompanying Issues and Decision Memorandum at 35.

[14] *Id.*

[15] *See Drawn Stainless Steel Sinks from the People's Republic of China: Antidumping Duty Investigation,* 77 FR 60673 (October 4, 2012) (''unchanged in *Drawn Stainless Steel Sinks form the People's Republic of China: Investigation, Final Determination,* 78 FR 13019 (February 26, 2013). Because the lowest export subsidy rate determined for any party in the companion CVD investigation, which is 0.00 percent for Taian Modern, the Department is not adjusting the cash deposit rate applicable to the PRC-wide entity. *See Geogrids CVD Preliminary Determination* at 31–2 (Foreign Trade Promotion Fund section).

is no basis to grant a domestic subsidy pass-through adjustment. *See* Preliminary Decision Memorandum.

Disclosure and Public Comment

We intend to disclose the calculations performed to interested parties in this proceeding within five days of the date of announcement of this preliminary determination in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs, rebuttal briefs, and hearing requests.[16] For a schedule of the deadlines for filing case briefs, rebuttal briefs, and hearing requests, *see* the Preliminary Decision Memorandum at Section IX.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by Petitioners. 19 CFR 351.210(e)(2) requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On July 11, 2016, pursuant to 19 CFR 351.210(b) and (e), Taian Modern requested that, contingent upon an affirmative preliminary determination of sales at LTFV, the Department postpone the final determination and that provisional measures be extended to a period not to exceed six months.[17]

In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because (1) our preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, we are postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, we will make our final determination no later than 120 days after the date of publication of this preliminary determination, pursuant to section 735(a)(2) of the Act.[18]

International Trade Commission (ITC) Notification

In accordance with section 733(f) of the Act, we will notify the ITC of our affirmative preliminary determination of sales at LTFV. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: August 16, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The products covered by the scope are certain biaxial integral geogrid products. Biaxial integral geogrid products are a polymer grid or mesh material (whether or not finished, slit, cut-to-length, attached to woven or non-woven fabric or sheet material, or packaged) in which four-sided openings in the form of squares, rectangles, rhomboids, diamonds, or other four-sided figures predominate. The products covered have integral strands that have been stretched to induce molecular orientation into the material (as evidenced by the strands being thinner in width toward the middle between the junctions than at the junctions themselves) constituting the sides of the openings and integral junctions where the strands intersect. The scope includes products in which four-sided figures predominate whether or not they also contain additional strands intersecting the four-sided figures and whether or not the inside corners of the four-sided figures are rounded off or not sharp angles. As used herein, the term ''integral'' refers to strands and junctions that are homogenous with each other. The products covered have a tensile strength of greater than 5 kilonewtons per meter (''kN/m'') according to American Society for Testing and Materials (''ASTM'') Standard Test Method D6637/D6637M in any direction and average overall flexural stiffness of more than 100,000 milligram-centimeter according to the ASTM D7748/D7748M Standard Test Method for Flexural Rigidity of Geogrids, Geotextiles and Related Products, or other equivalent test method standards.

Subject merchandise includes material matching the above description that has been finished, packaged, or otherwise further processed in a third country, including by trimming, slitting, coating, cutting, punching holes, stretching, attaching to woven or non-woven fabric or sheet material, or any other finishing, packaging, or other further processing that would not otherwise remove the merchandise from the scope of the investigations if performed in the country of manufacture of the biaxial integral geogrid.

The products subject to the scope are currently classified in the Harmonized Tariff Schedule of the United States (''HTSUS'') under the following subheading: 3926.90.9995. Subject merchandise may also enter under subheadings 3920.20.0050 and 3925.90.0000. The HTSUS subheadings set forth above are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2016–20024 Filed 8–19–16; 8:45 am]

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[16] *See* 19 CFR 351.309(c)–(d), 19 CFR 351.310(c).

[17] *See* Letter to the Secretary of Commerce from Taian Modern Plastic Co., Ltd.,''Certain Biaxial Integral Geogrid Products from the People's Republic of China: Request to Extend Final Determination'' (July 11, 2016).

[18] *See also* 19 CFR 351.210(e).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–985]

Xanthan Gum From the People's Republic of China: Rescission of 2014–2015 Antidumping Duty New Shipper Review

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

SUMMARY: The Department of Commerce (''Department'') finds that the sale made by Inner Mongolia Jianlong Biochemical Co., Ltd. (''IMJ'') is a non-*bona fide* sale. Therefore, we are rescinding this new shipper review (''NSR'').

DATES: Effective August 22, 2016.

FOR FURTHER INFORMATION CONTACT: Patrick O'Connor, AD/CVD Operations,

Office IV, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0989.

SUPPLEMENTARY INFORMATION:

Background

The Department published its *Preliminary Results* in this NSR on March 22, 2016.[1] Subsequently, IMJ filed a case brief on May 15, 2016 and CP Kelco U.S. (Petitioner) filed a rebuttal brief on May 16, 2016.

Scope of the Order

The scope of the order covers dry xanthan gum, whether or not coated or blended with other products. Further, xanthan gum is included in this order regardless of physical form, including, but not limited to, solutions, slurries, dry powders of any particle size, or unground fiber. Merchandise covered by the scope of this order is classified in the Harmonized Tariff Schedule (''HTS'') of the United States at subheading 3913.90.20. This tariff classification is provided for convenience and customs purposes; however, the written description of the scope is dispositive.[2]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties are addressed in the Issues and Decision Memorandum.[3] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content. A list of the issues which parties raised is attached to this notice as an Appendix.

Rescission of New Shipper Review

For the reasons explained in the Issues and Decision Memorandum, the Department continues to find that IMJ's one sale is a non-*bona fide* sale. Because the non-*bona fide* sale was the only reported sale of subject merchandise during the POR, and thus there are no reviewable transactions, the Department is rescinding this NSR.

Assessment

As the Department is rescinding this NSR, we have not calculated a company-specific dumping margin for IMJ. IMJ remains part of the PRC-wide entity and, accordingly, entries of its subject merchandise will be assessed at the PRC-wide rate.

Cash Deposit Requirements

Effective upon publication of this notice of final rescission of the NSR of IMJ, the Department will instruct U.S. Customs and Border Protection to discontinue the option of posting a bond or security in lieu of a cash deposit for entries of subject merchandise from IMJ. IMJ continues to be part of the PRC-wide entity, and subject to the PRC-wide entity rate of 154.07 percent.[4] These cash deposit requirements shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a reminder to parties subject to Administrative Protective Order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in these segments of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this notice in accordance with sections 751(a)(2)(B) and 777(i) of the Tariff Act of 1930, as amended, and 19 CFR 351.214.

Dated: August 12, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—Issues and Decision Memorandum

[FR Doc. 2016–20014 Filed 8–19–16; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–016]

Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Notice of Final Results of Antidumping Duty Changed Circumstances Review

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

SUMMARY: On July 8, 2016, the Department of Commerce (the Department) published its notice of initiation and preliminary results of a changed circumstances review of the antidumping duty (AD) order on certain passenger vehicle and light truck tires (passenger tires) from the People's Republic of China (PRC). In that notice, we preliminarily determined that Sailun Jinyu Group (HONG KONG) Co., Limited (Sailun Jinyu HK) is the successor-in-interest to Jinyu International Holding Co., Limited (Jinyu HK) for purposes of determining antidumping duty cash deposits and liabilities. No interested party submitted comments regarding the initiation and preliminary results. For these final results, the Department continues to find that Sailun Jinyu HK is the successor-in-interest to Jinyu HK.

DATES: Effective August 22, 2016.

FOR FURTHER INFORMATION CONTACT: Toni Page, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1398.

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[1] *See Xanthan Gum From the People's Republic of China: Preliminary Rescission of 2014–2015 Antidumping Duty New Shipper Review,* 81 FR 15240 (March 22, 2016) (''*Preliminary Results*''); *see also* Memorandum to Abdelali Elouaradia, Director, Office IV, AD/CVD Operations, from Cara Lofaro and Brandon Farlander, International Trade Analysts, entitled ''2014–2015 Antidumping Duty New Shipper Review of Xanthan Gum From the People's Republic of China: Preliminary *Bona Fide* Sales Analysis for Inner Mongolia Jianlong Biochemical Co., Ltd.,'' dated March 15, 2016.

[2] For a complete description of the scope of the order, *see* the Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, entitled ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty New Shipper Review of Xanthan Gum from the People's Republic of China'' issued concurrently with and hereby adopted by this notice (''Issues and Decision Memorandum'').

[3] *Id.*

[4] *See Xanthan Gum From the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 78 FR 43143 (July 19, 2013).

SUPPLEMENTARY INFORMATION:

Background

On August 10, 2015, the Department published in the **Federal Register** an AD order on passenger tires from the PRC.[1] On December 21, 2015, Jinyu HK, an exporter of passenger tires covered by this order, changed its name from Jinyu HK to Sailun Jinyu HK. On February 23, 2016, Jinyu HK requested that the Department conduct a changed circumstances review under section 751(b) of the Tariff Act of 1930 (the Act), as amended, 19 CFR 351.216, and 19 CFR 351.221(c)(3).[2] In this request, Jinyu HK asked the Department to determine that Sailun Jinyu HK it is the successor-in-interest to Jinyu HK and, accordingly, to assign it Jinyu HK's cash deposit rate.[3]

On July 8, 2016, the Department published its notice of initiation and preliminary results of this changed circumstances review, determining that Sailun Jinyu HK is the successor-in-interest to Jinyu HK.[4] In the *Initiation and Preliminary Results,* we provided all interested parties with an opportunity to comment and to request a public hearing regarding our preliminary finding that Sailun Jinyu HK is the successor-in-interest to Jinyu HK. We received no comments regarding our preliminary finding and no requests for a public hearing from interested parties within the time period set forth in the *Initiation and Preliminary Results.*

Scope of the Order

The products covered by the scope of this order are passenger vehicle and light truck tires. Passenger vehicle and light truck tires are new pneumatic tires, of rubber, with a passenger vehicle or light truck size designation. Tires covered by this order may be tube-type, tubeless, radial, or non-radial, and they may be intended for sale to original equipment manufacturers or the replacement market.

Subject tires have, at the time of importation, the symbol ''DOT'' on the sidewall, certifying that the tire conforms to applicable motor vehicle safety standards. Subject tires may also have the following prefixes or suffix in their tire size designation, which also appears on the sidewall of the tire:

Prefix designations:

P—Identifies a tire intended primarily for service on passenger cars.

LT—Identifies a tire intended primarily for service on light trucks.

Suffix letter designations:

LT—Identifies light truck tires for service on trucks, buses, trailers, and multipurpose passenger vehicles used in nominal highway service.

All tires with a ''P'' or ''LT'' prefix, and all tires with an ''LT'' suffix in their sidewall markings are covered by this investigation regardless of their intended use.

In addition, all tires that lack a ''P'' or ''LT'' prefix or suffix in their sidewall markings, as well as all tires that include any other prefix or suffix in their sidewall markings, are included in the scope, regardless of their intended use, as long as the tire is of a size that is among the numerical size designations listed in the passenger car section or light truck section of the Tire and Rim Association Year Book, as updated annually, unless the tire falls within one of the specific exclusions set out below.

Passenger vehicle and light truck tires, whether or not attached to wheels or rims, are included in the scope. However, if a subject tire is imported attached to a wheel or rim, only the tire is covered by the scope.

Specifically excluded from the scope are the following types of tires:

(1) Racing car tires; such tires do not bear the symbol ''DOT'' on the sidewall and may be marked with ''ZR'' in size designation;

(2) new pneumatic tires, of rubber, of a size that is not listed in the passenger car section or light truck section of the Tire and Rim Association Year Book;

(3) pneumatic tires, of rubber, that are not new, including recycled and retreaded tires;

(4) non-pneumatic tires, such as solid rubber tires;

(5) tires designed and marketed exclusively as temporary use spare tires for passenger vehicles which, in addition, exhibit each of the following physical characteristics:

(a) the size designation and load index combination molded on the tire's sidewall are listed in Table PCT–1B (''T'' Type Spare Tires for Temporary Use on Passenger Vehicles) of the Tire and Rim Association Year Book,

(b) the designation ''T'' is molded into the tire's sidewall as part of the size designation, and,

(c) the tire's speed rating is molded on the sidewall, indicating the rated speed in MPH or a letter rating as listed by Tire and Rim Association Year Book, and the rated speed is 81 MPH or a ''M'' rating;

(6) tires designed and marketed exclusively for specialty tire (ST) use which, in addition, exhibit each of the following conditions:

(a) the size designation molded on the tire's sidewall is listed in the ST sections of the Tire and Rim Association Year Book,

(b) the designation ''ST'' is molded into the tire's sidewall as part of the size designation,

(c) the tire incorporates a warning, prominently molded on the sidewall, that the tire is ''For Trailer Service Only'' or ''For Trailer Use Only'',

(d) the load index molded on the tire's sidewall meets or exceeds those load indexes listed in the Tire and Rim Association Year Book for the relevant ST tire size, and

(e) either

(i) the tire's speed rating is molded on the sidewall, indicating the rated speed in MPH or a letter rating as listed by Tire and Rim Association Year Book, and the rated speed does not exceed 81 MPH or an ''M'' rating; or

(ii) the tire's speed rating molded on the sidewall is 87 MPH or an ''N'' rating, and in either case the tire's maximum pressure and maximum load limit are molded on the sidewall and either

(1) both exceed the maximum pressure and maximum load limit for any tire of the same size designation in either the passenger car or light truck section of the Tire and Rim Association Year Book; or

(2) if the maximum cold inflation pressure molded on the tire is less than any cold inflation pressure listed for that size designation in either the passenger car or light truck section of the Tire and Rim Association Year Book, the maximum load limit molded on the tire is higher than the maximum load limit listed at that cold inflation pressure for that size designation in either the passenger car or light truck section of the Tire and Rim Association Year Book;

(7) tires designed and marketed exclusively for off-road use and which, in addition, exhibit each of the following physical characteristics:

(a) the size designation and load index combination molded on the tire's sidewall are listed in the off-the-road, agricultural, industrial or ATV section

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[1] *See Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Order; and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 FR 47902 (August 10, 2015) (*AD Order*).

[2] *See* letter from Jinyu HK entitled, ''Jinyu International Holding Co., Limited's Request for a Changed Circumstances Review in Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China, Case No. A–570–016,'' at 1 (February 23, 2016) (CCR Request).

[3] *Id.*

[4] *See* ''*Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China,''* 88 FR 44588 (July 8, 2016) (*Initiation and Preliminary Results*).

of the Tire and Rim Association Year Book,

(b) in addition to any size designation markings, the tire incorporates a warning, prominently molded on the sidewall, that the tire is ''Not For Highway Service'' or ''Not for Highway Use'',

(c) the tire's speed rating is molded on the sidewall, indicating the rated speed in MPH or a letter rating as listed by the Tire and Rim Association Year Book, and the rated speed does not exceed 55 MPH or a ''G'' rating, and

(d) the tire features a recognizable off-road tread design.

The products covered by the order are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4011.10.10.10, 4011.10.10.20, 4011.10.10.30, 4011.10.10.40, 4011.10.10.50, 4011.10.10.60, 4011.10.10.70, 4011.10.50.00, 4011.20.10.05, and 4011.20.50.10. Tires meeting the scope description may also enter under the following HTSUS subheadings: 4011.99.45.10, 4011.99.45.50, 4011.99.85.10, 4011.99.85.50, 8708.70.45.45, 8708.70.45.60, 8708.70.60.30, 8708.70.60.45, and 8708.70.60.60. While HTSUS subheadings are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive.

Final Results of Changed Circumstances Review

For the reasons stated in the *Initiation and Preliminary Results,* and because we received no comments from interested parties to the contrary, the Department continues to find that Sailun Jinyu HK is the successor-in-interest to Jinyu HK. As a result of this determination, we find that Sailun Jinyu HK should receive the AD cash deposit rate previously assigned to Jinyu HK in the *AD Order* for passenger tires from the PRC.[5] Consequently, the Department will instruct U.S. Customs and Border Protection to suspend liquidation of all shipments of subject merchandise produced or exported by Sailun Jinyu HK and entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register** at 0.00 percent, which is the current AD cash deposit rate for Jinyu HK.[6] This cash deposit requirement shall remain in effect until further notice.

We are issuing this determination and publishing these final results and notice in accordance with sections 751(b)(1) and 777(i)(1) and (2) of the Act and 19 CFR 351.216 and 351.221(c)(3).

Dated: August 15, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–20023 Filed 8–19–16; 8:45 am]

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[5] *See AD Order.*

[6] Jinyu HK (as part of the Sailun Group Co., Ltd.) received a cash deposit rate of 0.00 percent in the investigation of passenger tires from the PRC. *See AD Order,* at 47904. Because we determined that Sailun Jinyu HK is the successor-in-interest to Jinyu HK, we will assign Sailun Jinyu HK a cash deposit rate based on the amended final determination of that investigation.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE435

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Site Characterization Surveys off the Coast of Massachusetts

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with regulations implementing the Marine Mammal Protection Act (MMPA), notification is hereby given that NMFS has issued an Incidental Harassment Authorization (IHA) to Bay State Wind LLC (Bay State Wind) to take marine mammals, by harassment, incidental to high-resolution geophysical (HRG) and geotechnical survey investigations associated with marine site characterization activities off the coast of Massachusetts in the area of the Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (OCS–A 0500) (the Lease Area).

DATES: Effective August 13, 2016, through August 12, 2017.

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

SUPPLEMENTARY INFORMATION:

Availability

An electronic copy of Bay State Wind's IHA application (the application) and supporting documents, as well as a list of the references cited in this document, may be obtained by visiting the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental/.* In case of problems accessing these documents, please call the contact listed above (see **FOR FURTHER INFORMATION CONTACT**).

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On December 4, 2015, NMFS received an application from Bay State Wind for the taking of marine mammals incidental to spring 2016 geophysical survey investigations off the coast of Massachusetts in the OCS–A 0500 Lease Area, designated and offered by the U.S. Bureau of Ocean Energy Management (BOEM), to support the development of an offshore wind project. NMFS determined that the application was adequate and complete on January 27, 2016. On January 20, 2016, Bay State Wind submitted a separate request for the taking of marine mammals incidental to proposed geotechnical

survey activities within the Lease Area scheduled for fall 2016. On February 26, 2016, Bay State Wind submitted a revision to the take request for the geotechnical activities and an addendum requesting that the two IHA requests be processed as a single application and IHA. NMFS determined that the combined application was adequate and complete on February 26, 2016. NMFS published a notice making preliminary determinations and proposing to issue an IHA on April 5, 2016 (81 FR 19557). The notice initiated a 30-day comment period.

The proposed geophysical survey activities would occur for four weeks beginning in August 2016, and geotechnical survey activities would take place in September 2016 and last for approximately 6 days. The following specific aspects of the proposed activities are likely to result in the take of marine mammals: shallow and medium-penetration sub-bottom profiler (chirper and sparker) and equipment positioning system (also referred to as acoustic positioning system, or pinger) use during the HRG survey, and dynamically positioned (DP) vessel thruster use in support of geotechnical survey activities. Take, by Level B Harassment only, of individuals of nine species of marine mammals is anticipated to result from the specified activities.

Description of the Specified Activity

Overview

Bay State Wind's proposed activities discussed here are based on its February 26, 2016, final IHA application. Bay State Wind proposes to conduct a geophysical and geotechnical survey in the Lease Area to support the characterization of the existing seabed and subsurface geological conditions in the Lease Area. This information is necessary to support the siting and design of up to two floating light and detection ranging buoys (FLIDARs) and up to two metocean monitoring buoys, as well as to obtain a baseline assessment of seabed/sub-surface soil conditions in the Bay State Wind Massachusetts Lease Area to support the siting of the proposed wind farm.

Dates and Duration

HRG surveys are anticipated to commence in August 2016 and will last for approximately 30 days. Geotechnical surveys requiring the use of the DP drill ship will take place in September 2016, at the earliest, and will last for approximately 6 days.

Specified Geographic Region

Bay State Wind's survey activities will occur in the approximately 187,532-acre Lease Area designated and offered by BOEM, located approximately 14 miles (mi) south of Martha's Vineyard, Massachusetts, at its closest point (see Figure 1–1 of the application). The Lease Area falls within the Massachusetts Wind Energy Area (MA WEA; Figure 1–1 of the application). An evaluation of site assessment activities within the MA WEA was fully assessed in the BOEM Environmental Assessment (EA) and associated Finding of No Significant Impact (BOEM 2014). A Biological Opinion on site assessment activities within the MA WEA was issued by NMFS' Greater Atlantic Regional Fisheries Office (formerly Northeast Regional Office) to BOEM in April 2013.

Detailed Description of Activities

The **Federal Register** notice for the proposed IHA (81 FR 19557; April 5, 2016; pages 19558–19560) contains a full detailed description of the geotechnical and geophysical survey activities, including the sources proposed to be used and vessel details. That information has not changed and is therefore not repeated here.

Comments and Responses

A notice of NMFS' proposal to issue an IHA to Bay State Wind was published in the **Federal Register** on April 5, 2016 (81 FR 19557). That notice described, in detail, Bay State Wind's proposed activities, the marine mammal species that may be affected by the proposed activities, and the anticipated effects on marine mammals and their habitat. During the 30-day public comment period, NMFS only received comments from the Marine Mammal Commission (Commission). Specific comments and responses are provided below. Comments are also posted at *http://www.nmfs.noaa.gov/pr/permits/incidental/.*

Comment 1: The Commission recommended a 24-hour ''reset'' for enumerating takes by applying standard rounding rules *before* summing the numbers of estimated takes across days. The Commission has made similar rounding recommendations for other recent proposed incidental harassment authorizations.

Response: NMFS generally does not round take calculations to derive a daily take estimate prior to summing values across total project days. Rather, we apply standard rounding rules at the end of our calculations, which we feel results in a more accurate estimation of takes over the duration of the project and authorization. NMFS appreciates the Commission's recommendation and concurs that a consistent approach to estimating potential takes, where appropriate, is important. We will consider the Commission's recommended methodology on an action-specific basis.

Comment 2: The Commission recommended that NMFS revise its take estimates for harbor and gray seals by removing the 80 percent reduction factor that was used to calculate takes in Bay State Wind's application and in the proposed IHA (81 FR 19557; ''Estimated Take by Incidental Harassment,'' pages 19573–19575).

Response: NMFS agrees with the Commission's recommendation to no longer use a reduction factor to estimate harbor and gray seal densities in the project area. In the proposed IHA, NMFS had applied an 80 percent reduction factor for harbor and gray seal densities based on the presumption that original density estimates for the project area were an overestimation because they included breeding populations of Cape Cod (Schroeder 2000; Ronald and Gots 2003). NMFS has since determined that the findings used to inform that reduction factor are outdated and do not accurately reflect the average annual rate of population increase (especially for gray seal) (refer to Waring *et al.,* 2015 for information on population size and current population trend), and this reduction factor is no longer appropriate for calculating takes for harbor and gray seals. NMFS has revised the take estimates accordingly for harbor and gray seals in this final IHA, using the densities reported in the Northeast Navy Operations Area (OPAREA) Density Estimates (see Table 3). Despite the resulting increase in take numbers for harbor and gray seals, estimated takes continue to represent extremely small numbers (less than 1 percent) relative to the affected species or stock sizes. NMFS will continue to advise future applicants to use up to date density estimates that reflect best available information for harbor and gray seals (and other marine mammals) as these data become available.

Comment 3: The Commission recommended that until behavior thresholds are updated, that NMFS require applicants to use the 120-dB rather than 160-dB Level B harassment threshold for sub-bottom profilers. The Commission has made similar comments on other NMFS authorizations (*e.g.,* ExxonMobil Alaska liquefied natural gas geophysical surveys; NMFS Fisheries Science Center fisheries research) proposed for

activities using acoustic non-impulsive sources, including sub-bottom profilers, echosounders, and other sonars (*e.g.,* side scan and fish-finding).

Response: The 120-dB threshold is typically associated with continuous sources. Continuous sounds are those whose sound pressure level remains above that of the ambient sound, with negligibly small fluctuations in level (NIOSH 1998; ANSI 2005). Intermittent sounds are defined as sounds with interrupted levels of low or no sound (NIOSH 1998). Sub-bottom profiler signals are intermittent sounds. Intermittent sounds can further be defined as either impulsive or non-impulsive. Impulsive sounds have been defined as sounds which are typically transient, brief (<1 second), broadband, and consist of a high peak pressure with rapid rise time and rapid decay (ANSI 1986; NIOSH 1998). Non-impulsive sounds typically have more gradual rise times and longer decays (ANSI 1995; NIOSH 1998). Sub-bottom profiler signals have durations that are typically very brief (<1 second), with temporal characteristics that more closely resemble those of impulsive sounds than non-impulsive sounds. With regard to behavioral thresholds, we therefore consider the temporal and spectral characteristics of sub-bottom profiler signals to more closely resemble those of an impulse sound rather than a continuous sound. The 160-dB threshold is typically associated with impulsive sources.

The Commission has suggested that, for certain sources considered here, the interval between pulses is so small it should be considered continuous. However, a sub-bottom profiler chirp's pulse train is emitted in a similar fashion as odontocete echolocation click trains. Research indicates that marine mammals, in general, have extremely fine auditory temporal resolution and can detect each signal separately (*e.g.,* Au *et al.,* 1988; Dolphin *et al.,* 1995; Supin and Popov 1995; Mooney *et al.,* 2009), especially for species with echolocation capabilities. Therefore, it is highly unlikely that marine mammals would perceive sub-bottom profiler signals as being continuous.

In conclusion, sub-bottom profiler signals are intermittent rather than continuous signals, and the fine temporal resolution of the marine mammal auditory system allows them to perceive these sounds as such. Further, the physical characteristics of these signals indicate a greater similarity to the way that intermittent, impulsive sounds are received. Therefore, the 160-dB threshold (typically associated with impulsive sources) is more appropriate than the 120-dB threshold (typically associated with continuous sources) for estimating takes by behavioral harassment incidental to use of such sources.

NMFS agrees with the Commission's recommendation to update existing acoustic criteria and thresholds as necessary to specify threshold levels that would be more appropriate for a wider range of sound sources, and is currently in the process of producing such revisions. In particular, NMFS recognizes the importance of context (*e.g.,* behavioral state of the animals, distance) in behavioral responses. The current behavioral categorization (*i.e.,* impulse vs. continuous) does not account for context and is not appropriate for all sound sources. Thus, updated NMFS Acoustic Guidance (*http://www.nmfs.noaa.gov/pr/acoustics/guidelines.htm*), once finalized, will more appropriately categorize behavioral harassment criteria by activity type. NMFS recognizes, as new science becomes available, that our current categorizations (*i.e.,* impulse vs. continuous) may not fully encompass the complexity associated with behavioral responses (*i.e.,* context, etc.) and are working toward addressing these issues in future acoustic guidance. However, in the meanwhile, while our current behavioral acoustic thresholds may not fully account for some of the differences observed across taxa and contexts, they still serve as somewhat conservative generalized indicators of received levels at which we anticipate behavioral harassment, and are not undermined by newer information.

Comment 4: The Commission commented that the number of days used to estimate takes for the planned HRG and geotechnical surveys was determined in an inconsistent manner. The Commission recommended that if NMFS plans to include weather contingency days in its calculation of takes for HRG surveys it should also include weather contingency days for the geotechnical surveys as well.

Response 4: The notice of the proposed IHA was not clear regarding NMFS' consideration of weather contingency days in the calculating of takes. To clarify, additional days for weather downtime were not factored into the calculation of takes for either the HRG or geotechnical surveys. Takes for the HRG survey were calculated based on the 30 days estimated for completion of that survey effort, and takes for the geotechnical survey were based on a total of 6 days of survey work. There was no difference in NMFS' approach to calculating takes for these two survey activities.

Comment 5: The Commission recommended that NMFS work with the BOEM Office of Renewable Energy to develop clear and consistent guidance for applicants regarding appropriate mitigation measures and the circumstances under which adoption of such measures would avoid the potential for taking marine mammals and the need for an incidental harassment authorization. The Commission further recommended that NMFS use a consistent approach for reducing (or not reducing) the numbers of estimated takes based on the requirement to implement mitigation measures to preclude taking in the respective Level B harassment zones.

Response 5: NMFS agrees with the Commission that close coordination with BOEM is needed to maintain appropriate and consistent guidance for potential applicants, including with regards to mitigation and monitoring strategies that might potentially reduce the potential for taking marine mammals or preclude the need for a MMPA authorization. NMFS has been working closely with BOEM to develop a stage-based approach to mitigation, monitoring, and reporting for each stage of offshore wind farm development. This is especially important in light of the growing potential for OCS wind farm development in the Atlantic, where there is uncertainty regarding impacts and in which an applicant may need to engage in multi-regulatory and compliance efforts and processes that involve other agencies (*e.g.,* BOEM, Federal Energy Regulatory Commission, U.S. Army Corps of Engineers) who may include standard mitigation measures for protected species as part of their compliance requirements. Often these compliance efforts occur well before an applicant considers an MMPA authorization (as an example, the mitigation requirements and other standard operating conditions for the geophysical and geotechnical activities covered by the BOEM Lease OCS–A 0500 were developed over a year ago).

NMFS appreciates the Commission's recommendation and concurs that a consistent approach to estimating potential takes, where appropriate, is important. With few exceptions (*e.g.,* pile-driving activities in Cook Inlet—as referenced in the Commission's comment letter), NMFS generally does not factor in the implementation of mitigation measures to reduce Level B harassment takes in its MMPA authorizations. Rather, we base our analysis and negligible impact determinations on the actual number of

takes that are authorized and without accounting for any potential post-mitigation reductions in take numbers. In the case of this IHA, and despite the fact that the total number of takes authorized is unlikely to actually occur due to the very restrictive mitigation measures (*e.g.,* shutdown/powerdown if an animal enters the Level B harassment isopleths), it was NMFS' opinion that some Level B takes would still occur due to the nature and duration of the survey activities within these harassment zones (*e.g.,* night time operations; large [up to 3.4 km] Level B harassment zones in some cases) and the potential to take listed species (as corroborated by the 2013 Biological Opinion), thus, warranting the issuance of an MMPA authorization.

Description of Marine Mammals in the Area of the Specified Activity

The ''Description of Marine Mammals in the Area of the Specified Activities'' section has not changed from what was in the proposed IHA (81 FR 19557; April 5, 2016; pages 19560–19561). The following species are both common in the waters of the Northwest Atlantic Outer Continental Shelf (OCS) region south of Massachusetts and have the highest likelihood of occurring, at least seasonally, in the Lease Area: North Atlantic right whale (*Eubalaena glacialis*), humpback whale (*Megaptera novaeangliae*), fin whale (*Balaenoptera physalus*), minke whale (*Balaenoptera acutorostrata*), harbor porpoise (*Phocoena phocoena*), Atlantic white-sided dolphin (*Lagenorhynchus acutus*), short-beaked common dolphin (*Delphinus delphis*), harbor seal (*Phoca vitulina*), and gray seal (*Halichorus grypus*). Three of these species are listed under the Endangered Species Act (ESA): North Atlantic right whale, humpback whale, and fin whale.

Further information on the biology, ecology, abundance, and distribution of those species likely to occur in the Lease Area can be found in Bay State Wind's application and in the NMFS Marine Mammal Stock Assessment Reports (see Waring *et al.,* 2015), which are available online at: *http://www.nmfs.noaa.gov/pr/species/mammals.*

Potential Effects of the Specified Activity on Marine Mammals and Their Habitat

We provided a detailed discussion of the potential effects of the specified activity on marine mammals and their habitat in the notice of the proposed IHA (81 FR 19557; April 5, 2016; pages 19561–19567). That information has not changed and is not repeated here.

Mitigation

In order to issue an incidental take authorization under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (where relevant).

Mitigation Measures

With NMFS' input during the application process, and as per the BOEM Lease, Bay State Wind shall implement the following mitigation measures during site characterization surveys utilizing HRG survey equipment and use of the DP thruster. The mitigation measures outlined in this section are based on protocols and procedures that have been successfully implemented for similar offshore projects and previously approved by NMFS (ESS 2013; Dominion 2013 and 2014).

Marine Mammal Exclusion Zones

Protected species observers (PSOs) shall monitor the following exclusion/monitoring zones for the presence of marine mammals:

- A 400-m exclusion zone during HRG surveys when the sub-bottom profiler is in operation.
- A 200-m exclusion zone during HRG surveys when all other equipment (*i.e.,* equipment positioning systems) is in operation.
- A 3,500-m monitoring zone during the use of DP thrusters during geotechnical survey activities.

The radial distances from the sound sources for these exclusion/monitoring zones were derived from acoustic modeling (see Appendix A of the application) and cover the area for both the Level A and Level B harassment zones (*i.e.,* the 190/180 dB and 160 dB isopleths, respectively) when HRG survey equipment is in use, and the Level B harassment zone (the 120 dB isopleth) when DP thrusters are in use; DP thrusters will not produce sound levels at 180 dB re 1 μPa (rms). Acoustic modeling of the HRG survey equipment and DP thrusters was completed based on a version of the U.S. Naval Research Laboratory's Range-dependent Acoustic Model (RAM) and BELLHOP Gaussian beam ray-trace propagation model (Porter and Liu, 1994). The representative area ensonified to the Level B harassment threshold for each of the pieces of HRG survey equipment and for the DP thruster use represents the zone within which take of a marine mammal could occur. The distances to the Level A and Level B harassment thresholds were used to support the estimate of take as well as the development of the monitoring and/or mitigation measures. The complete acoustic modeling assessment can be found in Appendix A of the application, and is also summarized in the notice of the proposed IHA (81 FR 19557; April 5, 2016; pages 19567–19568). Radial distance to NMFS' Level A and Level B harassment thresholds are summarized in Tables 1 and 2.

TABLE 1—MODELED DISTANCES TO MMPA THRESHOLDS FOR MARINE MAMMALS DURING HRG SURVEY

HRG equipment	Marine mammal Level A harassment 180 dB_{RMS} re 1 μPa (m)*	Marine mammal Level B harassment 160 dB_{RMS} re 1 μPa (m)
ixBlue GAPS (pinger)	<10	25
Sonardyne Scout USBL (pinger)	0	25
GeoPulse Sub-bottom Profiler (chirper)	30	75
Geo-Source 800 (sparker)	80	250
Geo-Source 200 (sparker)	90	380

* Distances to NMFS' 190 dB Level A harassment threshold for pinnipeds are smaller.

TABLE 2—MODELED DISTANCES TO MMPA THRESHOLDS FOR MARINE MAMMALS DURING GEOTECHNICAL SURVEY USING DP THRUSTERS

Survey equipment	Marine mammal Level A harassment 180 dB_{RMS} re 1 µPa (m)	Marine mammal Level B harassment 120 dB_{RMS} re 1 µPa (m)
DP Thrusters—at 38 m depth	N/A	2,875
DP Thrusters—at 44 m depth	N/A	3,225
DP Thrusters—at 54 m depth	N/A	3,400

Visual monitoring of the established exclusion zone(s) for the HRG and geotechnical surveys will be performed by qualified and NMFS-approved PSOs, the resumes of whom will be provided to NMFS for review and approval prior to the start of survey activities. Observer qualifications will include direct field experience on a marine mammal observation vessel and/or aerial surveys in the Atlantic Ocean/Gulf of Mexico. An observer team comprising a minimum of four NMFS-approved PSOs and two certified Passive Acoustic Monitoring (PAM) operators (PAM operators will not function as PSOs), operating in shifts, will be stationed aboard either the survey vessel or a dedicated PSO-vessel. PSOs and PAM operators will work in shifts such that no one monitor will work more than four consecutive hours without a two-hour break or longer than 12 hours during any 24-hour period. During daylight hours the PSOs will rotate in shifts of one on and three off, while during nighttime operations PSOs will work in pairs. The PAM operators will also be on call as necessary during daytime operations should visual observations become impaired. Each PSO will monitor 360 degrees of the field of vision.

PSOs will be responsible for visually monitoring and identifying marine mammals approaching or within the established exclusion zone(s) during survey activities. It will be the responsibility of the Lead PSO on duty to communicate the presence of marine mammals as well as to communicate and enforce the action(s) that are necessary to ensure mitigation and monitoring requirements are implemented as appropriate. PAM operators will communicate detections/vocalizations to the Lead PSO on duty, who will then be responsible for implementing the necessary mitigation procedures. A mitigation and monitoring communications flow diagram has been included as Appendix B in the IHA application.

PSOs will be equipped with binoculars and have the ability to estimate distances to marine mammals located in proximity to the vessel and/or exclusion zone using range finders. Reticulated binoculars will also be available to PSOs for use as appropriate based on conditions and visibility to support the siting and monitoring of marine species. Digital single-lens reflex camera equipment will be used to record sightings and verify species identification. During night operations or when visual observation is otherwise impaired (*e.g.,* during bad weather, rough sea conditions, poor lighting conditions), PAM (see *Passive Acoustic Monitoring* requirements below) and night-vision devices with infrared light-emitting diodes spotlights, in combination with infrared video monitoring, will be used (for additional details regarding proposed PAM, night-vision, and infrared technologies, refer to Section 2.5 Alternative Monitoring Plan in the Bay State Wind Offshore Wind Farm Site Assessment Plan [SAP] Survey Plan [BOEM 2016], which was submitted pursuant to Addendum C, Lease Stipulation 2.1.1.1 of the BOEM Lease). Position data will be recorded using hand-held or vessel global positioning system (GPS) units for each sighting.

The PSOs will begin observation of the exclusion zone(s) at least 60 minutes prior to ramp-up of HRG survey equipment. Use of noise-producing equipment will not begin until the exclusion zone is clear of all marine mammals for at least 60 minutes, as per the requirements of the BOEM Lease.

If a marine mammal is detected approaching or entering the 200-m or 400-m exclusion zones during the HRG survey, or the 3,500-m monitoring zone during DP thrusters use, the vessel operator would adhere to the shutdown (during HRG survey) or powerdown (during DP thruster use) procedures described below to minimize noise impacts on the animals.

At all times, the vessel operator will maintain a separation distance of 500 m from any sighted North Atlantic right whale as stipulated in the *Vessel Strike Avoidance* procedures described below. These stated requirements will be included in the site-specific training to be provided to the survey team.

Vessel Strike Avoidance

Bay State Wind will ensure that vessel operators and crew maintain a vigilant watch for cetaceans and pinnipeds and slow down or stop their vessels to avoid striking these species. Survey vessel crew members responsible for navigation duties will receive site-specific training on marine mammal and sea turtle sighting/reporting and vessel strike avoidance measures. Vessel strike avoidance measures will include the following, except under extraordinary circumstances when complying with these requirements would put the safety of the vessel or crew at risk:

- All vessel operators will comply with 10 knot (<18.5 km per hour [km/h]) speed restrictions in any Dynamic Management Area (DMA). In addition, all vessels operating from November 1 through July 31 will operate at speeds of 10 knots (<18.5 km/h) or less.
- All survey vessels will maintain a separation distance of 500 m or greater from any sighted North Atlantic right whale.
- If underway, vessels must steer a course away from any sited North Atlantic right whale at 10 knots (<18.5 km/h) or less until the 500 m minimum separation distance has been established. If a North Atlantic right whale is sited in a vessel's path, or within 100 m to an underway vessel, the underway vessel must reduce speed and shift the engine to neutral. Engines will not be engaged until the North Atlantic right whale has moved outside of the vessel's path and beyond 100 m. If stationary, the vessel must not engage engines until the North Atlantic right whale has moved beyond 100 m.
- All vessels will maintain a separation distance of 100 m or greater from any sighted non-delphinoid (*i.e.,* mysticetes and sperm whales) cetaceans. If sighted within 100 m, the vessel underway must reduce speed and shift the engine to neutral, and must not engage the engines until the non-delphinoid cetacean has moved outside of the vessel's path and beyond 100 m.

If a survey vessel is stationary, the vessel will not engage engines until the non-delphinoid cetacean has moved out of the vessel's path and beyond 100 m.

- All vessels will maintain a separation distance of 50 m or greater from any sighted delphinoid cetacean. Any vessel underway will remain parallel to a sighted delphinoid cetacean's course whenever possible, and avoid excessive speed or abrupt changes in direction. Any vessel underway will reduce vessel speed to 10 knots or less when pods (including mother/calf pairs) or large assemblages of delphinoid cetaceans are observed. Vessels may not adjust course and speed until the delphinoid cetaceans have moved beyond 50 m and/or abeam (*i.e.,* moving away and at a right angle to the centerline of the vessel) of the underway vessel.
- All vessels will maintain a separation distance of 50 m (164 ft) or greater from any sighted pinniped.

The training program will be provided to NMFS for review and approval prior to the start of surveys. Confirmation of the training and understanding of the requirements will be documented on a training course log sheet. Signing the log sheet will certify that the crew members understand and will comply with the necessary requirements throughout the survey event.

Seasonal Operating Requirements

Between watch shifts, members of the monitoring team will consult the NMFS North Atlantic right whale reporting systems for the presence of North Atlantic right whales throughout survey operations. The proposed survey activities will, however, occur outside of the seasonal management area (SMA) located off the coast of Massachusetts and Rhode Island. The proposed survey activities will also occur in August and September, which is outside of the seasonal mandatory speed restriction period for this SMA (November 1 through April 30).

Throughout all survey operations, Bay State Wind will monitor the NMFS North Atlantic right whale reporting systems for the establishment of a DMA. If NMFS should establish a DMA in the Lease Area under survey, within 24 hours of the establishment of the DMA Bay State Wind will work with NMFS to shut down and/or alter the survey activities to avoid the DMA.

Passive Acoustic Monitoring

As per the BOEM Lease, alternative monitoring technologies (*e.g.,* active or passive acoustic monitoring) are required if a Lessee intends to conduct geophysical or geotechnical surveys at night or when visual observation is otherwise impaired (*e.g.,* during bad weather, rough sea conditions, poor lighting conditions). To support 24-hour survey operations, Bay State Wind will use certified PAM operators with experience reviewing and identifying recorded marine mammal vocalizations, as part of the project monitoring during nighttime operations to provide for optimal acquisition of species detections at night, or as needed during periods when visual observations may be impaired. In addition, PAM systems shall be employed during daylight hours to support system calibration and PSO and PAM team coordination, as well as in support of efforts to evaluate the effectiveness of the various mitigation techniques (*i.e.,* visual observations during day and night, compared to the PAM detections/operations).

Given the range of species that could occur in the Lease Area, and that these species vary with regard to their vocalization frequencies (high vs. low), the PAM system will consist of an array of hydrophones with both broadband (sampling frequencies of 2 kHz to 200 kHz) and at least one low-frequency hydrophone (sampling range frequencies of 10 Hz to 30 kHz). Monitoring of the PAM system will be conducted from a customized processing station aboard the survey vessel. The on-board processing station provides the interface between the PAM system and the operator. The PAM operator(s) will monitor the hydrophone signals in real time both aurally (using headphones) and visually (via the monitor screen displays). Bay State Wind proposes the use of PAMGuard software for 'target motion analysis' to support localization in relation to the identified exclusion zone. PAMGuard is an open source and versatile software/hardware interface to enable flexibility in the configuration of in-sea equipment (number of hydrophones, sensitivities, spacing, and geometry). PAM operators will immediately communicate detections/vocalizations to the Lead PSO on duty who will ensure the implementation of the appropriate mitigation measure (*e.g.,* shutdown) even if visual observations by PSOs have not been made.

Additional details regarding the proposed PAM system can be found in Section 2.5 Alternative Monitoring Plan in the Bay State Wind Offshore Wind Farm SAP Survey Plan (BOEM, 2016).

Ramp-Up

As per the BOEM Lease, a ramp-up procedure will be used for HRG survey equipment capable of adjusting energy levels at the start or re-start of HRG survey activities. A ramp-up procedure will be used at the beginning of HRG survey activities in order to provide additional protection to marine mammals near the Lease Area by allowing them to vacate the area prior to the commencement of survey equipment use. The ramp-up procedure will not be initiated during daytime, night time, or periods of inclement weather if the exclusion zone cannot be adequately monitored by the PSOs using the appropriate visual technology (*e.g.,* reticulated binoculars, night vision equipment) and/or PAM for a 60-minute period. A ramp-up would begin with the power of the smallest acoustic HRG equipment at its lowest practical power output appropriate for the survey. The power would then be gradually turned up and other acoustic sources added such that the source level would increase in steps not exceeding 6 dB per 5-minute period. If marine mammals are detected within the HRG survey exclusion zone prior to or during the ramp-up, activities will be delayed until the animal(s) has moved outside the monitoring zone and no marine mammals are detected for a period of 60 minutes.

Shutdown and Powerdown

HRG Survey—The exclusion zone(s) around the noise-producing activities HRG survey equipment will be monitored, as previously described, by PSOs and at night by PAM operators for the presence of marine mammals before, during, and after any noise-producing activity. The vessel operator must comply immediately with any call for shutdown by the Lead PSO. Any disagreement should be discussed only after shutdown.

As per the BOEM Lease, if a non-delphinoid (*i.e.,* mysticetes and sperm whales) cetacean is detected at or within the established exclusion zone (200-m exclusion zone during equipment positioning systems use; 400-m exclusion zone during the operation of the sub-bottom profiler), an immediate shutdown of the HRG survey equipment is required. Subsequent restart of the electromechanical survey equipment must use the ramp-up procedures described above and may only occur following clearance of the exclusion zone for 60 minutes. These are conservative shutdown zones, as the 200 and 400-m exclusion radii exceed the distances to the estimated Level B harassment isopleths (Table 1).

As per the BOEM Lease, if a delphinoid cetacean or pinniped is detected at or within the exclusion zone, the HRG survey equipment (including the sub-bottom profiler) must

be powered down to the lowest power output that is technically feasible. Subsequent power up of the survey equipment must use the ramp-up procedures described above and may occur after (1) the exclusion zone is clear of a delphinoid cetacean and/or pinniped for 60 minutes or (2) a determination by the PSO after a minimum of 10 minutes of observation that the delphinoid cetacean or pinniped is approaching the vessel or towed equipment at a speed and vector that indicates voluntary approach to bow-ride or chase towed equipment.

If the HRG sound source (including the sub-bottom profiler) shuts down for reasons other than encroachment into the exclusion zone by a marine mammal including but not limited to a mechanical or electronic failure, resulting in the cessation of sound source for a period greater than 20 minutes, a restart for the HRG survey equipment (including the sub-bottom profiler) is required using the full ramp-up procedures and clearance of the exclusion zone of all cetaceans and pinnipeds for 60 minutes. If the pause is less than 20 minutes, the equipment may be restarted as soon as practicable at its operational level as long as visual surveys were continued diligently throughout the silent period and the exclusion zone remained clear of cetaceans and pinnipeds. If the visual surveys were not continued diligently during the pause of 20 minutes or less, a restart of the HRG survey equipment (including the sub-bottom profiler) is required using the full ramp-up procedures and clearance of the exclusion zone for all cetaceans and pinnipeds for 60 minutes.

Geotechnical Survey (DP Thrusters)—During geotechnical survey activities, a constant position over the drill, coring, or deep cone penetration test site must be maintained to ensure the integrity of the survey equipment. Any stoppage of DP thruster during the proposed geotechnical activities has the potential to result in significant damage to survey equipment. Therefore, during geotechnical survey activities if marine mammals enter or approach the established 3,500-m 120 dB isopleth monitoring zone, Bay State Wind shall reduce DP thruster to the maximum extent possible, except under circumstances when reducing DP thruster use would compromise safety (both human health and environmental) and/or the integrity of the equipment. Reducing thruster energy will effectively reduce the potential for exposure of marine mammals to sound energy. After decreasing thruster energy, PSOs will continue to monitor marine mammal behavior and determine if the animal(s) is moving towards or away from the established monitoring zone. If the animal(s) continues to move towards the sound source then DP thruster use would remain at the reduced level. Normal use will resume when PSOs report that the marine mammals have moved away from and remained clear of the monitoring zone for a minimum of 60 minutes since the last sighting.

Mitigation Conclusions

NMFS has carefully evaluated Bay State Wind's mitigation measures in the context of ensuring that we prescribe the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and
- The practicability of the measure for applicant implementation.

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

1. Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).

2. A reduction in the numbers of marine mammals (total number or number at biologically important time or location) exposed to received levels of activities that we expect to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

3. A reduction in the number of times (total number or number at biologically important time or location) individuals would be exposed to received levels of activities that we expect to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

4. A reduction in the intensity of exposures (either total number or number at biologically important time or location) to received levels of activities that we expect to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing the severity of harassment takes only).

5. Avoidance or minimization of adverse effects to marine mammal habitat, paying special attention to the food base, activities that block or limit passage to or from biologically important areas, permanent destruction of habitat, or temporary destruction/disturbance of habitat during a biologically important time.

6. For monitoring directly related to mitigation—an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on our evaluation of the proposed measures, as well as other measures considered by NMFS, NMFS has determined that the proposed mitigation measures provide the means of effecting the least practicable impact on marine mammals species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

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

Monitoring measures prescribed by NMFS should accomplish one or more of the following general goals:

1. An increase in our understanding of the likely occurrence of marine mammal species in the vicinity of the action, *i.e.,* presence, abundance, distribution, and/or density of species.

2. An increase in our understanding of the nature, scope, or context of the likely exposure of marine mammal species to any of the potential stressor(s) associated with the action (*e.g.,* sound or visual stimuli), through better understanding of one or more of the following: The action itself and its environment (*e.g.,* sound source characterization, propagation, and ambient noise levels); the affected species (*e.g.,* life history or dive pattern); the likely co-occurrence of marine mammal species with the action (in whole or part) associated with specific adverse effects; and/or the likely biological or behavioral context of exposure to the stressor for the marine

mammal (*e.g.,* age class of exposed animals or known pupping, calving, or feeding areas).

3. An increase in our understanding of how individual marine mammals respond (behaviorally or physiologically) to the specific stressors associated with the action (in specific contexts, where possible, *e.g.,* at what distance or received level).

4. An increase in our understanding of how anticipated individual responses, to individual stressors or anticipated combinations of stressors, may impact either: The long-term fitness and survival of an individual; or the population, species, or stock (*e.g.,* through effects on annual rates of recruitment or survival).

5. An increase in our understanding of how the activity affects marine mammal habitat, such as through effects on prey sources or acoustic habitat (*e.g.,* through characterization of longer-term contributions of multiple sound sources to rising ambient noise levels and assessment of the potential chronic effects on marine mammals).

6. An increase in understanding of the impacts of the activity on marine mammals in combination with the impacts of other anthropogenic activities or natural factors occurring in the region.

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

8. An increase in the probability of detecting marine mammals (through improved technology or methodology), both specifically within the safety zone (thus allowing for more effective implementation of the mitigation) and in general, to better achieve the above goals.

Monitoring Measures

Bay State Wind submitted a marine mammal monitoring and reporting plan as part of the IHA application.

Visual Monitoring—Visual monitoring of the established Level B harassment zones (400-m radius for sub-bottom profiler and 200-m radius for equipment positioning system use during HRG surveys [note that these are the same as the mitigation exclusion/shutdown zones established for HRG survey sound sources]; 3,500-m radius during DP thruster use [note that this is the same as the mitigation powerdown zone established for DP thruster sound sources]) will be performed by qualified and NMFS-approved PSOs (see discussion of PSO qualifications and requirements in *Marine Mammal Exclusion Zones* above).

The PSOs will begin observation of the monitoring zone during all HRG survey activities and all geotechnical operations where DP thrusters are employed. Observations of the monitoring zone will continue throughout the survey activity and/or while DP thrusters are in use. PSOs will be responsible for visually monitoring and identifying marine mammals approaching or entering the established monitoring zone during survey activities.

Observations will take place from the highest available vantage point on the survey vessel. General 360 degree scanning will occur during the monitoring periods, and target scanning by the PSO will occur when alerted of a marine mammal presence.

Data on all PSO observations will be recorded based on standard PSO collection requirements. This will include dates and locations of survey operations; vessel activity during sighting, time and location (*i.e.,* distance from sound source) of observation; weather conditions (*i.e.,* percent cloud cover, visibility, percent glare); water conditions (*i.e.,* Beaufort sea-state, tidal state, swell); details of the sightings (species, description of observed animal, sex, age classification [if known], numbers); and reaction of the animal(s) to relevant sound source (if any) and observed animal behavior (*e.g.,* avoidance, approach), including bearing and direction of travel. The data sheet will be provided to both NMFS and BOEM for review and approval prior to the start of survey activities. In addition, prior to initiation of survey work, all crew members will undergo environmental training, a component of which will focus on the procedures for sighting and protection of marine mammals. A briefing will also be conducted between the survey supervisors and crews, the PSOs, and Bay State Wind. The purpose of the briefing will be to establish responsibilities of each party, define the chains of command, discuss communication procedures, provide an overview of monitoring purposes, and review operational procedures.

Acoustic Field Verification—As per the requirements of the BOEM Lease, field verification of the exclusion/monitoring zones will be conducted to determine whether the proposed zones correspond accurately to the relevant isopleths and are adequate to minimize impacts to marine mammals. The details of the field verification strategy will be provided in a Field Verification Plan no later than 45 days prior to the commencement of field verification activities.

Bay State Wind must conduct field verification of the exclusion zone (the 160 dB isopleth) for HRG survey equipment and the powerdown zone (the 120 dB isopleth) for DP thruster use for all equipment operating below 200 kHz. Bay State Wind must take acoustic measurements at a minimum of two reference locations and in a manner that is sufficient to establish source level (peak at 1 meter) and distance to the 180 dB and 160 dB isopleths (the Level A and B harassment zones for HRG surveys) and 120 dB isopleth (the Level B harassment zone) for DP thruster use. Sound measurements must be taken at the reference locations at two depths (*i.e.,* a depth at mid-water and a depth at approximately 1 meter [3.28 ft] above the seafloor).

Bay State Wind may use the results from its field-verification efforts to request modification of the exclusion/monitoring zones for the HRG or geotechnical surveys. Any new exclusion/monitoring zone radius proposed by Bay State Wind must be based on the most conservative measurements (*i.e.,* the largest safety zone configuration) of the target Level A or Level B harassment acoustic threshold zones. The modified zone must be used for all subsequent use of field-verified equipment. Bay State Wind must obtain approval from NMFS and BOEM of any new exclusion/monitoring zone before it may be implemented.

Reporting Measures

Bay State Wind will provide the following reports as necessary during survey activities:

- Bay State Wind will contact NMFS and BOEM within 24 hours of the commencement of survey activities and again within 24 hours of the completion of the activity.
- As per the BOEM Lease: Any observed significant behavioral reactions (*e.g.,* animals departing the area) or injury or mortality to any marine mammals must be reported to NMFS and BOEM within 24 hours of observation. Dead or injured protected species are reported to the NMFS Greater Atlantic Regional Fisheries Office Stranding Hotline (800–900–3622) within 24 hours of sighting, regardless of whether the injury is caused by a vessel. In addition, if the injury or death was caused by a collision with a project related vessel, Bay State Wind must ensure that NMFS and BOEM are notified of the strike within 24 hours. Bay State Wind must use the form included as Appendix A to Addendum C of the Lease to report the sighting or incident. If Bay State Wind is responsible for the injury or death, the vessel must assist with any salvage

effort as requested by NMFS. Additional reporting requirements for injured or dead animals are described below (*Notification of Injured or Dead Marine Mammals*).

• *Notification of Injured or Dead Marine Mammals*—In the unanticipated event that the specified HRG and geotechnical activities lead to an injury of a marine mammal (Level A harassment) or mortality (*e.g.,* ship-strike, gear interaction, and/or entanglement), Bay State Wind would immediately cease the specified activities and report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources and the NOAA Greater Atlantic Regional Fisheries Office (GARFO) Stranding Coordinator. The report would include the following information:

• Time, date, and location (latitude/longitude) of the incident;

• Name and type of vessel involved;

• Vessel's speed during and leading up to the incident;

• Description of the incident;

• Status of all sound source use in the 24 hours preceding the incident;

• Water depth;

• Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);

• Description of all marine mammal observations in the 24 hours preceding the incident;

• Species identification or description of the animal(s) involved;

• Fate of the animal(s); and

• Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the event. NMFS would work with Bay State Wind to minimize reoccurrence of such an event in the future. Bay State Wind would not resume activities until notified by NMFS.

In the event that Bay State Wind discovers an injured or dead marine mammal and determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.,* in less than a moderate state of decomposition), Bay State Wind would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources and the GARFO Stranding Coordinator. The report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with Bay State Wind to determine if modifications in the activities are appropriate.

In the event that Bay State Wind discovers an injured or dead marine mammal and determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Bay State Wind would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Greater Atlantic Regional Fisheries Office Regional Stranding Coordinator, within 24 hours of the discovery. Bay State Wind would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS. Bay State Wind can continue its operations under such a case.

• Within 90 days after completion of the marine site characterization survey activities, a draft technical report will be provided to NMFS and BOEM that fully documents the methods and monitoring protocols, summarizes the data recorded during monitoring (as identified above in *Visual Monitoring*), estimates the number of marine mammals that may have been taken during survey activities, and provides an interpretation of the results and effectiveness of all monitoring tasks. Any recommendations made by NMFS must be addressed in the final report prior to acceptance by NMFS.

• In addition to the reporting requirements outlined above, Bay State Wind will provide an assessment report of the effectiveness of the various mitigation techniques, *i.e.* visual observations during day and night, compared to the PAM detections/operations. This will be submitted as a draft to NMFS and BOEM 30 days after the completion of the HRG and geotechnical surveys and as a final version 60 days after completion of the surveys.

Estimated Take by Incidental Harassment

Project activities that have the potential to harass marine mammals, as defined by the MMPA, include underwater noise from operation of the HRG survey sub-bottom profilers and equipment positioning systems, and noise propagation associated with the use of DP thrusters during geotechnical survey activities that require the use of a DP drill ship. Harassment could take the form of temporary threshold shift, avoidance, or other changes in marine mammal behavior. NMFS anticipates that impacts to marine mammals would be in the form of behavioral harassment and no take by injury, serious injury, or mortality is proposed. NMFS does not anticipate take resulting from the movement of vessels associated with construction because there will be a limited number of vessels moving at slow speeds over a relatively shallow, nearshore area.

The basis for the take estimate is the number of marine mammals that would be exposed to sound levels in excess of NMFS' Level B harassment criteria for impulsive noise (160 dB re 1 μPa (rms) and continuous noise (120 dB re 1 μPa (rms.)). NMFS' current acoustic exposure criteria for estimating take are shown in Table 3 below. Bay State Wind's modeled distances to these acoustic exposure criteria are shown in Tables 1 and 2. Details on the model characteristics and results are provided in the hydroacoustic modeling assessment found in Appendix A of the IHA application. As discussed in the application and in Appendix A, modeling took into consideration sound sources using the loudest potential operational parameters, bathymetry, geoacoustic properties of the Lease Area, time of year, and marine mammal hearing ranges. Results from the hydroacoustic modeling assessment showed that estimated maximum critical distance to the 160 dB re 1 μPa (rms) MMPA threshold for all water depths for the HRG survey sub-bottom profilers (the HRG survey equipment with the greatest potential for effect on marine mammal) was approximately 380 m from the source (see Table 1), and the estimated maximum critical distance to the 120 dB re 1 μPa (rms) MMPA threshold for all water depths for the drill ship DP thruster was approximately 3,400 m from the source (see Table 2). Bay State Wind and NMFS believe that these estimates represent the worst-case scenario and that the actual distances to the Level B harassment threshold may be shorter.

TABLE 3—NMFS' CURRENT ACOUSTIC EXPOSURE CRITERIA

Criterion	Criterion definition	Threshold
Non-Explosive Sound:		
Level A Harassment (Injury)	Permanent Threshold Shift (PTS) (Any level above that which is known to cause TTS).	180 dB re 1 μPa-m (cetaceans)/190 dB re 1 μPa-m (pinnipeds) root mean square (rms).
Level B Harassment	Behavioral Disruption (for impulse noises)	160 dB re 1 μPa-m (rms).
Level B Harassment	Behavioral Disruption (for continuous noise)	120 dB re 1 μoPa-m (rms).

Bay State Wind estimated species densities within the proposed project area in order to estimate the number of marine mammal exposures to sound levels above the 120 dB Level B harassment threshold for continuous noise (*i.e.,* DP thrusters) and the 160 dB Level B harassment threshold for intermittent, impulsive noise (*i.e.,* pingers and sub-bottom profiler). Research indicates that marine mammals generally have extremely fine auditory temporal resolution and can detect each signal separately (*e.g.,* Au *et al.,* 1988; Dolphin *et al.,* 1995; Supin and Popov 1995; Mooney *et al.,* 2009b), especially for species with echolocation capabilities. Therefore, it is likely that marine mammals would perceive the acoustic signals associated with the HRG survey equipment as being intermittent rather than continuous, and we base our takes from these sources on exposures to the 160 dB threshold.

The data used as the basis for estimating cetacean species density for the Lease Area are sightings per unit effort (SPUE) taken from Kenney and Vigness-Raposa (2009). SPUE (or, the relative abundance of species) is derived by using a measure of survey effort and number of individual cetaceans sighted. Species density (animals per km^2) can be computed by dividing the SPUE value by the width of the marine mammal survey track, and numbers of animals can be computed by multiplying the species density by the size of the geographic area in question (km^2). SPUE allows for comparison between discrete units of time (*i.e.* seasons) and space within a project area (Shoop and Kenney 1992). SPUE calculated by Kenney and Vigness-Raposa (2009) was derived from a number of sources including: (1) North Atlantic Right Whale Consortium (NARWC) database; (2) University of Rhode Island Cetacean and Turtle Assessment Program (CeTAP); (3) sightings data from the Coastal Research and Education Society of Long Island, Inc. and Okeanos Ocean Research Foundation; (4) the Northeast Regional Stranding network (marine mammals); and (5) the NOAA Northeast Fisheries Science Center's Fisheries Sampling Branch.

The OPAREA Density Estimates (U.S. Department of the Navy 2007) were used for estimating takes for harbor and gray seals. In the proposed IHA, NMFS had applied an 80 percent reduction factor for harbor and gray seal densities based on the presumption that original density estimates for the project area were an overestimation because they included breeding populations of Cape Cod (Schroeder 2000; Ronald and Gots 2003). NMFS has since determined that the findings used to inform that reduction factor are outdated and do not accurately reflect the average annual rate of population increase (especially for gray seal), and this reduction factor is no longer appropriate for calculating takes for harbor and gray seals.

The methodology for calculating takes was described in the **Federal Register** notice for the proposed IHA (81 FR 19557; April 5, 2016). Estimated takes were calculated by multiplying the species density (per 100 km^2) by the zone of influence (ZOI), multiplied by the number of days of the specified activity. A detailed description of the acoustic modeling used to calculate zones of influence is provided in the acoustic modeling assessment found in Appendix A of the IHA application (also see the discussion in the ''Mitigation'' section above).

Bay State Wind used a ZOI of 23.6 m^2 (61 km^2) and a survey period of 30 days to estimate take from use of the HRG survey equipment during geophysical survey activities. The ZOI is based on the worst case (since it assumes the higher powered GeoSource 200 sparker will be operating all the time) ensonified area of 380 m, and a maximum survey trackline of 49 mi (79 km) per day. Based on the proposed HRG survey schedule, take calculations were based on the species density as derived from seasonal SPUE data reported in Kenney and Vigness-Raposa (2009) and seasonal OPAREA density estimates (U.S. Department of the Navy 2007). The resulting take estimates (rounded to the nearest whole number) are presented in Table 4.

TABLE 4—ESTIMATED LEVEL B HARASSMENT TAKES FOR HRG SURVEY ACTIVITIES

Species	Density [1] (number/100 km^2)	Calculated take (number)	Take authorization (number)	Percentage of stock potentially affected
North Atlantic Right Whale	0.07	1.28	1	0.22
Humpback Whale	0.05	0.92	1	0.01
Fin Whale	0.14	2.56	3	0.19
Minke Whale	0.44	8.05	8	0.04
Common Dolphin	8.21	150.24	150	0.12
Atlantic White-sided Dolphin	7.46	136.52	137	0.28
Harbor Porpoise	0.23	4.21	4	0.01
Harbor Seal [2]	9.74	178.24	178	0.23
Gray Seal [2]	14.16	259.13	259	0.07

[1] Densities have been updated since the publishing of the proposed IHA to more accurately reflect the seasonality of the proposed HRG survey activities (August–September). Seasonal densities, and resulting takes, depicted in the proposed IHA were based on a projected spring HRG survey, which is no longer accurate. Despite this change in seasonal densities and take numbers there were no changes in our analysis or negligible impact determination since the publishing of the proposed IHA.

[2] An 80 percent reduction factor for harbor and gray seal densities was applied in the proposed IHA based on the presumption that original density estimates for the project area were an overestimation because they included breeding populations of Cape Cod (Schroeder, 2000; Ronald and Gots, 2003). NMFS has since determined that the findings used to inform that reduction factor are outdated and do not accurately reflect the average annual rate of population increase (especially for gray seal). Therefore, NMFS no longer considers this reduction factor appropriate for calculating takes for harbor and gray seals.

Bay State Wind used a ZOI of 9.8 m^2 (25.4 km^2) and a maximum DP thruster use period of 6 days to estimate take from use of the DP thruster during geotechnical survey activities. The ZOI represents the worst-case ensonified area across the three representative water depths within the Lease Area (125 ft, 144 ft, and 177 ft [38m, 44 m, and 54 m]). Based on the proposed geotechnical survey schedule, take calculations were based on the species density as derived from seasonal abundance data reported in Kenney and Vigness-Raposa (2009) and seasonal OPAREA density estimates (U.S. Department of the Navy 2007) (Table 5). The resulting take estimates (rounded to the nearest whole number) based upon these conservative assumptions for common and Atlantic white-sided dolphins are presented in Table 5. These numbers are based on six days and represent only 0.011 and 0.022 percent of the stock for these two species, respectively. Take calculations for North Atlantic right whale, humpback whale, fin whale, minke whale, harbor porpoise, gray seal, and harbor seal are at or near zero (refer to the IHA application); therefore, no takes for these species are requested or proposed for authorization.

TABLE 5—ESTIMATED LEVEL B HARASSMENT TAKES FOR GEOTECHNICAL SURVEY ACTIVITIES

Species	Fall Density (number/100 km^2)	Calculated take (number)	Take authorization (number)	Percentage of stock potentially affected
Common Dolphin	8.21	12.5	13	0.01
Atlantic White-sided Dolphin	7.46	11	11	0.02

Bay State Wind's authorized take numbers are provided in Tables 4 and 5. Bay State Wind's calculations do not take into account whether a single animal is harassed multiple times or whether each exposure is a different animal. Therefore, the numbers in Tables 4 and 5 are the maximum number of animals that may be harassed during the HRG and geotechnical surveys (*i.e.,* Bay State Wind assumes that each exposure event is a different animal). These estimates do not account for prescribed mitigation measures that Bay State Wind would implement during the specified activities and the fact that shutdown/powerdown procedures shall be implemented if an animal enters the Level B harassment zone (160 dB and 120 dB for HRG survey equipment and DP thruster use, respectively), further reducing the potential for any takes to occur during these activities.

Analysis and Determinations

Negligible Impact

Negligible impact is ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival'' (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes, alone, is not enough information on which to base an impact determination, as the severity of harassment may vary greatly depending on the context and duration of the behavioral response, many of which would not be expected to have deleterious impacts on the fitness of any individuals. In determining whether the expected takes will have a negligible impact, in addition to considering estimates of the number of marine mammals that might be ''taken,'' NMFS must consider other factors, such as the likely nature of any responses (their intensity, duration, etc.), the context of any responses (critical reproductive time or location, migration, etc.), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, and the status of the species.

To avoid repetition, the discussion of our analyses applies to all the species listed in Tables 4 and 5, given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar. There is no information about the nature or severity of the impacts, or the size, status, or structure of any species or stocks that would lead to a different analysis for this activity.

As discussed in the ''Potential Effects'' section of the notice of the proposed IHA (81 FR 19557; April 5, 2016; pages 19561–19567), permanent threshold shift, masking, non-auditory physical effects, and vessel strike are not expected to occur. There is some potential for limited TTS; however, animals in the area would likely incur no more than brief hearing impairment (*i.e.,* TTS) due to generally low SPLs—and in the case of the HRG survey equipment use, highly directional beam pattern, transient signals, and moving sound sources—and the fact that most marine mammals would more likely avoid a loud sound source rather than swim in such close proximity as to result in TTS or PTS. Further, once an area has been surveyed, it is not likely that it will be surveyed again, therefore reducing the likelihood of repeated impacts within the project area.

Potential impacts to marine mammal habitat were discussed previously in the ''Anticipated Effects on Marine Mammal Habitat'' section of the notice of the proposed IHA (81 FR 19557; April 5, 2016; page 19567). Marine mammal habitat may be impacted by elevated sound levels and some sediment disturbance, but these impacts would be temporary. Feeding behavior is not likely to be significantly impacted, as marine mammals appear to be less likely to exhibit behavioral reactions or avoidance responses while engaged in feeding activities (Richardson *et al.,* 1995). Prey species are mobile, and are broadly distributed throughout the Lease Area; therefore, marine mammals that may be temporarily displaced during survey activities are expected to be able to resume foraging once they have moved away from areas with disturbing levels of underwater noise. Because of the temporary nature of the disturbance, the availability of similar habitat and resources in the surrounding

area, and the lack of important or unique marine mammal habitat, the impacts to marine mammals and the food sources that they utilize are not expected to cause significant or long-term consequences for individual marine mammals or their populations. Furthermore, there are no feeding areas, rookeries, or mating grounds known to be biologically important to marine mammals within the proposed project area. A biologically important area (BIA) for feeding for North Atlantic right whale encompasses the Lease Area (LaBrecque, *et al.,* 2015); however, there is no temporal overlap between the BIA (effective March–April; November–December) and the proposed survey activities. ESA-listed species for which takes are proposed are North Atlantic right, humpback, and fin whales. Recent estimates of abundance indicate a stable or growing humpback whale population, while examination of the minimum number alive population index calculated from the individual sightings database for the years 1990–2010 suggests a positive and slowly accelerating trend in North Atlantic right whale population size (Waring *et al.,* 2015). There are currently insufficient data to determine population trends for fin whale (Waring *et al.,* 2015). There is no designated critical habitat for any ESA-listed marine mammals within the Lease Area, and none of the stocks for non-listed species proposed to be taken are considered ''depleted'' or ''strategic'' by NMFS under the MMPA.

The mitigation measures are expected to reduce the number and/or severity of takes by (1) giving animals the opportunity to move away from the sound source before HRG survey equipment reaches full energy; (2) reducing the intensity of exposure within a certain distance by reducing the DP thruster power; and (3) preventing animals from being exposed to sound levels reaching 180 dB during HRG survey activities (sound levels in excess of 180 dB are not anticipated for DP thruster use). Additional vessel strike avoidance requirements will further mitigate potential impacts to marine mammals during vessel transit to and within the Study Area.

Bay State Wind did not request, and NMFS is not proposing, take of marine mammals by injury, serious injury, or mortality. NMFS expects that most takes would be in the form of short-term Level B behavioral harassment in the form of brief startling reaction and/or temporary vacating of the area, or decreased foraging (if such activity were occurring)—reactions that are considered to be of low severity and with no lasting biological consequences (*e.g.,* Southall *et al.,* 2007). This is largely due to the short time scale of the proposed activities, the low source levels and intermittent nature of many of the technologies proposed to be used, as well as the required mitigation.

Based on the best available science, NMFS concludes that exposures to marine mammal species and stocks due to Bay State Wind's HRG and geotechnical survey activities would result in only short-term (temporary and short in duration) and relatively infrequent effects to individuals exposed, and not of the type or severity that would be expected to be additive for the very small portion of the stocks and species likely to be exposed. Given the duration and intensity of the activities, and the fact that shipping contributes to the ambient sound levels in the surrounding waters (vessel traffic in this area is relatively high; some marine mammals may be habituated to this noise), NMFS does not anticipate the proposed take estimates to impact annual rates of recruitment or survival. Animals may temporarily avoid the immediate area, but are not expected to permanently abandon the area. Major shifts in habitat use, distribution, or foraging success, are not expected.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS finds that the total marine mammal take from Bay State Wind's proposed HRG survey and DP thruster use during geotechnical survey activities will have a negligible impact on the affected marine mammal species or stocks.

Small Numbers

The requested takes proposed to be authorized for the HRG and geotechnical surveys represent 0.22 percent of the Western North Atlantic (WNA) stock of North Atlantic right whale, 0.01 percent of the Gulf of Maine stock of humpback whale, 0.43 percent of the WNA stock of fin whale, 0.01 percent of the Canadian East Coast stock of minke whale, 0.04 percent of the WNA stock of short-beaked common dolphin, 0.30 percent of the WNA stock of Atlantic white-sided dolphin, 0.01 percent of the Gulf of Maine/Bay of Fundy stock of harbor porpoise, 0.23 percent of the WNA stock of harbor seal, and 0.07 percent of the North Atlantic stock of gray seal. These take estimates represent the percentage of each species or stock that could be taken by Level B behavioral harassment and are extremely small numbers (less than 1 percent) relative to the affected species or stock sizes. Further, the proposed take numbers are the maximum numbers of animals that are expected to be harassed during the project; it is possible that some of these exposures may occur to the same individual. Therefore, NMFS finds that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Within the project area, fin, humpback, and North Atlantic right whale are listed as endangered under the ESA. Under section 7 of the ESA, BOEM consulted with NMFS on commercial wind lease issuance and site assessment activities on the Atlantic Outer Continental Shelf in Massachusetts, Rhode Island, New York and New Jersey Wind Energy Areas. NOAA's GARFO issued a Biological Opinion concluding that these activities may adversely affect but are not likely to jeopardize the continued existence of fin whale, humpback whale, or North Atlantic right whale. NMFS also consulted internally on the issuance of an IHA under section 101(a)(5)(D) of the MMPA for this activity. Following issuance of the Bay State Wind IHA, the Biological Opinion will be amended to include an incidental take exemption for these marine mammal species, as appropriate.

National Environmental Policy Act

BOEM prepared an Environmental Assessment (EA) in accordance with the National Environmental Policy Act (NEPA), to evaluate the issuance of wind energy leases covering the entirety of the Massachusetts Wind Energy Area (including the OCS–A 0500 Lease Area), and the approval of site assessment activities within those leases (BOEM 2014). NMFS has reviewed BOEM's EA, determined it to be sufficient, and adopted that EA and signed a Finding of No Significant Impact (FONSI). We believe that the adoption of BOEM's EA allows NMFS to meet its responsibilities under NEPA for the issuance of an IHA to Bay State Wind for HRG and geotechnical survey investigations in

the Lease Area. BOEM's EA and NMFS' FONSI are available on the internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental/energy_other.htm.*

Authorization

As a result of these determinations, NMFS has issued an IHA to Bay State Wind for HRG survey activities and use of DP vessel thrusters during geotechnical survey activities from August 2016 through August 2017, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–19889 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE825

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Groundfish Plan Teams will meet September 13 through September 16, 2016.

DATES: The meeting will be held on Tuesday, September 13, 2016 to Friday, September 16, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Alaska Fishery Science Center Traynor Room 2076 and NMML Room 2079, 7600 Sand Point Way NE., Building 4, Seattle, WA 98115.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252; telephone: (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Diana Stram, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, September 13, 2016 to Friday, September 16, 2016

The Plan Teams will review the preliminary stock assessments for Groundfish and receive the following reports: Halibut DMR, research priorities, and Economic Stock Assessment and Fishery Evaluation (SAFE).

The Agenda is subject to change, and the latest version will be posted at *http://www.npfmc.org*

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: August 17, 2016.

Tracey L. Thompson,

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

[FR Doc. 2016–19951 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE821

Western Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings and hearings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold a meeting of its Social Science Planning Committee (SSPC) to discuss and make recommendations on relevant issues in Hawaii and the Western Pacific region.

DATES: The SSPC meeting will be held on Thursday, September 15, 2016, from 1 p.m. and 5 p.m., Hawaii Standard Time. For agenda, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The SSPC meeting will be held at the Council office, 1164 Bishop St., Honolulu, HI 96813; phone: (808) 522–8220 and by teleconference line at (888) 482–3560; Passcode: 5228220.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director, phone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: A public comment period will be provided. The order in which agenda items are addressed may change. The meeting will run as late as necessary to complete scheduled business.

Agenda for the SSPC Meeting

Thursday, September 15, 2016, 1 p.m.–5 p.m.

1. Welcome and Introductions
2. Approval of Agenda
3. Welcome New Members
4. Papahanaumokuakea MNM Update
5. Status of April 2016 SSPC Recommendation
6. Status of the Annual/SAFE Reports
7. Update on Human Communities Research Needs
8. SSPC Member Research Updates
9. Identification of Social Researchers
10. Saltonstall Kennedy Grant Solicitation
11. Other Business
12. Public Comment
13. Committee Discussion and Recommendations
14. Next Meeting

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 17, 2016.

Tracey L. Thompson,

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

[FR Doc. 2016–19949 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE826

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public workshop.

SUMMARY: The North Pacific Fishery Management Council's Abundance-

based Prohibited Species Catch (PSC) workshop will meet September 12, 2016.

DATES: The meeting will be held on Monday, September 12, 2016, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Alaska Fishery Science Center 4600 Sand Point Way NE., Building 4, Traynor Room, Seattle, WA 98115.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252; telephone: (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Diana Stram, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION:

Agenda

September 12, 2016

The Council will host a public workshop to provide a presentation on the discussion paper being prepared by the interagency workgroup on halibut abundance-based PSC management approaches. The purpose of the workshop is to provide a public preview of the discussion paper prior to the Council's review at the October Council meeting, to receive feedback on this discussion paper, to better inform the public of the progress on this initiative, and to better facilitate the development of comments from the public to the Council.

The Agenda is subject to change, and the latest version will be posted at *http://www.npfmc.org/*

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: August 17, 2016.

Tracey L. Thompson,

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

[FR Doc. 2016–19950 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE823

Atlantic Coastal Fisheries Cooperative Management Act Provisions; Horseshoe Crabs; Application for Exempted Fishing Permit, 2016

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

ACTION: Notification of a proposal to conduct exempted fishing; request for comments.

SUMMARY: The Director, Office of Sustainable Fisheries, has made a preliminary determination that the subject exempted fishing permit (EFP) application submitted by Limuli Laboratories (Limuli) of Cape May Court House, NJ, contains all the required information and warrants further consideration. The application seeks harvest of up to 10,000 horseshoe crabs from the Carl N. Shuster Jr. Horseshoe Crab Reserve (Reserve) for biomedical purposes and requires, as a condition of the EFP, the collection of data related to the status of horseshoe crabs within the reserve. The Atlantic States Marine Fisheries Commission's (Commission) Horseshoe Crab Technical Committee and Delaware Bay Ecosystem Technical Committee were consulted on the scientific merits of the application. The Director has also made a preliminary determination that the activities authorized under the EFP would be consistent with the goals and objectives of the Commission's Horseshoe Crab Interstate Fisheries Management Plan. Therefore, NMFS announces that the Director proposes to recommend that an EFP be issued that would allow up to two commercial fishing vessels to conduct fishing operations that are otherwise restricted by the regulations promulgated under the Atlantic Coastal Fisheries Cooperative Management Act (Atlantic Coastal Act). The EFP would allow for an exemption from the Reserve.

Regulations under the Atlantic Coastal Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed EFPs.

DATES: Written comments on this action must be received on or before September 12, 2016.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2016–0113, by either of the following methods:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2016-0113,* Click the ''Comment Now!'' icon, complete the required fields Enter or attach your comments.

Mail: Written comments should be sent to Chris Wright, Office of Sustainable Fisheries, NMFS, 1315 East-West Highway, Room 13464, Silver Spring, MD 20910. Mark the outside of the envelope ''Comments on Horseshoe Crab EFP Proposal.''

Fax: Comments may also be sent via fax to (301) 713–0596.

FOR FURTHER INFORMATION CONTACT: Chris Wright, Office of Sustainable Fisheries, (301) 427–8570.

SUPPLEMENTARY INFORMATION:

Background

Limuli submitted an application for an EFP dated April 26, 2016, to collect up to 10,000 horseshoe crabs for biomedical and data collection purposes from the Reserve. Of the collected horseshoe crabs, a portion will be tagged and analyzed for data collection purposes. All collected horseshoe crabs will be returned to the sea after they are bled. The applicant has applied for a similar EFP every year from 2001–2015. Permits were issued each year from 2001–2013, however no harvest and data collection occurred in years 2008, 2009, and 2012. Permits were not issued in 2014 or 2015 due to the pending listing under the Endangered Species Act (ESA) of the rufa red knot (*Calidris canutus rufa*) and ultimate determination as threatened species status under the ESA of 1973 (December 11, 2014; 79 FR 73706) and time needed to consult under the Endangered Species Act with U.S. Fish and Wildlife Service (FWS).

Limuli Laboratories EFP Application

The current EFP application specifies that: (1) The same methods in the 2001–2013 EFPs would be used, (2) at least 15 percent of the bled horseshoe crabs would be tagged, and (3) there had not been any sighting or capture of marine mammals or endangered species in the trawling nets of fishing vessels engaged in the collection of horseshoe crabs since 1993. The project submitted by Limuli would provide morphological data on horseshoe crab catch, would tag a portion of the caught horseshoe crabs, and would use the blood from the caught horseshoe crabs to manufacture Limulus Amebocyte Lysate (LAL), an important health and safety product used for the detection of endotoxins.

The LAL assay is used by medical professionals, drug companies, and pharmacies to detect endotoxins in intravenous pharmaceuticals and medical devices that come into contact with human blood or spinal fluid.

Limuli last harvested horseshoe crabs from the reserve in 2013. The results of that collection were summarized in a **Federal Register** Notice relating to Limuli's 2015 EFP application on October 7, 2015 (80 FR 60633).

Horseshoe Crab Technical Committee and Delaware Bay Ecosystem Technical Committee Consultation and Review

NMFS consulted with the Commission's Horseshoe Crab Technical Committee and Delaware Bay Ecosystem Technical Committee via conference call on June 8 and July 11, 2016, asking members comment on the utility of the data collected under the past EFPs.

The Technical Committees had varying opinions on the overall quality of the data from the EFP. Technical Committees members pointed out that the EFP data was some of the only data on horseshoe crabs from the reserve, and that the data was included in past scientific papers. Most members believed that the collection of the data was at least generally useful, and many suggested that the data should be further considered as part of the 2018 benchmark stock assessment for horseshoe crabs. The meetings summaries are available upon request (see **ADDRESSES**).

ESA Consultations

On August 5, 2014, NMFS completed an intra-agency consultation under section 7 of the ESA for proposed approval of an EFP to allow the biomedical harvest of horseshoe crabs from the Reserve which determined that the proposed action is not likely to adversely affect any listed species under our jurisdiction. The consultation covers the years from 2014–2018.

NMFS started to conference with FWS in May 2016 on starting the consultation under section 7 of the ESA for rufa red knot, because this species had no previous consultation. The consultation is ongoing and NMFS intends to conclude the consultation before making a final decision on the merits of the EFP application.

Past EFP Conditions and Requirements

Limuli Laboratories proposes to conduct an exempted fishery operation in 2016 using the same means, methods, and seasons proposed/utilized during the EFPs in 2001–2013. In past EFPs, NMFS required that the following conditions and requirements be met for issuance of the EFP:

1. The permit must be carried on board the vessel named.

2. A State of New Jersey Division of Fish and Wildlife (NJDFW) supplied observer must be taken when requested to do so by the New Jersey Bureau of Marine Fisheries.

3. When fishing under the permit in the Reserve during the participation period specified above, the vessel:

a. must use a 5 and ½ inch mesh flounder trawl net;

b. must not exceed 30 minutes during any one tow (measured from the time trawl doors enter the water until they are removed from the water per 50 CFR 223.206(d)(3)(i));

c. must notify State of New Jersey Law Enforcement daily of when and where the collection will take place;

d. must abide by any other federal fishery regulation in effect in the Reserve;

e. must withdraw from this exempted fishery before enrolling or participating in any other exempted fishery.

4. The following species may be possessed by the vessel when fishing under this permit with the specified trawl gear during the participation period above: Horseshoe Crab.

5. The fishing vessel that is issued a permit to conduct this experimental fishing activity may not possess or land catch in excess of a combined total of 500 horseshoe crabs per day during the participation period.

6. The fishing vessel that is issued a permit to conduct this experimental fishing activity may not possess or land in excess of a combined total of 10,000 horseshoe crabs from the Reserve during the participation period.

7. Participant must return all captured horseshoe crabs to waters adjacent to those from which they were captured as soon as possible after blood collection.

8. Participant must supply to National Marine Fisheries Service, the Atlantic States Marine Fisheries Commission (Commission), and the NJDFW, one month after the end of the participation period, the following data on all horseshoe crabs bled for biomedical purposes:

a. sex ratio; and

b. daily numbers of horseshoe crabs caught.

9. Participant must tag 15 percent of all horseshoe crabs bled for biomedical purposes, and supply to NMFS, the Commission, and NJDFW, one month after the end of the participation period, data on horseshoe crabs tagged, released, and recaptured.

10. Participant must supply to NMFS, the Commission, and the NJDFW, one month after the end of the participation period, the following data on a minimum of 200 randomly selected crabs tagged:

a. morphometric data, by sex, *e.g.* interocular distance and weight; and

b. levels of activity, as measured by a horseshoe crab struggles after being placed on a weighing scale or by distance traveled after release on beach.

The EFP exempted two commercial vessels from regulations at 50 CFR 697.7(e) and 697.23(f), which prohibit the harvest and possession of horseshoe crabs from the Reserve on a vessel with a trawl or dredge gear aboard.

Proposed Modifications for the 2016 EFP

Conditions and requirements may be added or amended prior to the issuance of the EFP or on an annual basis. NMFS is considering modifying past terms and conditions on the permit to possibly include or modify harvest, data collection and reporting requirements.

A final decision on issuance of the EFP will depend on NMFS' review of public comments received on the application, an ESA consultation with the FWS, and a determination that the EFP is consistent with all applicable laws.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 17, 2016.

Emily H. Menashes,

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

[FR Doc. 2016–19996 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE806

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice of receipt.

SUMMARY: Notice is hereby given that NMFS has received one permit application from the United States Fish and Wildlife Service (USFWS) to enhance the propagation and survival of species listed under the Endangered Species Act (ESA) of 1973, as amended, for a 10 year period. As part of this permit application, USFWS has submitted two HGMPs. The HGMPs specify methods for the operation of two

hatchery programs at Livingston Stone National Fish Hatchery (LSNFH); the Winter Chinook Integrated-Recovery Supplementation Program, and the Winter Chinook Captive Broodstock Program. LSNFH is located on the Upper Sacramento River in California's Central Valley. This document serves to notify the public of the availability of the permit application and associated HGMPs for review and comment, prior to a decision by NMFS whether to issue the permit. The permit application and associated HGMPs may be viewed online at: *https://apps.nmfs.noaa.gov/preview/preview_open_for_comment.cfm.*

DATES: Comments or requests for a public hearing on the applications must be received at the appropriate address or fax number (see **ADDRESSES**) no later than 5 p.m. Pacific standard time on September 21, 2016.

ADDRESSES: Written comments on the application should be submitted to the California Central Valley Office, NMFS, 650 Capitol Mall, Suite 5–100, Sacramento, CA 95814. Comments may also be submitted via fax to 916–930–3629 or by email to *Amanda.Cranford@noaa.gov* (include the permit number in the subject line of the fax or email).

FOR FURTHER INFORMATION CONTACT: Amanda Cranford, Sacramento, CA (ph.: 916–930–3706), Fax: 916–930–3629, email: *Amanda.Cranford@noaa.gov*). Permit application instructions are available from the address above, or online at *https://apps.nmfs.noaa.gov.*

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

The following listed species are covered in this notice:

Chinook salmon (*Oncorhynchus tshawytscha*): Threatened Central Valley spring-run (CVSR); endangered Sacramento River winter-run (SRWR).

Steelhead (*O. mykiss*): Threatened California Central Valley (CCV).

Authority

Scientific research permits are issued in accordance with section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et seq.*) and regulations governing listed fish and wildlife permits (50 CFR parts 222–227). NMFS issues permits based on findings that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

Anyone requesting a hearing on an application listed in this notice should set out the specific reasons why a hearing on that application would be appropriate (see **ADDRESSES**). Such hearings are held at the discretion of the Assistant Administrator for Fisheries, NMFS.

Permit Application(s) Received

Permit 16477

The USFWS has applied for a permit under section 10(a)(1)(A) of the ESA for a period of 10 years that would allow take of adult and juvenile SRWR Chinook salmon, from the endangered Sacramento River Evolutionarily Significant Unit pursuant to HGMPs, which were developed with technical assistance from NMFS. Take of adult CVSR Chinook salmon and adult CCV steelhead may also occur as a result of hatchery activities at LSNFH. The HGMPs will be implemented as part of the existing Integrated-Recovery Supplementation Program and Captive Broodstock Program at LSNFH. Actions taken pursuant to the permit are designed to enhance the survival of SRWR Chinook salmon residing in the Upper Sacramento River below Keswick Dam. The HGMPs incorporate two main components: Artificial propagation activities and research, monitoring and evaluation (RM&E).

Artificial propagation activities that could lead to the take of ESA-listed salmonids include; adult broodstock collection, spawning, rearing, handling, evaluation, tagging and release of progeny. Additionally, USFWS will maintain a Captive Broodstock Program at LSNFH sourced from fish originating from the Integrated-Recovery Supplementation Program. Release of captive broodstock will not be authorized under Permit 16477. Release of these fish will be permitted through separate section 10(a)(1)(A) Permits or authorizations, as needed. The HGMPs include measures to minimize the likelihood of genetic or ecological effects to naturally produced, ESA-listed salmonids resulting from hatchery operations and propagation of SRWR Chinook salmon.

RM&E activities will collect necessary data to document achievement of performance indicators specified in the HGMPs. USFWS is currently involved with the following research and monitoring projects directly involved with evaluating the effects of the hatchery programs at LSNFH: (1) The Adult Acoustic Telemetry Study to monitor the movements of adult winter-run Chinook salmon that are captured at the Keswick Dam Fish Trap and not retained for broodstock; and (2) the Juvenile Acoustic Tracking Study using acoustic tags to study emigration patterns and survival of juvenile hatchery-origin winter-run Chinook salmon. For a more detailed discussion of the RM&E activities, please see the permit application package.

Public Comments Solicited

NMFS invites the public to comment on the permit application and associated HGMPs during a 30 day public comment period beginning on the date of this notice. This notice is provided pursuant to section 10(c) of the ESA (16 U.S.C. 1529(c)). All comments and materials received, including names and addresses, will become part of the administrative record and may be released to the public. We provide this notice in order to allow the public, agencies, or other organizations to review and comment on these documents.

Next Steps

NMFS will evaluate the applications, associated documents, and comments submitted to determine whether the applications meet the requirements of section 10(a)(1)(A) of the ESA and Federal regulations. The final permit decisions will not be made until after the end of the 30-day public comment period and after NMFS has fully considered all relevant comments received. NMFS will publish notice of its final action in the **Federal Register**.

Dated: August 15, 2016.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–19890 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Requesting Nominations for the Marine Protected Areas Federal Advisory Committee; Notice of Public Meeting

AGENCY: National Marine Protected Areas Center, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice and request for nominations and notice of public meeting.

SUMMARY: The Department of Commerce (Department) is seeking nominations for membership on the Marine Protected

Areas Federal Advisory Committee (Committee). The Committee advises the Secretaries of Commerce and Interior on implementing Section 4 of Executive Order 13158, specifically on strategies and priorities for developing the national system of marine protected areas (MPAs) and on practical approaches to further enhance and expand protection of new and existing MPAs. Nominations are sought for highly qualified non-Federal scientists, resource managers, and people representing other interests or organizations involved with or affected by marine protected areas, including in the Great Lakes. Ten of the 20 members of the Committee have terms that expire November 15, 2016, and nominations are sought to fill these vacancies. Additionally, notice is hereby given of a Committee meeting to be held via webinar on Monday, October 3, 2016 from 3:00–5:30 p.m. ET. The Webinar is open to members of the public.

DATES:

Nominations: Nominations must be received before or on October 7, 2016.

Meeting: The Committee will convene a meeting via webinar on Monday, October 3, 2016 from 3:00–5:30 p.m. ET Webinars are open to the public and participants can dial in on a telephone for audio during the webinar. Additionally, participants who choose to use the webinar conference feature, in addition to a telephone, will also be able to view any presentations as they are being given. Members of the public that would like to participate in the meeting must to register in advance by Friday, September 30, 2016. These times and the agenda topics described below are subject to change. Refer to the following Web page for the most up-to-date meeting agenda: *http://marineprotectedareas.noaa.gov/fac/meetings/.*

ADDRESSES:

Nominations: Nominations should be sent to Nicole Capps at West Coast Region, Office of National Marine Sanctuaries, 99 Pacific Street, Suite 100 F, Monterey, CA, 93940, or *Nicole.Capps@noaa.gov.* Electronic submissions are acceptable.

Meeting: The meeting will be held via Web conference call. Register by contacting Nicole Capps at *Nicole.Capps@noaa.gov* or by telephone at (831) 647–6451. Webinar and teleconference capacity may be limited.

FOR FURTHER INFORMATION CONTACT: Lauren Wenzel, Designated Federal Officer, MPA FAC, National Marine Protected Areas Center, 1305 East West Highway, Silver Spring, Maryland 20910. (Phone: 240–533–0652, Fax: 301–713–3110); email: *Lauren.Wenzel@noaa.gov;* or visit the National MPA Center Web site at *http://www.marineprotectedareas.noaa.gov*).

SUPPLEMENTARY INFORMATION: Executive Order 13158 directed the Department of Commerce and the Department of the Interior to seek the expert advice and recommendations of non-federal scientists, resource managers, and other interested people and organizations through a Marine Protected Areas Federal Advisory Committee (Committee). The Committee was established in June 2003 and includes 20 members.

The Committee meets at least twice annually; meetings may be in person or via teleconference/webinar. Committee members serve one, four-year nonrenewable term. Members of the Committee are not compensated for their time, but their travel expenses associated with attending Committee meetings are reimbursed.

Nominations: Anyone is eligible to nominate and self-nominations will be accepted. Each nomination submission should include: (1) The nominee's full name, title, institutional affiliation, and contact information; (2) the nominee's area(s) of expertise; (3) a short description of his/her qualifications relative to the kinds of advice being solicited; and (4) a resume or CV not to exceed four pages in length. Nominations may choose to include letters of support (no more than three) describing the nominee's qualifications and interest in serving on the Committee. The intent is to select from the nominees; however, NOAA retains the prerogative to nominate people to the Committee that were not nominated through the process outlined in this **Federal Register** notice if it deems it is necessary to achieve the desired balance. Once selected, Committee members' names will be posted at: *http://marineprotectedareas.noaa.gov/fac/.*

Individuals seeking membership on the Committee should possess demonstrable expertise in a related field or represent a stakeholder interest in MPAs. Nominees will also be evaluated based on the following factors: Marine policy experience; leadership and organizational skills; region of country represented; and member demographics. The membership reflects the Department's commitment to attaining balance and diversity. The full text of the Committee charter and its current membership can be viewed at the Agency's Web page at *http://marineprotectedareas.noaa.gov.*

Meeting: The focus of the Committee's meeting will be to finalize and vote on subcommittee products focused on External Financing and Ecological Connectivity. Public comment will be accepted from 5:00–5:30 p.m. ET. The agenda, subject to change, will be posted at *http://marineprotectedareas.noaa.gov/fac/meetings/.*

Dated: August 8, 2016.

John Armor,

Acting Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2016–19952 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE807

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Issuance of two scientific research permits.

SUMMARY: Notice is hereby given that NMFS has issued scientific research Permit 14808–2M and enhancement Permit 18181–2M to the California Department of Fish and Wildlife (CDFW). The authorized research and monitoring activities are intended to increase knowledge of the species listed under the Endangered Species Act of 1973 (ESA) and to help guide management and conservation efforts. Rescue and relocation efforts are conducted in order to enhance the survival of ESA-listed species.

ADDRESSES: The approved application for each issued permit is available on the Applications and Permits for Protected Species (APPS), *https://apps.nmfs.noaa.gov* Web site by searching the permit number within the Search Database page. The applications, issued permits and supporting documents are also available upon written request or by appointment: NMFS West Coast Region, 650 Capitol Mall, Suite 5–100, Sacramento, California 95814 (Phone: (916) 930–3600, Fax: (916) 930–3629).

FOR FURTHER INFORMATION CONTACT: Amanda Cranford, Sacramento, CA (Phone: 916–930–3706), Fax: 916–930–3629, email: *Amanda.Cranford@noaa.gov*).

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

The following listed species are covered in this notice:

Chinook salmon (*Oncorhynchus tshawytscha*): threatened Central Valley spring-run (CVSR); endangered Sacramento River winter-run (SRWR).

Steelhead (*O. mykiss*): threatened California Central Valley (CCV).

North American green sturgeon (*Acipenser medisrostris*): threatened southern distinct population segment (SDPS).

Authority

Scientific research and enhancement permits are issued in accordance with section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et seq.*) and regulations governing listed fish and wildlife permits (50 CFR parts 222–227). NMFS issues permits based on findings that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of Section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

Anyone requesting a hearing on an application listed in this notice should set out the specific reasons why a hearing on that application would be appropriate (see **ADDRESSES**). Such hearings are held at the discretion of the Assistant Administrator for Fisheries, NMFS.

Permits Issued

Permit 14808–2M

A notice of the receipt of an application for the modification of scientific research and enhancement Permit 14808 was published in the **Federal Register** on August 20, 2015 (80 FR 161). Permit 14808–2M was issued to CDFW on December 9, 2015 and expires on December 31, 2020. Permit 14808–2M authorizes take of CVSR Chinook salmon, SRWR Chinook salmon, CCV steelhead, and SDPS green sturgeon associated with scientific research and monitoring activities in Sacramento River and San Joaquin River basins. The permit modification was requested in order to refine sampling methods, increase take levels and address changes to the proposed procedures. Additionally, CDFW requested that all ongoing research and monitoring be consolidated into a single section 10(a)(1)(A) Permit to improve efficiencies associated with reporting. In addition to the juvenile emigration monitoring at Knights Landing, which aims to compile information on timing, composition (species/run), and relative abundance of juvenile Chinook salmon and steelhead emigrating from the Upper Sacramento River system into the Sacramento-San Joaquin Delta, CDFW requested that the following research and monitoring efforts be included under Permit 14808–2M: (1) The Central Valley Steelhead Monitoring Program, that includes studies targeting CCV steelhead throughout the Sacramento River and San Joaquin River basins in order to examine the distribution, abundance, and population trends of CCV steelhead and provide the data necessary to help assess progress towards restoration and recovery goals; and (2) the Upper Sacramento River Restoration Site Monitoring, which will establish baseline use at proposed restoration sites to help determine the success once restoration projects are implemented through juvenile presence/absence surveys at various sites within the Upper Sacramento River.

Permit 18181–2M

A notice of the receipt of an application for the modification of enhancement Permit 18181 was published in the **Federal Register** on August 20, 2015 (80 FR 161). Permit 18181–2M was issued to CDFW on December 9, 2015 and expires on December 31, 2020. Permit 18181–2M authorizes take of CVSR Chinook salmon, SRWR Chinook salmon, CCV steelhead, and SDPS green sturgeon associated with enhancement activities in the Upper Sacramento River and associated tributaries in Shasta and Tehama counties, the Colusa Basin Drainage Canal (CBDC), Wallace and Fremont weirs in the Yolo Bypass, and Tisdale Weir in the Sutter Bypass. Permit 18181–2M includes additional rescue and monitoring efforts that routinely occur throughout California's Central Valley. Further, after conducting capture and relocation activities within the CBDC and at Wallace Weir, the project description, sampling methodologies and take estimates have been refined to better reflect the current rescue and enhancement operations. The primary purpose of this monitoring is to assess entrainment of ESA-listed salmonids and SDPS green sturgeon resulting from extreme environmental conditions and complex water operations within California's Central Valley. CDFW will assess the conditions leading to entrainment and determine whether rescue and relocation activities are warranted. The rescue and relocation efforts authorized under Permit 18181–2M are: (1) The CBDC Trapping and Relocation Operation, which aims to trap and relocate adult Chinook salmon and other species of management concern before they enter and become entrained within the CDBC; (2) Monitoring of Sacramento River Flood Control Project Weirs and Flood Relief Structures, where bypasses are surveyed after high flow events to determine the level of entrainment and if warranted rescues will be conducted, with a specific focus on Tisdale and Fremont weirs in the Sacramento River basin; and (3) Upper Sacramento River Redd Dewatering Surveys and Rescue of Stranded Juvenile Winter-run Chinook Salmon, which allows CDFW biologists to predict the flow at which redds will be dewatered on a redd-by-redd basis and conduct rescues if necessary.

Dated: August 15, 2016.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–19891 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Licensing of Private Remote-Sensing Space Systems

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before October 21, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov).*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Tahara Dawkins,

tahara.dawkins@noaa.gov or (301) 713–3385.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for an extension of a current information collection.

NOAA has established requirements for the licensing of private operators of remote-sensing space systems. The information in applications and subsequent reports is needed to ensure compliance with the Land Remote-Sensing Policy Act of 1992 and with the national security and international obligations of the United States. The requirements are contained in 15 CFR part 960.

II. Method of Collection

Information is submitted via email.

III. Data

OMB Control Number: 0648–0174.

Form Number: None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 18.

Estimated Time per Response: 40 hours for the submission of a license application; 10 hours for the submission of a data protection plan; 5 hours for the submission of a plan describing how the licensee will comply with data collection restrictions; 3 hours for the submission of an operations plan for restricting collection or dissemination of imagery of Israeli territory; 3 hours for submission of a data flow diagram; 2 hours for the submission of satellite subsystems drawings; 3 hours for the submission of a final imaging system specifications document; 2 hours for the submission of a public summary for a licensed system; 2 hours for the submission of a preliminary design review; 2 hours for the submission of a critical design review; 1 hour for notification of a binding launch services contract; 1 hour for notification of completion of pre-ship review; 10 hours for the submission of a license amendment; 2 hours for the submission of a foreign agreement notification; 2 hours for the submission of spacecraft operational information submitted when a spacecraft becomes operational; 2 hours for notification of deviation in orbit or spacecraft disposition; 2 hours for notification of any operational deviation; 2 hours for notification of planned purges of information to the National Satellite Land Remote Sensing Data Archive; 3 hours for the submission of an operational quarterly report; 8 hours for an annual compliance audit; 10 hours for an annual operational audit; and 2 hours for notification of the demise of a system or a decision to discontinue system operations.

Estimated Total Annual Burden Hours: 552.

Estimated Total Annual Cost to Public: $1,000 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: August 17, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–19984 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–HR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Evaluation of State Coastal Management Programs

AGENCY: Office for Coastal Management (OCM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA), Office for Coastal Management will hold a public meeting to solicit comments on the performance evaluation of the Guam Coastal Management Program.

DATES: *Guam Coastal Management Program Evaluation:* The public meeting will be held on September 28, 2016, and written comments must be received on or before October 5, 2016.

For specific dates, times, and locations of the public meetings, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: You may submit comments on the program or reserve NOAA intends to evaluate by any of the following methods:

Public Meeting and Oral Comments: A public meeting will be held in Sinajana, Guam. For the specific location, see **SUPPLEMENTARY INFORMATION**.

Written Comments: Please direct written comments to Ralph Cantral, Senior Advisor, Policy, Planning, and Communications Division, Office for Coastal Management, NOS/NOAA, 1305 East-West Highway, 11th Floor, N/OCM1, Silver Spring, Maryland 20910, or email comments *Ralph.Cantral@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Ralph Cantral, Senior Advisor, Policy, Planning and Communications Division, Office for Coastal Management, NOS/NOAA, 1305 East-West Highway, 11th Floor, N/OCM1, Silver Spring, Maryland 20910, or *Ralph.Cantral@noaa.gov.* Copies of the previous evaluation findings and related material (including past performance reports and notices prepared by NOAA's Office for Coastal Management) may be obtained upon written request by contacting the person identified under **FOR FURTHER INFORMATION CONTACT**. Copies of the most recent evaluation findings and most recent progress report may also be downloaded or viewed on the Internet at *http://coast.noaa.gov/czm/evaluations.*

SUPPLEMENTARY INFORMATION: Section 312 of the Coastal Zone Management Act (CZMA) requires NOAA to conduct periodic evaluations of federally approved state and territorial coastal programs. The process includes one or more public meetings, consideration of written public comments and consultations with interested Federal, state, and local agencies and members of the public. During the evaluation, NOAA will consider the extent to which the state has met the national objectives, adhered to the management program approved by the Secretary of Commerce, and adhered to the terms of financial assistance under the CZMA. When the evaluation is completed, NOAA's Office for Coastal Management will place a notice in the **Federal Register** announcing the availability of the Final Evaluation Findings.

Specific information on the periodic evaluation of the state and territorial coastal program that is the subject of this notice is detailed below as follows:

Guam Coastal Management Program Evaluation

You may participate or submit oral comments at the public meeting scheduled as follows:

Date: September 28, 2016.

Time: 5:30 p.m., local time.

Location: Sinajana Community Center, 178 Chalan Guma Yu'os, Sinajana, Guam 96910.

Written public comments must be received on or before October 5, 2016.

Federal Domestic Assistance Catalog 11.419 Coastal Zone Management Program Administration

Dated: August 5, 2016.

Josh Lott,

Policy Program Manager, Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2016–19946 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Patent Term Extension

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the extension of a continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before October 21, 2016.

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

- *Email: InformationCollection@uspto.gov.* Include ''0651–0020 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Marcie Lovett, Records Management Division Director, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–7728; or by email to *Raul.Tamayo@uspto.gov* with ''0651–0020 comment'' in the subject line. Additional information about this collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The patent term restoration portion of the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98–417), which is codified at 35 U.S.C. 156, permits the United States Patent and Trademark Office (USPTO) to extend the term of protection under a patent to compensate for delay during regulatory review and approval by the Food and Drug Administration (FDA) or Department of Agriculture. Only patents for drug products, medical devices, food additives, or color additives are potentially eligible for extension. The maximum length that a patent may be extended under 35 U.S.C. 156 is five years.

Under 35 U.S.C. 156(d), an application for patent term extension must identify the approved product; the patent to be extended; and the claims included in the patent that cover the approved product, a method of using the approved product, or a method of manufacturing the approved product. 35 U.S.C. 156(d) also requires the application for patent term extension to provide a brief description of the activities undertaken by the applicant during the regulatory review period with respect to the approved product and the significant dates of these activities.

Under 35 U.S.C. 156(e), an interim extension may be granted if the term of an eligible patent for which an application for patent term extension has been submitted would expire before a certificate of extension is issued. Under 35 U.S.C. 156(d)(5), an interim extension may be granted if the applicable regulatory review period that began for a product is reasonably expected to extend beyond the expiration of the patent term in effect.

The USPTO administers 35 U.S.C. 156 through 37 CFR 1.710–1.791. These rules provide for the public to, inter alia, submit 35 U.S.C. 156 patent term extension applications to the USPTO, request interim extensions and review of final eligibility decisions, and withdraw an application requesting a patent term extension after it is submitted.

Separate from the extension provisions of 35 U.S.C. 156, the USPTO may in some cases extend the term of an original patent due to certain delays in the prosecution of the patent application, including delays caused by interference proceedings, secrecy orders, or appellate review by the Patent Trial and Appeal Board or a Federal court in which the patent is issued pursuant to a decision reversing an adverse determination of patentability. The patent term provisions of 35 U.S.C. 154(b), as amended by title IV, subtitle D of the Intellectual Property and Communications Omnibus Reform Act of 1999, require the USPTO to notify the applicant of the patent term adjustment in the notice of allowance and give the applicant an opportunity to request reconsideration of the USPTO's patent term adjustment determination.

The USPTO may also reduce the amount of patent term adjustment granted if delays were caused by an applicant's failure to make a reasonable effort to respond within three months of the mailing date of a communication from the USPTO. Applicants may petition for reinstatement of a reduction in patent term adjustment with a showing that, in spite of all due care, the applicant was unable to respond to a communication from the USPTO within the three-month period. The USPTO administers 35 U.S.C. 154 through 37 CFR 1.701–1.705.

The information in this collection is used by the USPTO to consider whether an applicant is eligible for a patent term extension or reconsideration of a patent term adjustment and, if so, to determine the length of the patent term extension or adjustment.

II. Method of Collection

By mail, facsimile, hand delivery, or electronically to the USPTO.

III. Data

OMB Number: 0651–0020.

IC Instruments and Forms: There are no forms associated with this collection.

Type of Review: Revision of a Previously Existing Information Collection.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 1,340 responses per year. The USPTO estimates that approximately 25% of these responses will be from small entities.

Estimated Time per Response: The USPTO estimates that it will take the public from 1 to 25 hours, depending on the complexity of the situation, to gather the necessary information, prepare the appropriate documents, and submit the information to the USPTO.

Estimated Total Annual Respondent Burden Hours: 6,187 hours.

Estimated Total Annual Respondent (Hourly) Cost Burden: $2,536,670.00. The USPTO expects that attorneys will complete these applications. The professional hourly rate for attorneys is $410. Using this hourly rate, the USPTO estimates that the total respondent cost burden for this collection is $2,536,670.00 per year.

Item	Estimated time for response (hours) (a)	Estimated annual responses (b)	Estimated annual burden hours (a) × (b) = (c)	Rate ($/hr) (d)
1. Application to Extend Patent Term Under 35 U.S.C. § 156	25	95	2,375	$410
2. Request for Interim Extension Under 35 U.S.C. § 156(e)(2)	1	10	10	410
3. Petition to Review Final Eligibility Decision Under 37 CFR 1.750	25	4	100	410
4. Initial Application for Interim Extension Under 37 CFR 1.790	20	2	40	410
5. Subsequent Application for Interim Extension Under 37 CFR 1.790	1	1	1	410
6. Response to Requirement to Elect	1	15	15	410
7. Response to Request to Identify Holder of Regulatory Approval	2	1	2	410
8. Declaration to Withdraw an Application to Extend Patent Term	2	1	2	410
9. Petition for Reconsideration of Patent Term Adjustment Determination	3	1,200	3,600	410
10. Petition for Reinstatement of Reduced Patent Term Adjustment	4	10	40	410
11. Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	2	1	2	410
Total		1,340	6,187	

Estimated Total Annual (Non-hour) Respondent Cost Burden: $351,505.08. There are no capital startup, maintenance, or operating fees associated with this collection. There are, however, annual (non-hour) costs in the form of postage costs and fees.

Customers may incur postage costs when submitting some of the items covered by this collection to the USPTO by mail. The USPTO expects that approximately 93 percent of the responses in this collection will be submitted electronically. Of the remaining 7 percent, the vast majority—98 percent—will be submitted by mail, for a total of 92 mailed submissions. The average first class USPS postage cost for a mailed submission is 49 cents. Therefore, the USPTO estimates that the postage costs for the mailed submissions in this collection will total $45.08.

The fees associated with this collection are being returned from their previous location in collection 0651–0072, which has been discontinued. These fees are listed in the accompanying table below.

Item	Estimated annual responses (a)	Filing fee ($) (b)	Total non-hour cost burden ($) (a) × (b) = (c)
1. Filing an application for patent term adjustment	1,200	200	240,000.00
2. Request for reinstatement of term reduced	10	400	4,000.00
3. Extension of term of patent	95	1,120	106,400.00
4. Initial application for interim extension (see 37 CFR 1.790)	2	420	840.00
5. Subsequent application for interim extension (see 37 CFR 1.790)	1	220	220.00
Total			351,460.00

Therefore, the USPTO estimates that the total annual (non-hour) cost burden for this collection, in the form of postage costs and fees is $351,505.08 per year.

IV. Request for Comments

Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information;

(c) ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) ways to minimize the burden of the collection of information on respondents, *e.g.,* the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: August 16th 2016.

Marcie Lovett,

Records Management Division Director, OCIO United States Patent and Trademark Office.

[FR Doc. 2016–19864 Filed 8–19–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Post Allowance and Refiling

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before October 21, 2016.

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

- *Email: InformationCollection@uspto.gov.* Include ''0651–0033 comment'' in the subject line of the message.
- *Mail:* Marcie Lovett, Records Management Division Director, Office of the Chief Information Officer; United States Patent and Trademark Office; P.O. Box 1450, Alexandria, VA 22313–1450.
- *Federal Rulemaking Portal: http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–7728; or by email to *Raul.Tamayo@uspto.gov.* Additional information about this collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

This collection of information encompasses the action an applicant must take to submit an issue fee payment to the USPTO. The United States Patent and Trademark Office (USPTO) is required by 35 U.S.C. 131 and 151 to examine applications and, when appropriate, allow applications and issue them as patents. When an application for a patent is allowed by the USPTO, the USPTO issues a notice of allowance and the applicant must pay the specified issue fee (including the publication fee, if applicable) within three months to avoid abandonment of the application. If the appropriate fees are paid within the proper time period, the USPTO can then issue the patent. If the fees are not paid within the designated time period, the application is abandoned (applicant may petition the Director to accept a delayed payment with a satisfactory showing that the delay was unintentional; the Petition for Revival of an Application for Patent Abandoned Unintentionally (Form PTO/SB/64) is approved under information collection 0651–0031). The rules outlining the procedures for payment of the issue fee and issuance of a patent are found at 37 CFR 1.18 and 1.311–1.317.

This collection of information also encompasses several actions that may be taken after issuance of a patent, pursuant to Chapter 25 of Title 35 U.S.C. A certificate of correction may be requested to correct an error or errors in the patent. If the USPTO determines that the request should be approved, the USPTO will issue a certificate of correction. For an original patent that is believed to be wholly or partly inoperative or invalid, the assignee(s) or inventor(s) may apply for reissue of the patent, which entails several formal requirements, including provision of an oath or declaration specifically identifying at least one error being relied upon as the basis for reissue and stating the reason for the belief that the original patent is wholly or partly inoperative or invalid (*e.g.,* a defective specification or drawing, or claiming more or less than the patentee had the right to claim in the patent). The rules outlining these procedures are found at 37 CFR 1.171–1.178 and 1.322–1.325.

II. Method of Collection

By mail, facsimile, hand delivery, or electronically to the USPTO.

III. Data

OMB Number: 0651–0033.

Form Number(s): PTO/SB/44/50/51/51S/52/53/56/141, PTO/AIA/05/06/07, and PTOL–85B.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households; businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 379,600 responses per year. The USPTO estimates that approximately 25% of these responses will be from small entities (22%) and micro entities (3%).

Estimated Time per Response: The USPTO estimates that it will take the public from 12 minutes (0.20 hours) to 5 hours to gather the necessary information, prepare the appropriate form or document, and submit the information to the USPTO.

Estimated Total Annual Respondent Burden Hours: 207,065 hours.

Estimated Total Annual Respondent Cost Burden: $35,734,150.00. The USPTO expects that the information in this collection will be prepared by attorneys at an estimated rate of $410 per hour, except for the Issue Fee Transmittal, which will be prepared by paraprofessionals at an estimated rate of $125 per hour. Therefore, the USPTO estimates that the respondent cost burden for this collection will be approximately $35,734,150.00 per year.

IC No.	Item	Estimated time for response (hr) (a)	Estimated annual responses (b)	Estimated annual burden hours (a) × (b) = (c)	Rate ($/hr) (d)	Total cost burden ($/hr) (c) × (d) = (e)
1	Certificate of Correction (PTO/SB/44).	1	28,000	28,000.00	$410.00	$11,480,000.00
2	Petition to Correct Assignee After Payment of Issue Fee (37 CFR 3.81(b)) (PTO/SB/141).	0.50 (30 minutes)	850	425.00	410.00	174,250.00
3	Reissue Documentation	5	950	4,750.00	410.00	1,947,500.00
4	Reissue Patent Application Transmittal (PTO/SB/50)Office (RO/US) (PTO–1382).	0.20 (12 minutes)	950	190.00	410.00	77,900.00

IC No.	Item	Estimated time for response (hr) (a)	Estimated annual responses (b)	Estimated annual burden hours (a) × (b) = (c)	Rate ($/hr) (d)	Total cost burden ($/hr) (c) × (d) = (e)
5	Reissue Application Declaration by the Inventor or the Assignee (PTO/SB/51/52 and PTO/AIA/05/06) or Substitute Statement in Lieu of an Oath or Declaration for Reissue Patent Application (35 U.S.C. § 115(d) and 37 CFR 1.64) (PTO/AIA/07).	0.50 (30 minutes)	1,350	675.00	410.00	276,750.00
6	Supplemental Declaration for Reissue Patent Application to Correct ''Errors'' Statement (37 CFR 1.175) (PTO/SB/51S).	0.30 (18 minutes)	250	75.00	410.00	30,750.00
7	Reissue Application: Consent of Assignee; Statement of Non-assignment (PTO/SB/53).	0.20 (12 minutes)	1,300	260.00	410.00	106,600.00
8	Reissue Application Fee Transmittal Form (PTO/SB/56).	0.20 (12 minutes)	950	190.00	410.00	77,900.00
9	Issue Fee Transmittal (PTOL–85B).	0.50 (30 minutes)	35,000	17,500.00	125.00	2,187,500.00
10	Issue Fee Transmittal (electronic) (PTOL–85B).	0.50 (30 minutes)	310,000	155,000.00	125.00	19,375,000.00
Totals			379,600	207,065.00		35,734,150.00

Estimated Total Annual Non-hour Respondent Cost Burden: $274,403,312.19. There are no capital start-up, maintenance, or recordkeeping costs associated with this information collection. However, this collection does have annual (non-hour) costs in the forms of postage costs.

IC No.	Information collection instrument	Estimated annual responses (a)	Filing fee ($) (b)	Total non-hour cost burden (yr) (a) × (b) = (c)
1	Certificate of correction	12,200	$100.00	$1,220,000.00
3	Basic filing fee—Reissue (Large entity)	850	280.00	238,000.00
3	Basic filing fee—Reissue (Small entity)	250	140.00	35,000.00
3	Basic filing fee—Reissue (Micro entity)	10	70.00	700.00
3	Reissue Search Fee (Large entity)	850	600.00	510,000.00
3	Reissue Search Fee (Small entity)	250	300.00	75,000.00
3	Reissue Search Fee (Micro entity)	10	150.00	1,500.00
3	Reissue independent claims in excess of three (Micro entity).	1,150	420.00	483,000.00
3	Reissue independent claims in excess of three (Small entity).	200	210.00	42,000.00
3	Reissue independent claims in excess of three (Micro entity).	15	105.00	1,575.00
3	Reissue claims in excess of 20 (Large entity).	7,535	80.00	602,800.00
3	Reissue claims in excess of 20 (Small entity).	2,030	40.00	81,200.00
3	Reissue claims in excess of 20 (Micro entity).	90	20.00	1,800.00
8	Reissue Application Size Fee—for each additional 50 sheets that exceeds 100 sheets (Large entity).	25	400.00	10,000.00
8	Reissue Application Size Fee—for each additional 50 sheets that exceeds 100 sheets (Small entity).	5	200.00	1,000.00
8	Reissue Application Size Fee—for each additional 50 sheets that exceeds 100 sheets (Micro entity).	0	100.00	0.00
8	Reissue Examination Fee (Large entity)	840	2,160.00	1,814,400.00
8	Reissue Examination Fee (Small entity)	245	1,080.00	264,600.00
8	Reissue Examination Fee (Micro entity)	10	540.00	5,400.00

IC No.	Information collection instrument	Estimated annual responses (a)	Filing fee ($) (b)	Total non-hour cost burden (yr) (a) × (b) = (c)
9, 10	Utility issue fee (Large entity)	236,380	960.00	226,924,800.00
9, 10	Utility issue fee (Small entity)	57,830	480.00	27,758,400.00
9, 10	Utility issue fee (Micro entity)	5,625	240.00	1,350,000.00
9, 10	Design issue fee (Large entity)	15,230	560.00	8,528,800.00
9, 10	Design issue fee (Small entity)	11,150	280.00	3,122,000.00
9, 10	Design issue fee (Micro entity)	2,210	140.00	309,400.00
9, 10	Plant issue fee (Large entity)	610	760.00	463,600.00
9, 10	Plant issue fee (Small entity)	655	380.00	248,900.00
9, 10	Plant issue fee (Micro entity)	10	190.00	1,900.00
9, 10	Reissue issue fee (Large entity)	265	960.00	254,400.00
9, 10	Reissue issue fee (Small entity)	90	480.00	43,200.00
9, 10	Reissue issue fee (Micro entity)	5	240.00	1,200.00
Total		356,625		274,394,575.00

Customers may incur postage costs when submitting the information in this collection by the USPTO by mail. The USPTO estimates that the average first-class postage cost for a mailed submission will be 49 cents and that approximately 5% submissions will be mailed to the USPTO per year, for a total estimated postage cost of $8,737.19 per year.

The total annual (non-hour) respondent cost burden for this collection is estimated to be approximately $274,403,312.19 per year.

IV. Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

The USPTO is soliciting public comments to:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Marcie Lovett,

Records Management Division Director, Office of the Chief Information Officer.

[FR Doc. 2016–19921 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submission for OMB Review; Comment Request; ''Pro Bono Survey''

The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Title: Pro Bono Survey.

OMB Control Number: 0651—New.

Form Number(s): N/A.

Type of Request: Regular.

Number of Respondents: 20 respondents providing quarterly responses, for a total of 80 responses per year.

Average Hours per Response: 2 hours.

Burden Hours: 160 hours.

Cost Burden: $65,600.00

Needs and Uses: The Leahy-Smith America Invents Act (AIA), Public Law 112–29 § 32 (2011) directs the USPTO to work with and support intellectual property law associations across the country in the establishment of pro bono programs designed to assist financially under-resourced independent inventors and small businesses. In support of this law, the USPTO, in collaboration with various non-profit organizations, has established a series of autonomous regional hubs that act as matchmakers to help connect low income inventors with volunteer patent attorneys across the United States.

This information collection will ascertain the effectiveness of each individual regional hub with respect to their matchmaking efforts. The USPTO has worked with the Pro Bono Advisory Council (PBAC) to determine what information is necessary to ascertain the effectiveness of each regional pro bono hub's matchmaking operations. PBAC is a well-established group of patent practitioners and patent pro bono regional hub administrators who have committed to provide support and guidance to patent pro bono programs across the country. The USPTO is responsible for the collection of this information, which is collected on a quarterly basis.

Specifically, the information will allow PBAC and the USPTO to ascertain the origination state of applicants, where applicants are being referred from, and what portion of applicants are completing and returning financial screening applications. Additionally the information will help track the number of invention screenings, disqualified applicants, corporations/law firms agreeing to accept cases, backlog of unmatched applicants, hours donated by lawyer referral service panel attorneys, and provisional and non-provisional applications filed, all on a quarterly basis. The information will also allow PBAC and the USPTO to understand program financial information including project cost, and depth of donor support.

The information, at its highest level, will allow PBAC and the USPTO to ascertain whether the regional hubs are matching qualified low income inventors with volunteer patent attorneys. It will also help establish the total economic benefit derived by low-income inventors in the form of donated

legal services. This information can then be used to promote the program to under-resourced inventors and patent practitioners.

Affected Public: Not-for-profit institutions.

Frequency: Quarterly.

Respondent's Obligation: Required to Obtain or Maintain Benefits.

OMB Desk Officer: Nicholas A. Fraser, email: *Nicholas_A._Fraser@omb.eop.gov.*

Once submitted, the request will be publicly available in electronic format through *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Further information can be obtained by:

• *Email: InformationCollection@uspto.gov, John.Kirkpatrick@uspto.gov,* or *Gautam.Prakash@uspto.gov.* Include ''Pro Bono Survey copy request'' in the subject line of the message.

• *Mail:* Marcie Lovett, Records Management Division Director, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before September 21, 2016 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov,* or by fax to 202–395–5167, marked to the attention of Nicholas A. Fraser.

Dated: August 16, 2016.

Marcie Lovett,

Records Management Division Director, USPTO, Office of the Chief Information Officer.

[FR Doc. 2016–19865 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Patent Law Treaty

ACTION: Notice and request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the extension of a continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before October 21, 2016.

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

• *Email: InformationCollection@uspto.gov.* Include ''0651–0073 comment'' in the subject line of the message.

• *Federal Rulemaking Portal: http://www.regulations.gov.*

• *Mail:* Marcie Lovett, Records Management Division Director, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office (USPTO), P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–7728; or by email at *Raul.Tamayo.uspto.gov* with ''0651–0073 comment'' in the subject line. Additional information about this collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The Patent Law Treaties Implementation Act of 2012 (PLTIA) amends the patent laws to implement the provisions of the Patent Law Treaty (PLT) in title II. The PLT harmonizes and streamlines formal procedures pertaining to the filing and processing of patent applications.

By a final rule titled ''Changes to Implement the Patent Law Treaty'' (RIN 0651–AC85) and published in the **Federal Register** on October 21, 2013, the USPTO revised the rules of practice for consistency with the changes in the PLT and title II of the PLTIA. One notable change pertains to the restoration of the right of priority to a foreign application or the benefit of a provisional application in a subsequent application filed within two months of the expiration of the twelve-month period (six-month period for design applications) for filing such a subsequent application. The information in this collection relates to the petitions for restoration that may be filed in accordance with the revised rules.

The information in this collection can be submitted electronically through EFS-Web, the USPTO's Web-based electronic filing system, as well as on paper. The USPTO is therefore accounting for both electronic and paper submissions in this collection.

II. Method of Collection

Electronically if applicants submit the information using EFS-Web. By mail or hand delivery in paper form.

III. Data

OMB Number: 0651–0073.

Form Number(s): No form numbers.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households; businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 500 responses per year. The USPTO estimates that 120 responses will be received from small entities. Approximately 98% of the total responses for this collection will be submitted electronically.

Estimated Time per Response: The USPTO estimates it will take approximately 60 minutes (1 hour) to complete the information in this collection, including the time it takes for reading the instructions for the forms, gathering the necessary information, completing the forms, and submitting them to the USPTO. The time per response, estimated annual responses, and estimated annual hour burden associated with each instrument in this collection are shown in the table below.

Estimated Total Annual Respondent Burden Hours: 500 hours.

Estimated Total Annual Respondent (Hourly) Cost Burden: $205,000.00. The USPTO expects that attorneys in private firms will complete these applications. The professional hourly rate for attorneys is $410. Using this hourly rate, the USPTO estimates that the total respondent cost burden for this collection is [AMOUNT] per year.

IC No.	Item	Hours	Responses (yr)	Burden (hrs/yr)	Rate ($/hr)	Total cost burden
		(a)	(b)	(c) (a × b)	(d)	(e) (c × d)
1	Petition to Restore the Right of Priority under 37 CFR 1.55(b)(2).	1	250	250	$410.00	$102,500.00

IC No.	Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a × b)	Rate ($/hr) (d)	Total cost burden (e) (c × d)
2	Petition to Restore the Benefit of a Prior-Filed Provisional Application under 37 CFR 1.7(a)(1)(ii).	1	250	250	410.00	102,500.00
	Total		500	500		205,000.00

Estimated Total Annual (Non-hour) Respondent Cost Burden: $748,064.50, based on filing fees and postage costs.

Filing Fees

There are filing fees associated with this collection. The items with filing fees are listed in the table below.

IC No.	Item	Estimated annual responses (a)	Filing fee ($) (b)	Total non-hour cost burden ($) (a) × (b) = (c)
1	Grantable Petition to Restore the Right of Priority under 37 CFR 1.55(b)(2) ...	190	$1,700.00	$323,000.00
2	Grantable Petition to Restore the Right of Priority under 37 CFR 1.55(b)(2)(small entity).	60	850.00	51,000.00
3	Grantable Petition to Restore the Benefit of a Prior-Filed Provisional Application under 37 CFR 1.78(a)(1)(ii).	190	1,700.00	323,000.00
4	Grantable Petition to Restore the Benefit of a Prior-Filed Provisional Application under 37 CFR 1.78(a)(1)(ii) (small entity).	60	850.00	51,000.00
	Total	500		748,000.00

The USPTO estimates that the total non-hour cost burden associated with the filing fees for this collection will be $748,000.00

Postage Costs

Customers may incur postage costs when submitting *some of* the items covered by this collection to the USPTO by mail. The USPTO expects that approximately 98 percent of the responses in this collection will be submitted electronically. Of the remaining 2 percent, the vast majority (98%) will be submitted by mail, for a total of 10 mailed submissions. The average first class USPS postage cost for a one-pound mailed submission in a flat-rate envelope is $6.45. The USPTO estimates that the postage costs for the mailed submissions in this collection will total $64.50.

Therefore, the USPTO estimates that the total annual (non-hour) cost burden for this collection, in the form of fees and postage is $748,064.50 per year.

IV. Request for Comments

Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information;

(c) ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) ways to minimize the burden of the collection of information on respondents, *e.g.,* the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: August 16th, 2016.

Marcie Lovett,

Records Management Division Director, USPTO, Office of the Chief Information Officer.

[FR Doc. 2016–19863 Filed 8–19–16; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board; Notice of Advisory Committee Meetings

AGENCY: Department of Defense.

ACTION: Notice of Advisory Committee Meetings.

SUMMARY: The Defense Science Board (DSB) and the 2016 DSB Summer Study Task Force on Capabilities for Constrained Military Operations (''the Summer Study Task Force'') will meet in closed session.

DATES: August 15–19 and 22–24, 2016, from 8:30 a.m. to 5:00 p.m.; August 25, 2016, from 7:00 a.m. to 5:00 p.m.; and August 26, 2016, from 8:00 a.m. to 12:00 p.m.

ADDRESSES: Arnold and Mabel Beckman Center, 100 Academy Drive, Irvine, CA 92617.

FOR FURTHER INFORMATION CONTACT: Ms. Debra Rose, Executive Officer, Defense Science Board, 3140 Defense Pentagon, Room 3B888A, Washington, DC 20301–3140, via email at *debra.a.rose20.civ@mail.mil,* or via phone at (703) 571–0084.

SUPPLEMENTARY INFORMATION:

These meetings are being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Due to circumstances beyond the control of the Designated Federal Officer and the Department of Defense, the Defense Science Board (DSB) was unable to provide the 15-calendar day public notification of subcommittee

These meetings are being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Due to circumstances beyond the control of the Designated Federal Officer and the Department of Defense, the Defense Science Board (DSB) was unable to provide the 15-calendar day public notification of subcommittee meetings of the 2016 DSB Summer Study Task Force on Capabilities for Constrained Military Operations scheduled for August 15 through August 19, 2016; August 22 through August 24, 2016; August 25, 2016; and August 26, 2016, at the Arnold and Mabel Beckman Center, 100 Academy Drive, Irvine, California. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement for each meeting—August 15 through August 19, 2016; August 22 through August 24, 2016; August 25, 2016; and August 26, 2016.

The mission of the Defense Science Board is to advise the Secretary of Defense and the Under Secretary of Defense for Acquisition, Technology, and Logistics on scientific and technical matters as they affect the perceived needs of the Department of Defense. The objective of the 2016 Summer Study on Capabilities for Constrained Military Operations is to assess the military planning, shaping, and operational activities that address potential threats to U.S. interests and strive to establish stability in critical regions of the world that do not rise to the level of full-scale military operations. Areas of consideration will include an assessment of current planning processes within Department of Defense (DoD) Policy, the Joint Chiefs of Staff, Combatant Commands, and the Intelligence Community with a focus on the period before significant hostilities begin.

In accordance with section 10(d) of the FACA and 41 CFR 102–2.155, the DoD has determined that the DSB meetings will be closed to the public. Specifically, the Under Secretary of Defense (Acquisition, Technology, and Logistics), in consultation with the DoD Office of General Counsel, has determined in writing that all sessions will be closed to the public because matters covered by 5 U.S.C. 552b(c)(1) will be considered. The determination is based on the consideration that it is expected that discussions throughout will involve classified matters of national security concern. Such classified material is so intertwined with the unclassified material and non-proprietary information that it cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of the overall meetings. To permit the meetings to be open to the public would preclude discussion of such matters and would greatly diminish the ultimate utility of the DSB's findings or recommendations to the Secretary of Defense and to the Under Secretary of Defense for Acquisition, Technology and Logistics.

In accordance with section 10(a)(3) of the FACA and 41 CFR 102–3.105(j) and 102–3.140, interested persons may submit a written statement for consideration by the Defense Science Board at any time regarding its mission or in response to the stated agenda of a planned meetings. Individuals submitting a written statement may submit their statement to the Designated Federal Official at the address detailed in **FOR FURTHER INFORMATION CONTACT**; at any point, however, if a written statement is not received by August 24, 2016, then it may not be provided to or considered by the Defense Science Board. The Designated Federal Official will review all submissions with the Defense Science Board Chairperson, and ensure they are provided to members of the Defense Science Board before its final deliberations on August 26, 2016.

Dated: August 17, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–19980 Filed 8–19–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0070]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Guaranty Agency Financial Report

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before September 21, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0070. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–347, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Guaranty Agency Financial Report.

OMB Control Number: 1845–0026.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 672.

Total Estimated Number of Annual Burden Hours: 36,960.

Abstract: The Guaranty Agency financial Reports is used by a guaranty agency to request payments of reinsurance for defaulted student loans; make payments for amounts due the Department, for collections on default and lender of last resort loan (default) claims on which reinsurance has been paid and for refunding amounts previously paid for reinsurance claims. The form is also used to determine required reserve levels for agencies and to collect debt information as required for the ''Report on Accounts and Loans Receivable Due from the Public,'' SF 220–9 (Schedule 9 Report) as required by the U.S. Department of Treasury.

Dated: August 17, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–19928 Filed 8–19–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Preschool Development Grants—Preschool Pay for Success Feasibility Pilot

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

Overview Information

Preschool Development Grants—Preschool Pay for Success Feasibility Pilot Notice inviting applications for new awards for fiscal year (FY) 2016.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.419C.

DATES:

Applications Available: August 22, 2016.

Deadline for Notice of Intent to Apply: September 12, 2016.

Deadline for Transmittal of Applications: October 6, 2016.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program

The purpose of this Preschool Pay For Success (PFS) Feasibility Pilot is to encourage State and local PFS activity for preschool programs by providing grants for Feasibility Studies.[1] The Feasibility Studies will determine if PFS is a viable and appropriate strategy to implement preschool programs that are high-quality and yield meaningful results. The Department, in consultation with the Department of Health and Human Services (HHS), developed the Preschool PFS Feasibility Pilot. The ultimate aim of the Preschool PFS Feasibility Pilot is to improve early learning outcomes through a High-Quality Pay for Success Project by providing grants for Feasibility Studies. This pilot does not limit feasibility studies to programs that meet the definition of ''high-quality'' preschool used by the Preschool Development Grants program in its 2014 grant competition in order to allow the PFS demonstrations to demonstrate high-quality in different ways, including through the impacts that the pilots are able to achieve. In this way, such projects could further develop the evidence-base of programs that are demonstrated to be effective.[2] However, the Preschool PFS Feasibility Pilot does not fund the implementation of preschool services. These Feasibility Studies will test the viability of PFS for preschool models designed to effectively serve the Target Population, and identify a broad range of potential Outcome Measures designed to both demonstrate improved student outcomes and result in potential cost savings to school districts, Local Governments, and States, as well as provide more general benefits to society.

In awarding Preschool PFS Feasibility Pilot grants, the Department will only support Feasibility Studies that propose to identify rigorous safeguards to protect the interests of students and their families. This includes not creating incentives for reducing special education referrals or placement when Children with Disabilities need these services and related services under the Individuals with Disabilities Education Act (IDEA), 20 U.S.C. 1400 *et seq.,* in order to be successful. Such incentives would contravene the IDEA requirements that States and school districts have policies and procedures in effect to locate, identify, and evaluate children suspected of having disabilities and who are in need of special education and related services and to ensure that a free appropriate public education (FAPE) is made available to eligible children, 20 U.S.C. 1412(a)(3) (Child Find) and 20 U.S.C. 1412 (a)(1) (FAPE). Possible safeguards should include: Procedures to ensure that the determination of a child's eligibility for special education and related services under the IDEA is completely separated from the financial structure of the project; evaluation methods that mitigate the risk of incentives to exclude or prematurely exit children from needed services and support; stakeholder involvement with groups or families who represent students with disabilities in developing and evaluating the project; inclusion of longer-term impacts, such as third grade reading achievement, on both treatment and control groups; and may include other strategies. The Department is interested in proposals for possible outcome measures that reflect improved outcomes for students with disabilities while protecting their rights under IDEA.

The Department plans to make publicly available the completed Feasibility Studies and related reports in order to make tools and models available to the public, facilitate knowledge-sharing, and lessen the burden of future feasibility assessments in communities. Further, if the Feasibility Studies conclude that PFS is viable, it is the intent of the Department for grantees to use the Feasibility Studies, after the grant period, to develop a PFS project to improve early learning outcomes.

Background on the Pay For Success Model

Under this program, the Department will award grants to States, Local Governments, and Tribal Governments to conduct Preschool PFS Feasibility Pilots. PFS includes innovative contracting and financing models that seek to test and advance promising and proven interventions, while paying only for successful impacts and outcomes for families, individuals, and communities. Through a PFS project, a government (or other) entity enters into a contract to pay for the achievement of concrete, measurable outcomes for specific people or communities. Service providers deliver interventions to achieve these outcomes. Payments, known as Outcomes Payments, are made only if the interventions achieve those outcomes agreed upon in advance. In many cases, these outcomes are expected to occur over a period of years, meaning that the service providers need outside funding in order to cover their operating costs. In these cases, PFS financing is used by bringing in Investors, which are recruited typically by an Intermediary contracted by the government. The government or other

[1] Defined terms are used throughout the document and are indicated by capitalization.

[2] As published in the **Federal Register** on August 18, 2014 (79 FR 48853 and 79 FR 48873).

entity makes Outcomes Payments that, where PFS financing is used, repay Investors for their capital that covered the costs of services (and sometimes other projects costs) and offer them a modest return. In these cases payments are tied to the impact of the intervention, which means the improved outcomes for program recipients relative to a counterfactual, that is, what would have occurred absent the intervention. Ideally, with or without PFS financing, Outcomes Payments amount to a fraction of the short- and long-term cost savings to the government (or other) entity resulting from the successful outcomes. In other cases, these payments may represent an overall greater value to both the recipients of services and to the government or other payor based on the achievement of better outcomes than would otherwise have occurred.

The PFS contracting and financing model requires a partnership among multiple stakeholders. Partners typically include:

- One or more outcomes ''payors,'' generally Federal, State, Local Government, or Tribal Government entities, or other public or private entities that contract to pay for outcomes when achieved;
- Service provider(s), which deliver the intervention intended to achieve the outcomes;
- Investor(s), which cover the up-front cost of implementing the intervention and may also cover other associated costs through PFS financing; and
- An independent evaluator, which determines, through a Rigorous Evaluation, whether the intervention achieved the outcome(s) sought. Most PFS projects to date have also included a project coordinator or Intermediary to facilitate and manage the contracting process and project.

The development, implementation, and evaluation of PFS projects typically involve three stages: Feasibility Study; transaction structuring; and agreement implementation.

The first stage, the Feasibility Study which is the focus of this solicitation, includes the following activities:

- Identification of outcome(s) sought, in particular for the population being served;
- Assessment of community needs, assets, and capacity;
- Identification of a challenge(s) or barrier(s) for serving a particular population or addressing a social issue and determination of the total costs associated with the lack of intervention;
- Identification of interventions that can achieve the desired outcome(s);
- Projection of the potential public value, including any savings, to be achieved through potential interventions;
- Determination of the willingness and capacity of stakeholders to implement a PFS project; and
- Development of Rigorous Evaluation methodology to determine if Outcome Measures have been achieved.

If the Feasibility Study has determined that a PFS project is viable, the next steps to implement the PFS project through transaction structuring and agreement implementation, which are beyond the scope and period of this grant. These activities include structuring the financial agreements, finalizing the evaluation, implementing the intervention and evaluation, measuring outcomes, and making Outcomes Payments (if appropriate).

While not a ''silver bullet,'' PFS models offer many potential benefits; for example:

- People and communities in need are able to receive services as a result of the capital provided by investors;
- Governments can test the effectiveness of interventions—including long-standing models, promising innovations, or adaptations of existing models—or can scale proven interventions that might not otherwise be possible due to funding restrictions or other limitations;
- Service providers can assess the rigorous research measuring the impact of their interventions while also accessing a steady stream of funding for the life of the PFS project;
- Investors can create positive social impact and earn a modest return if outcomes are achieved;
- Multiple entities, including government, service providers, and stakeholders, can benefit from the cross-sector collaboration and appropriate data sharing (that complies with the Family Educational Rights and Privacy Act (20 U.S.C. 1232g; 34 CFR part 99) that PFS facilitates; and
- Rigorous Evaluation of PFS projects strengthens the field's knowledge about effective practices in order to drive better outcomes in the future.

Use of PFS Financing for Preschool

The PFS model can be a promising approach for preschool financing because of preschool's rigorous research base, which includes proven interventions that can generate measurable outcomes. Evidence demonstrates that participation in high-quality inclusive early learning programs can lead to both short- and long-term positive outcomes for children, especially those from low-income families and Children with Disabilities.[3] Additionally, early identification and early supports and services for Children with Disabilities is especially important in impacting long term outcomes. Research has shown multiple benefits of participating in preschool programs, including increased school readiness, lower rates of grade retention and need for remediation, improved high school graduation rates, reduced interaction with law enforcement and teen pregnancy, and higher rates of college attendance.[4] Longitudinal data show that increasing access to high-quality preschool programs, particularly for at-risk children from low-income families, can help close achievement gaps prior to kindergarten entry.[5]

PFS may also be an appropriate mechanism to finance and rigorously evaluate adaptations and other models of providing preschools services, in order to further develop the evidence base of effective models to achieve impacts. Communities where it is difficult or not possible to secure new or additional government resources may choose to pursue a preschool PFS project as a short-term strategy to finance the immediate costs of providing preschool services or as one strategy to promote more effective investments of public dollars. Taxpayer dollars in a PFS contract are only expended when the intervention—here, preschool services—actually benefit children's lives in the ways we anticipate and hope.

The Department notes, however, that preschool PFS is one supplemental financing strategy for early learning and not a substitute for local, State, and Federal funding for full expansion of high-quality early education. The Department also notes that PFS may not be the best or most cost-efficient model to provide high-quality preschool services, and may be more expensive than alternate financing models when

[3] Odom, S.L., et al. (2004). Preschool inclusion in the United States: A review of research from an ecological systems perspective. Journal of Research in Special Educational Needs, 4(1), 17–49.

[4] Yoshikawa, H., Weiland, C., Brooks-Gunn, J., Burchinal, M., Espinosa, L., Gormley, W., & Zaslow, M.J. (2013). Investing in Our Future: The Evidence Base for Preschool Education. Policy brief, Society for Research in Child Development and the Foundation for Child Development. Retrieved from the Foundation for Child Development Web site: *fcd-us.org/sites/default/files/EvidenceBaseonPreschoolEducationFINAL.pdf;* Council of Economic Advisors. (2014). The Economics of Early Childhood Investment. Accessed from *www.whitehouse.gov/sites/default/files/docs/early_childhood_report1.pdf.*

[5] Gormley, W.T., et al. (2005) . ''The Effects of Universal Pre-K on Cognitive Development,'' *Developmental Psychology* (41) (2005):872–884.

scaling up effective preschool programs. We hope to build on the evidence that further demonstrates the value of public investment in preschool [6] and identify innovative service models that produce larger impacts and more diverse outcomes across a broader range of domains.

PFS Outcome Measures

Identifying specific Outcome Measures on which to base the success of a program is a critical component of PFS. A PFS Feasibility Study identifies and explores potential Outcome Measures for an intervention to determine whether a PFS project is viable. This Preschool PFS Feasibility Pilot is designed to build upon PFS preschool projects conducted to date by identifying Outcome Measures that can both support a PFS project while providing structural safeguards against undesirable incentives and yielding evidence of the effectiveness of the preschool program. At this early stage in the development of State and local PFS as a financing model for preschool, projects have focused on a limited number of Outcome Measures that are easily quantifiable, such as the reduction in special education placement.

Project applicants for this grant may choose to use this measure among a number of Outcome Measures to be evaluated in the Feasibility Study. However, access to needed special education and related services is not only critical for Children with Disabilities but also required by IDEA for those preschool-age children who have been determined eligible for special education and related services. Preschool PFS projects should never result in reducing appropriate referrals for children who are suspected of having a disability and have the right to be evaluated to determine eligibility for special education and related services under IDEA. It is important that PFS projects that use the reduction in special education placement as one of the Outcome Measures not create incentives that would reduce referrals of children who are suspected of having a disability under IDEA and are in need of special education and related services. Such incentives would effectively result in denying eligible Children with Disabilities the special education and related services to which they are entitled under IDEA.

In addition to a reduction in the need for special education and related services and remediation in future years, research shows that the expansion of high-quality preschool can lead to improved student achievement, improved social and emotional well-being, improved Executive Functioning,[7] and earlier identification of Children with Disabilities.[8] As the research indicates investment in preschool results in a broad range of both short- and long-term outcomes that benefit children, government, and society, there are multiple savings and societal benefits worth exploring. Potential Outcome Measures may include: Increases in kindergarten readiness; improved reading and math growth or achievement; improved social and emotional skills; improved Executive Functioning; improved child outcomes due to the earlier identification of Children with Disabilities; reductions in grade retention, discipline referrals, and interactions with law enforcement; and increases in high school graduation.[9] The Department is interested in finding ways to quantify these benefits, and developing research-based workable data-driven approaches to monetize such short-, medium-, and long-term benefits. Additionally, the Department is interested in Feasibility Studies that include Outcome Measures that document the potential cost savings associated with, and societal benefits of, the participation of Children with Disabilities in inclusive preschool programs. We note, however, that savings to society are not the primary reason to invest in and expand preschool. There are meaningful benefits to the lives of children and families, such as those discussed above.

Priorities: We are establishing these priorities for the FY 2016 PFS Feasibility Pilot grant competition only, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1).

Absolute Priority: This priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Feasibility Study

Under this priority, the applicant must propose a Feasibility Study that will determine the viability of using a PFS approach to expand or improve a preschool program for a Target Population, and describe the potential Outcome Measures the applicant proposes to identify and evaluate for appropriateness for PFS. Any applicant that includes a Feasibility Study for a PFS project that proposes to reduce the need for special education and related services as an Outcome Measure must also include at least one other meaningful and substantive Outcome Measure of short-, medium-, or long-term student achievement, such as kindergarten readiness, reading and math growth or achievement, and improved social and emotional skills.

Competitive Preference Priority: This priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i) we award up to an additional five points to an application, depending on how well the application meets this priority.

This priority is:

Outcome Measures Across Various Domains

To meet this priority, an applicant must propose a Feasibility Study to evaluate if PFS is viable that would evaluate social and emotional or Executive Functioning Outcome Measures, or both. These potential outcome measures may be predictive of future school success, cost savings, cost avoidance, and other societal benefits, and may appropriate to include in a PFS project.

Application Requirements: An application for a Preschool PFS Feasibility Pilot must include the following:

(a) A project statement of need for the Target Population that includes—

(1) A definition of the Target Population to be served, based on data and analysis demonstrating the need for services within the relevant geographic area; and

[6] Gormley, W.T., et al. (2005). ''The Effects of Universal Pre-K on Cognitive Development,'' *Developmental Psychology* (41):872–884; Karoly, L.A. & Auger, A. (2016). Informing Investments in Preschool Quality and Access in Cincinnati. RAND. Accessed from *http://www.rand.org/pubs/research_reports/RR1461.html.*

[7] Gormley, W., Phillips, D., Welti, K., Newmark, K., & Adelstein, S. (2011). Social-emotional effects of early childhood education programs in Tulsa. *Child Development, 82,* 2095–2109; Weiland, C., & Yoshikawa, H. (2013). Impacts of a prekindergarten program on children's mathematics, language, literacy, executive function, and emotional skills. *Child Development. 84,* 2112–2130; Yoshikawa, H., Weiland, C., Brooks-Gunn, J., Burchinal, M., Espinosa, L., Gormley, W., & Zaslow, M.J. (2013). Investing in Our Future: The Evidence Base for Preschool Education. Policy brief, Society for Research in Child Development and the Foundation for Child Development. Retrieved from the Foundation for Child Development Web site: *fcd-us.org/sites/default/files/EvidenceBaseonPreschoolEducationFINAL.pdf.*

[8] Meisels, S.J. (2000). The elements of early childhood assessment. In J.P. Shonkoff & S.J. Meisels (Ed.), *Handbook of early childhood intervention.* New York, NY: Cambridge University Press.

[9] Various studies of preschool programs have found that preschool participation has improved these outcomes. For example, see Council of Economic Advisors (2014), Gormley, et al. (2011), Weiland & Yoshikawa (2013), and Yoshikawa, et al. (2013).

(2) Data demonstrating how the Target Population lags behind other groups in achieving key outcomes that a future PFS project will seek to achieve.

(b) A description of the preschool program, which must include an explanation of how the design of the program ensures it is high-quality, including evidence supporting its design and policies to ensure, at a minimum:

(1) An evidence-based curriculum;

(2) High-quality professional development for all staff;

(3) High Qualifications for Teachers;

(4) A child-to-instructional staff ratio of no more than 10 to 1;

(5) Inclusion of Children with Disabilities; and

(6) Inclusion of at-risk children and children representing other high-needs populations, such as homeless children and English Learners.[10]

(c) A description of—

(1) How the preschool program is likely to improve student outcomes in the short-, medium-, and long-term, based on quantitative, qualitative, or theoretical evidence (*e.g.,* prior research base or with a logic model);

(2) The goals, objectives, and outcomes to be achieved by the preschool program which are clearly specified and measurable and will demonstrate student success; and

(3) How the intervention is appropriate for, and will successfully address, the needs of the Target Population.

(d) An explanation for why PFS may be an appropriate financing strategy and how existing funding resources preclude serving this population or administering this program.

(e) A description of the Preschool PFS Partnership or, if a Preschool PFS Partnership does not already exist, a plan for developing a Preschool PFS Partnership, that includes a government entity that will serve as the outcomes payor and an Independent Evaluator, and may include an Intermediary.

(f) A description of potential Outcome Measures to be evaluated in the proposed Feasibility Study. If one of the identified Outcome Measures is the reduction in special education placement, the applicant must include at least one other meaningful and substantive Outcome Measures of student achievement such as kindergarten readiness, reading and math growth or achievement, or improved social and emotional skills. Applicants may also propose to include other longer-term measures such as reduced interactions with law enforcement and increased high school graduation rates. While these measures may not occur within the time frame of a PFS project, the Department is interested in workable, researched-based, and data driven analytical approaches to capturing these benefits based on research short and intermediate term indicators.

Program Requirements: Within the project period of the grant award, an eligible applicant awarded a Preschool PFS Feasibility Pilot Grant must—

(a) Submit a written Feasibility Study that consists of the following, at a minimum:

(1) A description of the preschool program model to be implemented, which must include an explanation of how the design of the program ensures it is high-quality, including evidence supporting its design and policies to ensure, at a minimum—

(i) An evidence-based curriculum;

(ii) High-quality professional development for all staff;

(iii) High Qualifications for Teachers;

(iv) A child-to-instructional staff ratio of no more than 10-to-1;

(v) Inclusion of Children with Disabilities;

(vi) Inclusion of at-risk children and children representing other high-needs populations, such as homeless children and English Learners; and

(vii) A description of—

(A) How the intervention is likely to improve student outcomes, based on quantitative, qualitative, or theoretical evidence;

(B) The goals, objectives, and outcomes to be achieved by the preschool program, which are clearly specified and measurable and will demonstrate student success; and

(C) How the intervention is appropriate to, and will successfully address, the needs of the Target Population.

(2) Identification of one or more clearly specified and measurable Outcome Measures. Any grantee that identifies the reduction in the need for special education as an Outcome Measure must include other meaningful and substantive measures of student achievement, such as kindergarten readiness, reading and math growth or achievement, or improved social and emotional skills to be evaluated in the short-, medium-, and longer-term, for both the treatment and control group. If the grantee uses reduction in special education placement as a potential Financial Benefit in its Feasibility Study, the grantee must provide a reasonably designed, detailed plan for safeguarding the rights of Children with Disabilities and their parents, and for meeting the IDEA Child Find requirements in 20 U.S.C. 1412(a)(3), to ensure that children suspected of having a disability under IDEA are properly identified and evaluated and that eligible children receive appropriate special education and related services in compliance with IDEA and relevant State and local laws. This plan must include, at a minimum—

(i) Processes to ensure that determination of eligibility for special education and related services is completely separate from the financial structure of the project;

(ii) A description of how the evaluation methodology to measure the reduction in the need for special education mitigates the risk of perverse incentives;

(iii) A description, based on research and data, of how the other Outcome Measure(s) are meaningful and substantive and indicative of student success; and

(iv) A description of how local stakeholders were involved with developing the plan for safeguards.

Grantees may also include longer-term measures such as reduced interactions with law enforcement and increased high school graduation rate.

(3) A Cost-Benefit Analysis that evaluates whether the preschool program is viable for PFS, including a framework and analysis for estimating the Benefits of the preschool program for the Target Population.

(4) Identification of any statutory or legal barriers to implementing PFS and recommendations of approaches to overcome these barriers.

(5) Identification of potential sources of Outcomes Payments from a government entity or other sources.

(b) If the Feasibility Study concludes that PFS is viable, submit a written report that—

(1) Identifies partners for a Preschool PFS Partnership and includes a description of—

(i) The roles and responsibilities of each partner; and

(ii) An effective governance structure in which partners necessary to implement PFS successfully are represented and have the necessary authority, resources, expertise, and incentives to achieve the PFS project's goals and resolve unforeseen issues;

(2) Describes a plan for Rigorous Evaluation of a PFS project to implement preschool services for the Target Population and demonstrates that the Preschool PFS Partnership has the capacity to collect, analyze, and use

[10] As noted in the Purpose section of this program does not require an applicant to conform to the definition of high-quality preschool in the 2014 Preschool Development Grants program.

data to determine if Outcome Measures have been achieved. Any necessary data sharing agreements must be identified; and

(3) Describes a proposed plan to implement or scale the preschool program for the Target Population, a preliminary financing strategy, and a proposed timeline and milestones, including next steps to proceed to transaction structuring.

(c) If the Feasibility Study concludes that PFS is not viable, provide a written description and explanation of why such a project is not feasible and a discussion of potential alternatives to PFS that would contribute to the public good and enhance or expand preschool services or a description of the steps necessary to make a PFS approach feasible.

(d) The Feasibility Study cannot include any Head Start-funded programs in its Preschool PFS Feasibility Pilot since Head Start is funded by the Federal government.

Definitions: We are establishing the following definitions for the FY 2016 grant competition only in accordance with section 437(d)(1) of GEPA, 20 U.S.C. 1232(d)(1).

Benefits means fiscal and other value to the public and society as a result of achieving the Outcome Measures through the implementation of the intervention for the Target Population. Benefits may include cost savings, cost avoidance, cost-effectiveness, and positive societal benefits.

Children with Disabilities has the same meaning as the term ''child with a disability'' under section 602(3) of the IDEA (20 U.S.C. 1401(3)).

Cost-Benefit Analysis means an analysis that compares the costs of an intervention with the Benefits that will result from achieving the Outcome Measures, including a framework and description of the process used for estimating Benefits that would result from implementation of the intervention.

For example, a Cost-Benefit Analysis of a preschool program may include the costs and Benefits of the initial program, later education, earnings, criminal behavior, tax payments, participation in public welfare, and health outcomes.

English Learner means an individual—

(a) Who is aged 3–21;

(b) Who is enrolled or preparing to enroll in an elementary school or secondary school;

(c)(1) Who was not born in the United States or whose native language is a language other than English;

(2)(i) Who is a Native American or Alaska Native, or a native resident of the outlying areas; and

(ii) Who comes from an environment where a language other than English has had a significant impact on the individual's level of English language proficiency; or

(3) Who is migratory, whose native language is a language other than English, and who comes from an environment where a language other than English is dominant; and

(d) Whose difficulties in speaking, reading, writing, or understanding the English language may be sufficient to deny the individual the—

(1) Ability to meet the challenging State academic standards;

(2) Ability to successfully achieve in classrooms where the language of instruction is English; or

(3) Opportunity to participate fully in society.

Executive Functioning means a set of skills that include sustained attention, impulse control, flexibility in thinking, and working memory (the ability to hold information and manipulate it to perform tasks).

Feasibility Study means a written report assessing the suitability of an intervention for PFS. A Feasibility Study includes, at a minimum—

(a) A description of the preschool program model to be implemented through PFS;

(b) One or more clearly specified and measurable Outcome Measures;

(c) A Cost-Benefit Analysis;

(d) Identification of any statutory or legal barriers to implementing PFS; and

(e) Potential sources of Outcomes Payments from a government entity or other sources.

Financial Benefit means a fiscal benefit to a government entity or entities as a result of a measurable current monetary cost savings and future avoided costs achieved from meeting the designated Outcome Measure.

Financial Model means a quantitative model that shows public sector value (or value to other non-governmental outcomes payors), including cost savings, cost avoidance or efficiency, and societal benefit and links the costs of implementing the preschool services that are covered, in whole or in part, by the Investors to the amount and timing of Outcomes Payments that are made by a government entity.

High-Quality Pay for Success Project means a PFS project that includes—

(a) A well-defined problem and associated Target Population;

(b) A service delivery strategy that is managed, coordinated, and guided by the service provider, is flexible and adaptive to the target problem and population, and has a robust, rigorous evidence base or a compelling theory of change with pre- and post-intervention outcomes;

(c) One or more clearly specified and measureable Outcome Measures that are a significant improvement on the current condition of the Target Population and have been agreed to by all required project partners;

(d) A plan for Rigorous Evaluation;

(e) A financial model that shows Benefits and costs, and tracks effects of the project on relevant Federal, State, and local funding sources;

(f) A commitment from an individual or entity to act as an outcomes payor (whose Outcomes Payments may be directed to Investors if they have covered, in part or in whole, costs associated with delivering the intervention);

(g) If needed, a binding commitment of funds from one or more independent Investors to cover all operating costs of the intervention, including administrative and overhead costs of the Intermediary; and

(h) A legal agreement and any associated necessary agreements that incorporate all elements above.

High Qualifications for Teachers means that a teacher must meet one of the following requirements:

(a) A bachelor's degree in early childhood education or a related field with coursework that demonstrates competence in early childhood education;

(b) A bachelor's degree with a credential, license, or endorsement that demonstrates competence in early childhood education; or

(c) A bachelor's degree in any field and—

(1) Has demonstrated knowledge of early childhood education by passing a State-approved assessment in early childhood education;

(2) While employed as a teacher in the preschool program, is engaged in on-going professional development in early childhood education for not less than two years; and

(3) Not more than four years after starting employment as a teacher in the preschool program, enrolls in and completes a State-approved educator preparation program in which the teacher receives training and support in early childhood education.

Inclusion of Children with Disabilities means, with respect to a preschool program, that Children with Disabilities have access to appropriate activities and settings that are available to their peers without disabilities and that the program:

(a) Includes Children with Disabilities in classrooms and programs where the majority of children are typically developing. The Inclusion of Children with Disabilities in a classroom or program should be in proportion to their presence in the general preschool population. Self-contained or separate classrooms for Children with Disabilities or classrooms where the majority of children are Children with Disabilities are not acceptable;

(b) Provides access to, and full participation of, Children with Disabilities in a wide range of learning opportunities and activities. To the maximum extent possible, and in alignment with their individualized education programs, Children with Disabilities, as appropriate are included in the preschool program throughout the entire day and across all learning opportunities;

(c) Provides modifications to the environment, multiple and varied formats for instruction, and individualized accommodations and supports along a continuum to meet the needs of children with various types of disabilities and levels of severity; and

(d) Ensures that special education and related services are coordinated and integrated within the preschool program as appropriate.[11]

Independent Evaluator means an independent entity that rigorously evaluates whether the intervention achieved the Outcome Measure(s) sought.

Intermediary means an entity that serves as the project facilitator between the parties in a PFS project. Responsibilities may include but are not limited to: Coordinating the development and execution of legal agreements, building a Financial Model to guide the terms of the legal agreements, and raising capital from Investors.

Investor means an individual, entity, or group thereof that provides upfront capital to cover the operating costs and other associated costs, in part or whole, of the intervention delivered by the service provider.

Local Government means any unit of government within a State, including a—

(a) County;

(b) Borough;

(c) Municipality;

(d) City;

(e) Town;

(f) Township;

(g) Parish;

(h) Local public authority, including any public housing agency under the United States Housing Act of 1937;

(i) Special district;

(j) School district;

(k) Intrastate district;

(l) Council of governments, whether or not incorporated as a nonprofit corporation under State law; and

(m) Any other agency or instrumentality of a multi-, regional, or intra-State or local government. (See 2 CFR 200.64).

Outcome Measure means a measure that provides an assessment of a program's impact and is applied to both target and comparison groups. It is determined using relevant program data and has defined units of measurement by which the impact can be tracked. Examples of Outcome Measures include, but are not limited to, improvement in knowledge and skills at kindergarten entry, reduction in the need for remedial services, reduction in the need for grade retention, improvement in third grade reading and math proficiency, and improvement in language development.

Outcomes Payments means payments, as agreed to in PFS legal agreements, to cover repayment of the principal investment and a return in the case that: (a) An Investor has covered part or all of the costs of service delivery and other associated costs, and (b) Outcome Measures have been achieved according to an Independent Evaluator.

Preschool Pay for Success (Preschool PFS) Partnership includes a government entity that makes Outcomes Payments and an Independent Evaluator and may also include an Intermediary. A Preschool PFS Partnership may also include one or more preschool service providers and Investor(s).

Rigorous Evaluation means an evaluation that will, if well implemented, produce evidence about the project's effectiveness that would meet the What Works Clearinghouse Evidence Standards without reservations or, when random assignment is not feasible, would meet What Works Clearinghouse Evidence Standards with reservations.

State means each of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

Target Population means, at a minimum, low-income and disadvantaged preschoolers who are three or four years of age at the time of enrollment, such as those at risk of failing to meet the State's academic content standards. The Target Population may include a more specific criteria.

Tribal Government means the governing body or a governmental agency of any Indian tribe, band, nation, or other organized group or community (including any native village as defined in Section 3 of the Alaska Native Claims Settlement Act, 43 U.S.C. 1602(c)) certified by the Secretary of the Interior as eligible for the special programs and services provided through the Bureau of Indian Affairs.

What Works Clearinghouse Evidence Standards means the standards set forth in the What Works Clearinghouse Procedures and Standards Handbook (Version 3.0, March 2014), which can be found at the following URL address: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19.*

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities, requirements, definitions, and selection criteria. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements, regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this program under the Preschool Development Grant national activities authorized by the Consolidated Appropriations Act, 2016, Title III, Division H (Pub. L. 114–113) and therefore qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forego public comment on the priorities, requirements, definitions, and selection criteria under section 437(d)(1) of GEPA. These priorities, requirements, definitions, and selection criteria will apply to the FY 2016 grant competition only.

Program Authority: Part D of Title V of the Elementary and Secondary Education Act of 1965, as amended by the No Child Left Behind Act of 2001 (ESEA), and Title III of Division H of The Consolidated Appropriations Act, 2016 (Pub. L. 114–113).

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department of Education in 2 CFR

[11] This definition is derived from the IDEA requirement that, to the maximum extent appropriate, children with disabilities are educated with children that are not disabled, and that special classes, separate schooling, or other removal of children with disabilities from the regular educational environment occurs only if the nature or severity of the disability is such that education in regular classes with the use of supplementary aids and services cannot be achieved satisfactorily. 20 U.S.C. 1412(a)(5).

part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department of Education in 2 CFR part 3474.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $2,800,000.

Estimated Range of Awards: $200,000–$400,000.

Maximum Award: We will reject any application that proposes a budget exceeding $400,000 for a single budget period of up to 30 months.

Note: In their budget narratives, applicants must identify which costs will be funded by the Preschool PFS Feasibility Pilot grant and identify any other sources of funds to support project activities. If an applicant plans to have a contractor conduct the Feasibility Study, the applicant must identify the percentage of the Federal dollars from this grant competition the applicant would retain for administrative costs, and the percentage of funds the contractor would retain for its administrative costs.

Estimated Number of Awards: 7–14.

Note: The Department is not bound by any estimates in this notice. The Department will determine the number of awards to be made based on the quality of applications received consistent with the selection criteria. The Department will also determine the size of an award made to an eligible applicant based on a review of the eligible applicant's budget.

Project Period: Up to 30 months.

III. Eligibility Information

1. *Eligible Applicants:* An applicant must be a State, Local Government, or Tribal Government.

2. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs).

To obtain a copy via the Internet, use the following address: *http://www2.ed.gov/programs/preschooldevelopmentgrants/index.html.*

To obtain a copy from ED Pubs, write, fax, or call: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this program or competition as follows: CFDA number 84.419C.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the person listed under *Accessible Format* in section VIII of this notice.

2.a. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program.

b. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the Preschool PFS Feasibility Pilot, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended). Applicants may wish to request confidentiality of business information as we plan to make successful applications available to the public on our Preschool PFS Feasibility Pilot Web site.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Submission Dates and Times:*

Applications Available: August 22, 2016.

Deadline for Notice of Intent to Apply: September 12, 2016.

Deadline for Transmittal of Applications: October 6, 2016.

Applications for grants under this program must be submitted electronically using the *Grants.gov* site (*Grants.gov*). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make awards before the funding lapses.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM) (formerly the Central Contractor Registry), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov.*

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *http://www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with *Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements:* Applications for grants under this program must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. Electronic Submission of Applications

Applications for grants under the Preschool PFS Feasibility Pilot, CFDA number 84.419C, must be submitted electronically using the Governmentwide *Grants.gov* Apply site at *www.Grants.gov*. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for Preschool PFS Feasibility Pilot at *www.Grants.gov*. You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.419, not 84.419C).

Please note the following:

- When you enter the *Grants.gov* site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by *Grants.gov* are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov*, we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov*.
- You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for this program to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department of Education's G5 system home page at *www.G5.gov.* In addition, for specific guidance and procedures for submitting an application through *Grants.gov*, please refer to the *Grants.gov* Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in a read-only Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the project narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. This notification indicates receipt by *Grants.gov* only, not receipt by the Department. *Grants.gov* will also notify you automatically by email if your application met all the *Grants.gov* validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). Once your application is successfully validated by *Grants.gov*, the Department will retrieve your application from *Grants.gov* and

send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by *Grants.gov*, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues With the Grants.gov System: If you are experiencing problems submitting your application through *Grants.gov*, please contact the *Grants.gov* Support Desk, toll free, at 1–800–518–4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with *Grants.gov*, along with the *Grants.gov* Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the *Grants.gov* system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the *Grants.gov* system. We will not grant you an extension if you failed to fully register to submit your application to *Grants.gov* before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if:

You are unable to submit an application through the *Grants.gov* system because you do not have access to the Internet or because you do not have the capacity to upload large documents to the *Grants.gov* system; *and* no later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application. If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Miriam Lund, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E334, Washington, 20202–6200. FAX: (202)

Your paper application must be submitted in accordance with the mail or hand-delivery instructions described in this notice.

b. Submission of Paper Applications by Mail

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.419C), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. Submission of Paper Applications by Hand Delivery

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.419C), 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* We are establishing the following selection criteria for the FY 2016 grant competition only, in accordance with section 437(d)(1) of GEPA, 20 U.S.C. 1232(d)(1). Eligible applicants may receive up to 100 points based on the extent to which their applications address the selection criteria. The

number of points that may be awarded for each criterion is indicated in parentheses next to the criterion.

(a) *Need for Project.* (up to 10 points). The Secretary will consider the needs of the Target Population. In determining the need for the proposed project, the Secretary will consider the magnitude of the need of the Target Population for the services to be provided by a potential PFS project. Applicants should clearly state and demonstrate the extent of the problem facing the Target Population using data and other relevant information.

(b) *Quality of the Preschool Program Design.* (up to 25 points). The Secretary will consider the quality of the design of the proposed preschool program. In determining the quality of the design of the proposed preschool program, the Secretary will consider the extent to which the intervention strategy is likely to improve student outcomes for the Target Population, based on quantitative, qualitative, or theoretical evidence, including the extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable and will demonstrate student success. In responding to this criterion, applicants should identify clearly specified and measurable outcomes for the preschool program and explain how these outcomes can be achieved by the program. While these outcomes will inform the selection of Outcome Measures for the PFS project, they do not limit a grantee from evaluating additional Outcome Measures in the course of completing the Preschool PFS Feasibility Study.

(c) *Quality of the Preschool PFS Partnership.* (up to 25 points). The Secretary will consider the quality of the Preschool PFS Partnership. In evaluating a Preschool PFS Partnership, the Secretary will consider the following:

(1) (up to 15 points). The quality of an existing Preschool PFS Partnership, including the history of the collaboration, or, if a Preschool PFS Partnership does not exist, the quality of the plan to form a Preschool PFS Partnership.

(2) (up to 10 points). The extent to which the roles and responsibilities of members or proposed members of a Preschool PFS Partnership are clearly described and are appropriate and sufficient to successfully implement a PFS project.

(d) *Quality of the Work Plan.* (up to 25 points). The Secretary will consider the quality of the work plan. In determining the quality of the work plan, the Secretary will consider the following factors:

(1) (up to 12 points). The adequacy of the work plan to achieve the objectives of the proposed Feasibility Study project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks on time. Applicants should identify whether a contractor will conduct the Feasibility Study and, if appropriate, the extent to which the timeline for selecting and hiring the contractor is reasonable and sufficient for completing the project on time and within budget.

(2) (up to 10 points). The adequacy of procedures for ensuring stakeholder feedback in the operation of the proposed Preschool PFS Feasibility Pilot. If the Feasibility Study includes the reduction in special education placement as a Financial Benefit, the extent to which the work plan includes outreach to and involvement of the representatives from the State and local special education community or individuals with special education expertise, including groups representing families.

(3) (up to 3 points). The extent to which the time commitments of the project director and team and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(e) *Quality of the Project Leadership and Team.* (up to 5 points). The Secretary will consider the quality of the project leadership and team. The Secretary will consider the extent to which the applicant has the project and financial management experience necessary to manage the Preschool PFS Feasibility Pilot, including:

(1) (up to 3 points). Managing and overseeing similar projects (*e.g.,* PFS or other project related work, experience with early childhood education) with specific examples of prior accomplishments and outcomes; and

(2) (up to 2 points). Managing Federal grants, including plans for ensuring compliance with Federal guidelines.

(f) *Adequacy of Resources.* (up to 10 points). The Secretary will consider the adequacy of resources necessary to complete the Feasibility Study, including any philanthropic or other resources that may be contributed toward the project. In determining the adequacy of resources, the Secretary will consider the extent to which the budget will adequately support program activities and achieve desired outputs and outcomes.

2. *Review and Selection Process:* Each application will be separately screened to determine whether each application meets requirements, and will be separately reviewed and scored.

We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this program the Department will conduct a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved

application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit annual performance reports that provide the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* The Department has established the following Government Performance and Results Act of 1993 (GPRA) performance measures for the Preschool PFS Feasibility Pilot:

1. Number and percentage of grantees that complete a Feasibility Study within the project period.

2. Number and percentage of Feasibility Studies that conclude that PFS approaches for Preschool expansion or improvement are viable.

3. Number and percentage of Feasibility Studies that identify feasible alternatives if PFS is not viable (*e.g.,* alternative funding strategies and mechanisms such as pay for performance, identifying additional outcome measures).

These measures constitute the Department's indicators of success for this program. Consequently, we advise an applicant for a grant under this program to give careful consideration to these measures in conceptualizing the approach and evaluation for its proposed project. Each grantee will be required to provide, in its annual performance and final reports, data about its progress in meeting these measures.

VII. Agency Contacts

FOR FURTHER INFORMATION CONTACT: Miriam Lund, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E334, Washington, DC 20202–6200. Telephone: (202) 401–2871 or by email: *PFS@ed.gov*; or Mary Moran, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E342, Washington, DC 20202–6200. Telephone: (202) 260–0940 or by email: *PFS@ed.gov.*

If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: August 17, 2016.

Ann Whalen,

Senior Advisor to the Secretary Delegated the Duties of Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2016–20021 Filed 8–19–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Announcement of an Open Public Teleconference Meeting

AGENCY: National Advisory Council on Indian Education (NACIE or Council), U.S. Department of Education.

ACTION: Announcement of an open public teleconference meeting.

SUMMARY: This notice sets forth the schedule of an upcoming public meeting conducted by the National Advisory Council on Indian Education (NACIE). Notice of the meeting is required by § 10(a)(2) of the Federal Advisory Committee Act and intended to notify the public of its opportunity to attend. In order to ensure there would be sufficient members in attendance to meet the quorum requirement, this notice is being published in less than 15 days prior to the date scheduled meeting.

DATES: The NACIE teleconference meeting will be held via conference call on Thursday, August 25, 2016 from 4:00 p.m.–5:00 p.m. Eastern Daylight Saving Time. Up to 25 dial-in, listen only phone lines will be made available to the public on a first come, first served basis. The conference call number is 1–800–779–5346 and the participant code is 4307639. Written comments will not be accepted for this meeting.

FOR FURTHER INFORMATION CONTACT: Tina Hunter, Designated Federal Official, Office of Elementary and Secondary Education, U.S. Department of Education, 400 Maryland Avenue SW., Washington, DC 20202. Telephone: 202–205–8527. Fax: 202–205–0310.

SUPPLEMENTARY INFORMATION:

NACIE's Statutory Authority and Function: (NACIE) is authorized by § 6141 of the Elementary and Secondary Education Act of 1965 (ESEA) as amended by the Every Student Succeeds Act (ESSA), 20 U.S.C. 7471. NACIE is governed by the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, which sets forth requirements for the formation and use of advisory committees. NACIE is established within the Department of Education to advise the Secretary of Education on the funding and administration (including the development of regulations, and administrative policies and practices) of any program over which the Secretary has jurisdiction and includes Indian children or adults as participants or programs that may benefit Indian children or adults, including any program established under Title VII, Part A of the Elementary and Secondary Education Act. NACIE submits to the Congress, not later than June 30 of each year, a report on the activities of NACIE that includes recommendations NACIE considers appropriate for the improvement of Federal education programs that include Indian children or adults as participants or that may benefit Indian children or adults, and recommendations concerning the funding of any such program.

Meeting Agenda: The purpose of the meeting is to convene NACIE to conduct the following business: (1) Final discussion, review, and approval of the annual report to Congress; (2) Discuss a schedule to submit recommendations to the Secretary of Education on funding and administration of programs; and (3) To discuss the hiring process for the Office of Indian Education Program Director.

Access to Records of the Meeting: The Department will post the official report of the meeting on the Office of Elementary and Secondary Education (OESE) Web site at: *http://www2.ed.gov/about/offices/list/oese/index.html?src=oc* 21 days after the meeting. Pursuant to the FACA, the public may also inspect the materials at the Office of Indian Education, United States Department of Education, 400 Maryland Avenue SW., Washington, DC 20202, Monday–Friday, 8:30 a.m. to 5:00 p.m. Eastern Daylight Saving Time or by emailing *TribalConsultation@ed.gov* or by calling Terrie Nelson on (202) 401–0424 to schedule an appointment.

Reasonable Accommodations: The teleconference is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify Brandon Dent on (202) 453–6450 no later than August 20, 2016. Although we will attempt to meet a request received after request due date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to make arrangements.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Ann Whalen,

Delegated the authority to perform the functions and duties of Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2016–20028 Filed 8–19–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Orders Granting Authority To Import and Export Natural Gas, and To Export Liquefied Natural Gas, During July 2016

	FE docket nos.
LAKE CHARLES EXPORTS, LLC.	11–59–LNG
CAMERON LNG, LLC	15–90–LNG
AMERICAN L&P CO d/b/a AMERICAN LIGHT AND POWER.	16–85–NG
ETC MARKETING, LTD	16–86–NG
MARATHON OIL COMPANY.	16–87–NG
PROVIDENCE SHIPPING GROUP, INC.	16–88–LNG
PROVIDENCE SHIPPING GROUP, INC.	16–89–LNG
VENTURE GLOBAL PLAQUEMINES LNG, LLC.	16–28–LNG
EAGLE LNG PARTNERS JACKSONVILLE, LLC.	16–15–LNG
LAKE CHARLES LNG EXPORT COMPANY, LLC.	13–04–LNG

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that during July 2016, it issued orders granting authority to import and export natural gas, and to export liquefied natural gas (LNG). These orders are summarized in the attached appendix and may be found on the FE Web site at *http://energy.gov/fe/listing-doefe-authorizationsorders-issued-2016.*

They are also available for inspection and copying in the U.S. Department of Energy (FE–34), Division of Natural Gas Regulation, Office of Regulation and International Engagement, Office of Fossil Energy, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478. The Docket Room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on August 15, 2016.

John A. Anderson,

Director, Office of Regulation and International Engagement, Office of Oil and Natural Gas.

Appendix

DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS

3324–A	07/29/16	11–59–LNG	Lake Charles Exports, LLC	Order 3324–A granting Long-term Multi-contract authority to export LNG by vessel from the Lake Charles Terminal in Calcasieu Parish, Louisiana, to Non-free Trade Agreement Nations.
3846	07/15/16	15–90–LNG	Cameron LNG, LLC	Order 3846 Opinion and Order granting Long-term, Multi-contract authority to export LNG by vessel from Trains 4 and 5 of the Cameron LNG terminal in Cameron and Calcasieu Parishes, Louisiana to Non-free Trade Agreement Nations.
3860	07/08/16	16–85–NG	American L&P Co d/b/a American Light and Power.	Order 3860 granting blanket authority to export natural gas to Mexico.
3861	07/08/16	16–86–NG	ETC Marketing, LTD	Order 3861 granting blanket authority to import/export natural gas from/to Mexico.
3862	07/08/16	16–87–NG	Marathon Oil Company	Order 3862 granting blanket authority to import/export natural gas from/to Canada/Mexico.
3863	07/08/16	16–88–LNG	Providence Shipping Group, Inc.	Order 3863 granting blanket authority to export LNG to Mexico by truck.
3864	07/08/16	16–89–LNG	Providence Shipping Group, Inc.	Order 3864 granting blanket authority to export LNG to Mexico by vessel.
3866	07/21/16	16–28–LNG	Venture Global Plaquemines LNG, LLC.	Order 3866 granting Long-term Multi-contract authority to export LNG by vessel from the Plaquemines LNG Terminal in Plaquemines Parish, Louisiana, to Free Trade Agreement Nations.

DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS—Continued

3867	07/21/16	16–15–LNG	Eagle LNG Partners, Jacksonville, LLC.	Order 3867 granting Long-term Multi-contract authority to export LNG by vessel from, or in ISO Containers loaded at, the proposed Eagle LNG facility in Jacksonville, Florida, to Free Trade Agreement Nations.
3868	07/29/16	13–04–LNG	Lake Charles LNG Export Company, LLC.	Order 3868 granting Long-term Multi-contract authority to export LNG by vessel from the Lake Charles Terminal in Calcasieu Parish, Louisiana, to Non-free Trade Agreement Nations.

[FR Doc. 2016–19971 Filed 8–19–16; 8:45 am]
BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TS16–2–000]

PPL Electric Utilities Corporation; Notice of Filing

Take notice that on December 23, 2015, pursuant to Rule 207 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure,[1] PPL Electric Utilities Corporation filed a request that the Commission confirm that the Standards of Conduct for Transmission Providers adopted in the Order No. 717 [2] and set forth in Part 358 [3] of the Commission's regulations do not apply to it at this time.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on September 6, 2016.

Dated: August 15, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–19904 Filed 8–19–16; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–372–002.
Applicants: PJM Interconnection, L.L.C.
Description: Compliance filing: Compliance Filing Implementing Hourly Offers and Cost-Based Offer Requirements to be effective 12/31/9998.
Filed Date: 8/16/16.
Accession Number: 20160816–5214.
Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2119–001.
Applicants: Hartree Partners, LP.
Description: Tariff Amendment: Hartree Partners, LP—Amended MBRA Baseline Filing to be effective 8/16/2016.
Filed Date: 8/16/16.
Accession Number: 20160816–5192.
Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2431–000.
Applicants: CP Power Sales Nineteen, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation to be effective 8/17/2016.
Filed Date: 8/16/16.
Accession Number: 20160816–5190.
Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2432–000.
Applicants: CP Power Sales Twenty, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation to be effective 8/17/2016.
Filed Date: 8/16/16.
Accession Number: 20160816–5191.
Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2433–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: SCE's Revision to Formula Rate Tariff Authorized PBOPs Expense Amounts to be effective 1/1/2016.
Filed Date: 8/16/16.
Accession Number: 20160816–5201.
Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2434–000.
Applicants: Copper Mountain Solar 4, LLC.
Description: § 205(d) Rate Filing: Notice of Non-Material Change in Status to be effective 5/20/2016.
Filed Date: 8/16/16.
Accession Number: 20160816–5223.
Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2435–000.
Applicants: Mesquite Solar 2, LLC.
Description: § 205(d) Rate Filing: Notice of Non-Material Change in Status to be effective 5/20/2016.
Filed Date: 8/16/16.
Accession Number: 20160816–5227.
Comments Due: 5 p.m. ET 9/6/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and

[1] 18 CFR 385.207 (2015).

[2] Standards of Conduct for Transmission Providers, Order No. 717, 73 FR 63,796 (Oct. 27, 2008), FERC Stats. & Regs. ¶ 31,280 (2008), *on reh'g,* Order No. 717–A, 74 FR 54,463 (Oct. 22, 2009), FERC Stats. & Regs. ¶ 31,297 (2009), *clarified,* Order No. 717–B, 74 FR 60,153 (Nov. 20, 2009), 129 FERC ¶ 61,123 (2009), *on reh'g,* Order No. 717–C, 75 FR 20,909 (Apr. 22, 2010), 131 FERC ¶ 61,045 (2010), *on reh'g and clarification,* Order No. 717–D, 76 FR 20,838 (Apr. 14, 2011), 135 FERC ¶ 61,017 (2011).

[3] 18 CFR 358.1(b).

385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 16, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–19963 Filed 8–19–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2437–003.

Applicants: Arizona Public Service Company.

Description: Second Supplement to December 22, 2015 Triennial Market Power Update [SIL Study] of Arizona Public Service Company.

Filed Date: 8/15/16.

Accession Number: 20160815–5226.

Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER15–943–003.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Report Filing: 2016–08–04_SA 6502 Refund Report related to Edwards SSR Settlement to be effective N/A.

Filed Date: 8/4/16.

Accession Number: 20160804–5040.

Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2414–000.

Applicants: PJM Interconnection, L.L.C.

Description: Section 205(d) Rate Filing: Service Agreement Nos. 4511 and 4512, Queue Positions AB1–127 and AB1–128 to be effective 7/13/2016.

Filed Date: 8/12/16.

Accession Number: 20160812–5145.

Comments Due: 5 p.m. ET 9/2/16.

Docket Numbers: ER16–2415–000.

Applicants: ISO New England Inc.

Description: ISO New England Inc. submits Second Quarter 2016 Capital Budget Report.

Filed Date: 8/12/16.

Accession Number: 20160812–5153.

Comments Due: 5 p.m. ET 9/2/16.

Docket Numbers: ER16–2416–000.

Applicants: Central Maine Power Company.

Description: Section 205(d) Rate Filing: Amended CSIA with Brookfield White Pine Hydro LLC to be effective 8/1/2016.

Filed Date: 8/12/16.

Accession Number: 20160812–5160.

Comments Due: 5 p.m. ET 9/2/16.

Docket Numbers: ER16–2417–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2016–08–12_Removal of MVP Pricing Limitation to PJM (ER10–1791) to be effective 7/13/2016.

Filed Date: 8/12/16.

Accession Number: 20160812–5197.

Comments Due: 5 p.m. ET 9/2/16.

Docket Numbers: ER16–2418–000.

Applicants: Southern California Edison Company.

Description: Section 205(d) Rate Filing: Letter Agreement ACES Project to be effective 8/15/2016.

Filed Date: 8/12/16.

Accession Number: 20160812–5202.

Comments Due: 5 p.m. ET 9/2/16.

Docket Numbers: ER16–2419–000.

Applicants: Duke Energy Progress, LLC, Duke Energy Florida, LLC, Duke Energy Carolinas, LLC.

Description: Compliance filing: Order No. 828 Compliance Filing to be effective 10/14/2016.

Filed Date: 8/15/16.

Accession Number: 20160815–5144.

Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2421–000.

Applicants: PJM Interconnection, L.L.C.

Description: Section 205(d) Rate Filing: Amendment to Original WMPA SA No. 3772, Queue No. Y2–088 to be effective 2/20/2014.

Filed Date: 8/15/16.

Accession Number: 20160815–5189.

Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2422–000.

Applicants: Illinois Power Generating Company.

Description: Section 205(d) Rate Filing: Revised Rate Schedule and Request for Expedited Treatment to be effective 9/15/2016.

Filed Date: 8/15/16.

Accession Number: 20160815–5200.

Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2423–000.

Applicants: Wisconsin Power and Light Company.

Description: Section 205(d) Rate Filing: City of Sheboygan Falls Wholesale Service Agreement to be effective 10/14/2016.

Filed Date: 8/15/16.

Accession Number: 20160815–5225.

Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2424–000.

Applicants: Alta Wind VIII, LLC.

Description: Section 205(d) Rate Filing: Clarification to MBR Change in Status for Alta Wind VIII LLC to be effective 6/29/2016.

Filed Date: 8/15/16.

Accession Number: 20160815–5247.

Comments Due: 5 p.m. ET 9/6/16.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES16–51–000.

Applicants: South Carolina Electric & Gas Company, South Carolina Generating Company, Inc.

Description: Application for Authorization under FPA Section 204 for South Carolina Electric & Gas Company to Issue Short-Term Debt Securities and to Assume Liabilities as Guarantor and for South Carolina Generating Company, Inc.

Filed Date: 8/12/16.

Accession Number: 20160812–5213.

Comments Due: 5 p.m. ET 9/2/16.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RD16–9–000.

Applicants: North American Electric Reliability Corp.

Description: Petition of the North American Electric Reliability Corporation for Approval of Proposed Reliability Standard COM–001–3.

Filed Date: 8/15/16.

Accession Number: 20160815–5245.

Comments Due: 5 p.m. ET 9/14/16.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RR16–5–000.

Applicants: North American Electric Reliability Corporation.

Description: Petition of North American Electric Reliability Corporation for Approval of Proposed Rules of Procedure Revisions.

Filed Date: 8/15/16.

Accession Number: 20160815–5180.

Comments Due: 5 p.m. ET 9/6/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 15, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–19901 Filed 8–19–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–1637–001.

Applicants: UIL Distributed Resources, LLC.

Description: Report Filing: Refund Report to be effective N/A.

Filed Date: 8/12/16.

Accession Number: 20160812–5201.

Comments Due: 5 p.m. ET 9/2/16.

Docket Numbers: ER16–2420–000.

Applicants: Southern Cross Transmission LLC.

Description: Application of Southern Cross Transmission LLC for Revision of Existing Negotiated Rate Authority to Allow Allocation of Transmission Capacity Under the Capacity Allocation Policy Statement and Request for Expedited Consideration etc.

Filed Date: 8/12/16.

Accession Number: 20160812–5217.

Comments Due: 5 p.m. ET 8/26/16.

Docket Numbers: ER16–2426–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original ISA SA No. 4508, Queue No. AA2–145 to be effective 7/18/2016.

Filed Date: 8/16/16.

Accession Number: 20160816–5090.

Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2427–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2016–08–16_SA 1632 ITC Midwest-Osceola Windpower GIA (G426/G538) to be effective 8/25/2010.

Filed Date: 8/16/16.

Accession Number: 20160816–5098.

Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2428–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1166R29 Oklahoma Municipal Power Authority NITSA and NOA to be effective 7/1/2016.

Filed Date: 8/16/16.

Accession Number: 20160816–5108.

Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2429–000.

Applicants: Louisville Gas and Electric Company.

Description: Tariff Cancellation: LGE KU Notice of Cancellation Long Form MBR Tariff to be effective 10/17/2016.

Filed Date: 8/16/16.

Accession Number: 20160816–5109.

Comments Due: 5 p.m. ET 9/6/16.

Docket Numbers: ER16–2430–000.

Applicants: Kentucky Utilities Company.

Description: Tariff Cancellation: Notice of Cancellation Concurrence Long Form MBR Tariff to be effective 10/17/2016.

Filed Date: 8/16/16.

Accession Number: 20160816–5110.

Comments Due: 5 p.m. ET 9/6/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 16, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–19962 Filed 8–19–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. TS16–1–000]

NorthWestern Corporation; Notice of Filing

Take notice that on November 2, 2015, NorthWestern Corporation filed a notice of change in facts and a request for continuance of waiver pursuant to the Commission's May 21, 2009 Order, *Material Changes in Facts Underlying Waiver of Order No. 889 and Part 358 of the Commission's Regulations,* 127 FERC ¶ 61,141 (2009), 18 CFR 35.28(e)(2) and 358.1(d).

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on September 6, 2016.

Dated: August 15, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–19903 Filed 8–19–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–2411–000]

Luning Energy Holdings LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding Luning Energy Holdings LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is September 6, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 16, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–19965 Filed 8–19–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–2412–000]

Luning Energy LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding Luning Energy LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is September 6, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 16, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–19966 Filed 8–19–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–2397–000]

Elevation Energy Group, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Elevation Energy Group, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is September 6, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access

who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 16, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–19964 Filed 8–19–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Rocky Mountain Region Transmission, Ancillary Services, Transmission Losses, and Sales of Surplus Products—Rate Order No. WAPA–174

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of order concerning transmission, ancillary services, transmission losses, and sales of surplus products formula rates.

SUMMARY: The Deputy Secretary of Energy has confirmed and approved Rate Order No. WAPA–174 and Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–UU1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, L–AS9, and L–M1 placing Loveland Area Projects (LAP) transmission; Colorado River Storage Project (CRSP), LAP, and Western Area Colorado Missouri Balancing Authority (WACM) ancillary services; WACM transmission losses, and LAP sales of surplus products formula rates of the Western Area Power Administration (WAPA), Rocky Mountain Region (WAPA–RMR) into effect on an interim basis (Provisional Formula Rates). The Provisional Formula Rates will provide sufficient revenue to pay all annual costs, including interest expense, and to repay applicable investments within the allowable periods.

DATES: The Provisional Formula Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–UU1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, L–AS9, and L–M1 are effective on the first day of the first full billing period beginning on or after October 1, 2016, and will remain in effect through September 30, 2021, pending approval by the Federal Energy Regulatory Commission (FERC) on a final basis or until superseded.

FOR FURTHER INFORMATION CONTACT: Mr. Bradley S. Warren, Regional Manager, Rocky Mountain Region, Western Area Power Administration, 5555 East Crossroads Boulevard, Loveland, CO 80538–8986, telephone (970) 461–7201, or Mrs. Sheila D. Cook, Rates Manager, Rocky Mountain Region, Western Area Power Administration, 5555 East Crossroads Boulevard, Loveland, CO 80538–8986, telephone (970) 461–7211, email *scook@wapa.gov.*

SUPPLEMENTARY INFORMATION: The Deputy Secretary of Energy approved WAPA–155, which provides the existing formula Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–UU1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, L–AS9, on September 2, 2011 (76 FR 61184).[1] Those formula rate schedules expire on September 30, 2016. WAPA–RMR published a **Federal Register** notice (Proposed FRN) on February 3, 2016 (81 FR 5744), proposing a change to the forward-looking transmission rate methodology; modifications to rate designs under Rate Schedules L–FPT1, L–AS2, and L–AS3; clarification of the language in all the existing rate schedules; and implementation of a new rate schedule for sales of surplus products, L–M1. The Proposed FRN also initiated a public consultation and comment period and set forth the date and location of the public information and public comment forums. WAPA–RMR held both forums in Loveland, Colorado, on March 28, 2016, where staff explained the proposed formula rates, answered questions, and provided the public with an opportunity to comment for the record.

WAPA–RMR modified the forward-looking transmission rate methodology; rate designs in Rate Schedules L–FPT1, L–AS2, and L–AS3; clarified language in all the existing rate schedules; and implemented a new formula rate schedule for sales of surplus products, Rate Schedule L–M1. The rate schedules contain formula-based charges which will be calculated annually to incorporate the most recent financial, load, and schedule information, as applicable.

By Delegation Order No. 00–037.00A, effective October 25, 2013, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the Administrator of WAPA; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to FERC. Federal rules (10 CFR part 903) govern Department of Energy procedures for public participation in power and transmission rate adjustments.

Under Delegation Order Nos. 00–037.00A and 00–001.00F and in compliance with 10 CFR part 903 and 18 CFR part 300, I hereby confirm, approve, and place Rate Order No. WAPA–174, which provides the formula rates for LAP transmission; LAP, CRSP, and WACM ancillary services; WACM transmission losses; and LAP sales of surplus products, into effect on an interim basis. The new Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–UU1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, L–AS9, and L–M1 will be submitted promptly to FERC for confirmation and approval on a final basis.

Dated: August 12, 2016.

Elizabeth Sherwood-Randall,

Deputy Secretary of Energy.

Department of Energy

Deputy Secretary

In the Matter of:

Western Area Power Administration, Rocky Mountain Region, Rate Adjustment for Transmission, Ancillary Services, Transmission, Losses, and Sales of Surplus Products,

Rate Order No. WAPA–174

Order Confirming, Approving, and Placing Transmission Service, Ancillary Services, Transmission Losses, and Sales of Surplus Products Formula Rates Into Effect on An Interim Basis

The transmission, ancillary services, transmission losses, and sales of surplus products formula rates set forth in this order are established pursuant to section 302 of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152). This act transferred to and vested in the Secretary of Energy the

[1] FERC confirmed and approved WAPA–155 on a final basis on December 2, 2011, in Docket No. EF11–10–000. *See United States Department of Energy, Western Area Power Administration,* 137 FERC ¶ 62,200.

power marketing functions of the Secretary of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Act of 1939 (43 U.S.C. 485h(c)) and section 5 of the Flood Control Act of 1944 (16 U.S.C. 825s), and other acts that specifically apply to the projects involved.

By Delegation Order No. 00–037.00A, effective October 25, 2013, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the Administrator of Western Area Power Administration; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to the Federal Energy Regulatory Commission. Federal rules (10 CFR part 903) govern DOE procedures for public participation in power rate adjustments.

Acronyms/Terms and Definitions

As used in this Rate Order, the following acronyms/terms and definitions apply:

Acronym/term	Definition
$/kW-month	Dollars per kilowatt per month.
12-cp	Rolling 12-month average of customers' loads in excess of applicable Federal Entitlement, coincident with the Loveland Area Projects transmission system peak.
AGC	Automatic Generation Control.
Balancing Authority	The responsible entity that integrates resource plans ahead of time, maintains load-interchange-generation balance within a Balancing Authority area, and supports interconnection frequency in real time.
Business Practices	Document that provides requirements for services and clarifies various aspects of the services offered.
Control Area	The term used for a Balancing Authority area in WAPA's Open Access Transmission Tariff.
Customer Brochure	Document that further explains the rate methodologies under Rate Order No. WAPA–174.
CRSP	Colorado River Storage Project.
CRCM	The CRSP Transmission Service Provider.
DOE	United States Department of Energy.
Federal Customers	LAP or CRSP customers taking delivery of long-term firm service under firm electric service contracts, project use, and special use contracts.
Firm Electric Service Contracts	Contracts for the sale of long-term firm LAP and CRSP Federal energy and capacity, pursuant to each Project's General Power Marketing and Allocation Criteria (Marketing Plan).
FERC	Federal Energy Regulatory Commission.
Federal Entitlements	The energy and capacity delivered to Federal Customers under Firm Electric Service Contracts.
Fry-Ark	Fryingpan-Arkansas Project.
FY	Fiscal Year, October 1 through September 30.
LAP	Loveland Area Projects.
LAPT	The LAP Transmission Service Provider.
M&I	Municipal and Industrial.
Monthly Entitlements	Maximum capacity to be delivered each month under Firm Electric Service Contracts. Each monthly entitlement is a percentage of the seasonal contract-rate-of-delivery.
MW	Megawatt. The unit of electrical capacity equal to 1,000 kW or 1,000,000 watts.
Open Access Same Time Information System (OASIS).	An electronic posting system a Transmission Service Provider maintains for transmission access data that allows all transmission customers to view the data simultaneously.
OATT	WAPA's revised Open Access Transmission Service Tariff, effective April 12, 2013.
Provisional Formula Rate	A formula rate confirmed, approved, and placed into effect on an interim basis by the Deputy Secretary.
P–SMBP	Pick-Sloan Missouri Basin Program.
P–SMBP—WD	Pick-Sloan Missouri Basin Program—Western Division.
RMR	Rocky Mountain Region.
Transmission Service Provider	An entity who administers a transmission tariff and provides transmission service to transmission customers under applicable transmission service agreements.
VAR	Volt-Ampere Reactive related to Reactive Supply and Voltage Control.
VER	Variable Energy Resource is one whose output is volatile and variable due to factors beyond direct operations control and, therefore, is not dispatchable.
WACM	Western Area Colorado Missouri Balancing Authority.
WAPA	Western Area Power Administration.

Effective Date

The Provisional Formula Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–UU1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, L–AS9, and L–M1 are effective on the first day of the first full billing period beginning on or after October 1, 2016, and will remain in effect through September 30, 2021, pending approval by FERC on a final basis or until superseded.

Public Notice and Comment

WAPA–RMR has followed the Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions, 10 CFR part 903, in the development of these formula rates and schedules. The steps WAPA–RMR took to involve interested parties in the rate process were:

1. On August 10, 2015, WAPA–RMR held an informal customer meeting to discuss changes, updates, and additions WAPA–RMR was considering recommending for LAP transmission; CRSP, LAP, and WACM ancillary services; WACM transmission losses; and LAP sales of surplus products. The meeting was announced through email notification to all customers, as well as posting on WAPA–RMR's Web site for all interested parties. WAPA–RMR posted all information presented at the informal customer meeting, as well as responses to questions asked at the meeting, on its Web site at *http://www.wapa.gov/regions/RM/rates/Pages/2017-rate-adjustment.aspx*.

2. WAPA–RMR published a **Federal Register** notice on February 3, 2016 (81 FR 5744) (Proposed FRN), announcing the proposed transmission, ancillary services, transmission losses, and sales of surplus products formula rates adjustment, initiating the public consultation and comment period, announcing the date and location of the public information and public comment forums, and outlining procedures for public participation.

3. On February 3, 2016, WAPA–RMR sent a letter to customers and interested

parties providing them with a copy of the Proposed FRN.

4. On March 28, 2016, WAPA–RMR held a public information forum in Loveland, Colorado, where WAPA–RMR representatives explained the need for the formula rates adjustment in detail and answered questions.

5. On March 28, 2016, following the public information forum, WAPA–RMR held a public comment forum in Loveland, Colorado, to provide an opportunity for customers and other interested parties to comment for the record. At this forum, one individual presented nine comments. Those comments and WAPA–RMR's responses are addressed below.

6. WAPA–RMR received one written comment letter during the 90-day consultation and comment period, which ended on May 3, 2016. The letter contained several comments, many of which were also presented during the comment forum. The comments and WAPA–RMR's responses are addressed below.

All comments received have been considered in the preparation of this Rate Order.

Project Descriptions

The Post-1989 General Power Marketing and Allocation Criteria, published in the **Federal Register** on January 31, 1986 (51 FR 4012), integrated the resources of the P–SMBP—WD and Fry-Ark. This operational and contractual integration, known as LAP, allowed an increase in marketable resources, simplified contract administration, and established a blended rate for LAP power sales. WAPA–RMR offers ancillary services from a combination of LAP generation resources and CRSP generation resources.

P–SMBP—WD

The P–SMBP was authorized by Congress in section 9 of the Flood Control Act of December 22, 1944 (Pub. L. 534, 58 Stat. 877, 891). This multipurpose program provides flood control, M&I water supply, irrigation, navigation, recreation, preservation and enhancement of fish and wildlife, and hydroelectric power. Multipurpose projects have been developed on the Missouri River and its tributaries in Colorado, Montana, Nebraska, North Dakota, South Dakota, and Wyoming.

In addition to the multipurpose water projects authorized by section 9 of the Flood Control Act of 1944, certain other existing projects have been integrated with the P–SMBP for power marketing, operation, and repayment purposes. The Colorado-Big Thompson, Kendrick, Riverton, and Shoshone Projects were combined with P–SMBP in 1954, followed by the North Platte Project in 1959. These projects are known as the ''Integrated Projects'' of the P–SMBP. The Riverton Project was reauthorized as a unit of the P–SMBP in 1970. Together, the P–SMBP—WD and the Integrated Projects have 19 power plants.

There are six power plants in P–SMBP—WD: Glendo, Kortes, and Fremont Canyon power plants on the North Platte River; Boysen and Pilot Butte power plants on the Wind River; and Yellowtail power plant on the Big Horn River. The Colorado-Big Thompson Project has six power plants: Green Mountain power plant on the Blue River is on the Western Slope of the Continental Divide; and Mary's Lake, Estes, Pole Hill, Flatiron, and Big Thompson power plants along the Big Thompson River are on the Eastern Slope of the Continental Divide. The Kendrick Project has two power plants: Alcova and Seminoe power plants on the North Platte River. Power plants in the Shoshone Project are the Shoshone, Buffalo Bill, Heart Mountain, and Spirit Mountain plants on the Shoshone River. The only power plant in the North Platte Project is the Guernsey power plant, also on the North Platte River.

Fry-Ark

Fry-Ark is a trans-mountain diversion development in southeastern Colorado authorized by the Act of Congress on August 16, 1962 (Pub. L. 87–590, 76 Stat. 389, as amended by Title XI of the Act of Congress on October 27, 1974 (Pub. L. 93–493, 88 Stat. 1486, 1497)). The Fry-Ark diverts water from the Fryingpan River and other tributaries of the Roaring Fork River in the Colorado River Basin on the Western Slope of the Rocky Mountains to the Arkansas River on the Eastern Slope of the Rocky Mountains. The water diverted from the Western Slope, together with regulated Arkansas River water, provides supplemental irrigation and M&I water supplies and produces hydroelectric power. Flood control, fish and wildlife enhancement, and recreation are other important purposes of Fry-Ark. The only generating facility in Fry-Ark is the Mt. Elbert Pumped-Storage power plant on the Eastern Slope.

CRSP

CRSP was authorized by the Colorado River Storage Project Act, ch. 203, 70 Stat. 105, (43 U.S.C. 620) on April 11, 1956. The project provides water-use developments for states in the Upper Basin (Colorado, New Mexico, Utah, and Wyoming) while still maintaining water deliveries to the states of the Lower Basin (Arizona, California, and Nevada) as required by the Colorado River Compact of 1922. Generation from CRSP and its participating projects, Dolores and Seedskadee, and from the Collbran and Rio Grande Projects have been marketed as the Salt Lake City Area/Integrated projects (SLCA/IP) since October 1, 1987. The CRSP Project has five plants: Blue Mesa, Crystal, and Morrow Point on the Gunnison River, Flaming Gorge located on the Green River, and Glen Canyon located on the Colorado River; Dolores Project has two plants: Towaoc located on the Towaoc Canal and McPhee located on the Dolores River; Seedskadee Project has one plant: Fontenelle located on the Green River; Collbran Project has two plants: Upper and Lower Molina located on the Cottonwood and Plateau Creeks respectively; and the Rio Grande Project has one plant: Elephant Butte located on the Rio Grande River.

Transmission, Ancillary Services, Transmission Losses, and Sales of Surplus Products

WAPA–RMR is implementing revised formula rates for transmission, ancillary services, and transmission losses under Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–UU1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, and L–AS9 and a new formula rate for sales of surplus products under Rate Schedule L–M1. The formula rates are each designed to recover the annual costs of providing the services, as applicable.

Existing and Provisional Formula Rates

The existing formula rates contained in Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–UU1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, and L–AS9 expire on September 30, 2016. Several of these rate schedules contain formula rates that were calculated each year to include the most recent financial, load, and schedule information, as applicable. The new rate schedules continue with this approach. The charges under the applicable formula rates are calculated annually in early summer; therefore, WAPA–RMR was unable to provide the specific charges for FY 2017 during the rate process and in this Rate Order. Once calculated, the FY 2017 charges will be posted to WAPA's Web sites at *http://www.wapa.gov/regions/RM/rates/Pages/Transmission-ancillary.aspx* and *https://www.wapa.gov/regions/CRSP/rates/Pages/Tariffs.aspx*.

Certification of Rates

WAPA's Administrator certified the Provisional Formula Rates for LAP

Transmission; CRSP, LAP and WACM Ancillary Services; WACM Transmission Losses; and LAP Sales of Surplus Products under Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–UU1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, L–AS9, and L–M1 are the lowest possible rates consistent with sound business principles. The Provisional Formula Rates were developed following administrative policies and applicable laws.

LAP Transmission Service Discussion

In accordance with WAPA's OATT, LAPT offers Network Integration Transmission Service (Network Service) and Firm and Non-Firm Point-to-Point Transmission Services. These services include the transmission of energy to points of delivery on the LAP interconnected high-voltage system, which is comprised of transmission lines, substations, and related facilities. Transmission service for the LAP Federal Customers is bundled in the LAP Firm Electric Service (FES) rate.

The methodology used for formula rate development and the implementation process are described below.

Annual Transmission Revenue Requirement

WAPA–RMR is not changing the calculation of the annual transmission revenue requirement (ATRR), which is applicable to both Network and Point-to-Point transmission services. The calculation for the ATRR is:

Annual Transmission Revenue Requirement	=	Annual Transmission Cost	+	Transmission Expenses for Increasing Transmission System Capacity	-	Revenues from N-F Point-to-Point Transmission Service	-	Revenues from Scheduling & Dispatch Service	+ or -	Miscellaneous Charges and Credits	+ or -	Prior Year True-Up

The annual transmission cost is the ratio of gross investment cost for transmission facilities to gross investment cost for all facilities multiplied by the applicable total annual costs, which include operations and maintenance, interest, and depreciation expenses. The calculation is:

$$\text{Annual Transmission Cost} = \frac{\text{Gross Investment Cost for Transmission Facilities}}{\text{Gross Investment Cost for All Facilities}} \times \text{Total Annual Costs}$$

The gross investment cost for transmission facilities will be determined by an analysis of the LAP Transmission System. Each LAP facility is classified by function: Transmission, sub-transmission, or generation-related. The facilities identified as performing the function of transmission include transmission lines normally operated in a continuously-looped manner and the associated substations and switchyard facilities. In the LAP Transmission System, these are primarily the 115-kV and above facilities. In addition, a portion of the communication and maintenance facilities is included in the investment cost for transmission. Only the investment costs of the facilities identified as ''transmission,'' including allocated costs for communication and maintenance facilities, are used in developing the annual transmission cost. The investment costs of facilities identified as ''sub-transmission'' are excluded from the ATRR, as the LAP sub-transmission system is used primarily for delivery of Federal Entitlements to Federal Customers. If a transmission customer, who does not have an FES agreement with LAP, requires the use of the sub-transmission system, an additional facility-use charge will be assessed. Fry-Ark facilities are considered generation-related and, therefore, are excluded from the ATRR.

The transmission expenses for increasing transmission system capacity will continue to include payments made to others for their systems' augmentation of the LAP Transmission System. Miscellaneous charges and credits will include, but not be limited to, Unreserved Use and facility charges for transmission facility investments included in the revenue requirement. Since the LAP transmission rates include LAP's Scheduling, System Control, and Dispatch Service (SSCD Service) costs, the revenue collected by WACM for providing this service is included as a credit to the ATRR, as shown above.

Forward-Looking Transmission Rate

Effective October 2011, WAPA–RMR used a forward-looking transmission rate methodology to calculate the ATRR to recover transmission expenses and investments on a current basis rather than a historical basis. As part of this methodology, WAPA–RMR projected transmission costs two years into the future, relying on current year actuals for approximately the first eight months of the year and projecting the remaining four months of the year plus twelve additional months. Western has determined, however, estimating the additional twelve months introduced unnecessarily large true-ups. As a result, starting in October 2016, WAPA–RMR is removing the additional twelve months from the projection, thus only having to true-up the projected costs for the four-month period of the current year. This method will allow WAPA–RMR to more accurately match cost recovery with cost incurrence. This method will be a change in the manner in which the inputs for the charge are developed, rather than a change to the formula rate itself.

When actual cost information for a year becomes available, WAPA–RMR will continue to calculate the actual revenue requirement. Revenue collected in excess of WAPA–RMR's actual revenue requirement will be included as a credit in the ATRR in the following year. Similarly, any under-collection of the revenue requirement will be recovered in the following year. This true-up procedure ensures WAPA–RMR recovers no more or no less than the actual transmission costs for the year. For example, as the remaining four months of FY 2016 actual financial data becomes available during FY 2017, the under-collection or over-collection of revenue for FY 2016 can be determined. When the FY 2018 charge is calculated, it will include an adjustment for revenue under-collection or over-collected in FY 2016.

Annual operation and maintenance expenses are projected using budgeted amounts. Depreciation and interest

expenses are projected using historical amounts modified to account for projected additions to plant in-service in the current year. Plant in-service expenses are projected using historical amounts plus an estimate for projects anticipated to be booked to plant in the current year and by removing current year retirements.

Network Integration Transmission Service

WAPA–RMR has made no changes to the Network Service formula rate, under Rate Schedule L–NT1. The monthly charge for Network Service will continue to be the product of one-twelfth of the ATRR times the transmission customer's load-ratio share.

The Provisional Formula Rate is as follows:

$$\text{Monthly Charge} = \frac{\text{Annual Transmission Revenue Requirement}}{12} \times \text{Network Service Customer's Load-Ratio Share}$$

The customer's load-ratio share is the ratio of its Network Service load to the LAP Transmission System total load at the LAP system peak. This is calculated on a rolling 12-month basis (12 coincident peak average or 12-cp).

Firm Point-to-Point Transmission Service

The formula rate for Firm Point-to-Point Transmission service, under Rate Schedule L–FPT1, has been modified in order to clarify the denominator includes the reserved capacity for Firm Point-to-Point Transmission Service, plus a 12-month average capacity value for Network Service (including Federal Entitlements) rather than stating it includes the ''LAP Transmission System total load.''

The Provisional Formula Rate is as follows:

$$\text{Firm Point-to-Point Transmission Service Formula Rate} = \frac{\text{Annual Transmission Revenue Requirement (\$)}}{\text{Firm Transmission Capacity Reservations} + \text{Network Integration Transmission Service Capacity (kW)}}$$

Just like the ATRR, the capacity used in this formula is determined once annually and is used to calculate the Firm Point-to-Point Transmission Service charges for the entire year.

Non-Firm Point-to-Point Transmission Service

WAPA–RMR has made no changes to the Non-Firm Point-to-Point Transmission Service formula rate, under Rate Schedule L–NFPT1. It will continue to equal the Firm Point-to-Point Transmission Service formula rate. The charge for Non-Firm Point-to-Point Transmission Service may be discounted based on market conditions, but will never be higher than the Firm Point-to-Point Transmission Service charge.

The Provisional Formula Rate for Non-Firm Point-to-Point Transmission Service is as follows:

$$\text{Maximum Non-Firm Point-to-Point Transmission Service Formula Rate} = \text{Firm Point-to-Point Transmission Service Formula Rate}$$

Penalty Rate for Unreserved Use of Transmission Service (Unreserved Use)

WAPA–RMR has made no changes to the Unreserved Use Penalties rate, under Rate Schedule L–UU1. LAP will continue to assess Unreserved Use penalties against a transmission customer who has not secured reserved capacity or exceeds their reserved capacity at any point of receipt or any point of delivery. Unreserved Use may also include a transmission customer's failure to curtail transmission when requested.

LAP transmission customers who engage in Unreserved Use are assessed a penalty charge of 200% of LAP's approved transmission service charge for Firm Point-to-Point Transmission Service, as well as, any related ancillary services as follows: The Unreserved Use penalty for a single hour of Unreserved Use will be based upon the charge for daily Firm Point-to-Point Transmission Service. The Unreserved Use penalty for more than one assessment for a given duration (*e.g.,* daily) will increase to the next longest duration (*e.g.,* weekly). The Unreserved Use penalty charge for multiple instances of Unreserved Use (*e.g.,* more than one hour) within a day will be based on the charge for daily Firm Point-to-Point Transmission Service. Multiple instances of Unreserved Use isolated to one calendar week will result in a penalty based on the charge for weekly Firm Point-to-Point Transmission Service. The penalty charge for multiple instances of Unreserved Use during more than one week during a calendar month will be based on the charge for monthly Firm Point-to-Point Transmission Service.

Ancillary Services Discussion

In accordance with WAPA's OATT, ancillary services are needed with transmission service to maintain reliability inside and among the Control Areas affected by the transmission service. CRCM and LAPT currently provide seven ancillary services under the OATT: Scheduling, System Control & Dispatch Service (SSCD Service); Reactive Supply & Voltage Control Support Service (VAR Support Service); Regulation and Frequency Response Service (Regulation Service); Energy and Generator Imbalance Services; and Operating Reserves—Spinning Reserve and Supplemental Reserve Services. The Provisional Formula Rates for these

services are designed to recover the costs incurred for providing each of the services. The Provisional Formula Rates are also applicable to WACM when, as the Control Area operator, WACM provides services as required or as requested by Transmission Service Providers and Load Serving Entities.

The first two of these seven ancillary services, SSCD Service and VAR Support Service, are services the Transmission Service Provider is required to provide, or offer to arrange with the Control Area operator, and the transmission customer is required to purchase.

The other five ancillary services, Regulation Service, Energy and Generator Imbalance Services, and Operating Reserves—Spinning Reserve and Supplemental Reserve Services, are services the Transmission Service Provider must offer when transmission service is used to serve load within the Transmission Service Provider's Control Area. The transmission customer must purchase these ancillary services from the Transmission Service Provider, acquire the services from a third party, or self-supply the services.

Scheduling, System Control, and Dispatch Service

WAPA–RMR has made no changes to the formula rate for SSCD Service, under Rate Schedule L–AS1. The Provisional Formula Rate for SSCD Service is as follows:

$$\text{Charge per Schedule} = \frac{\text{Annual Cost of Scheduling Personnel and Related Costs}}{\text{Number of Schedules per Year, excluding schedules for Delivery of Losses to WACM}}$$

The annual cost of scheduling personnel and related costs includes annual costs associated with transmission scheduling (*i.e.,* personnel, facilities, equipment and software, as well as credits representing fees for agent services).

The number of schedules per year is the yearly total of daily tags which result in a schedule, excluding loss schedules.

WAPA–RMR allocates the charge of each schedule equally among all Transmission Service Providers, both Federal and non-Federal, listed on the schedule who are inside WACM. The Federal transmission segments are exempt from invoicing, as costs for these segments continue to be included in the Federal (LAP and CRSP) Transmission Service rates.

Reactive Supply and Voltage Control Service From Generation or Other Sources Service

The formula rate for VAR Support Service, under Rate Schedule L–AS2, has been modified. The numerator has been changed to include not only LAP and CRSP's revenue requirements for Federal generation, but also the annual cost of other resources used to provide VAR Support Service and any applicable revenue credits related to WACM providing service. The wording of the denominator has been changed in order to clarify the denominator includes all ''transmission transactions'' requiring VAR Support Service rather than stating it includes ''load in WACM'' requiring VAR Support Service.

The Provisional Formula Rate for VAR Support Service is as follows:

$$\text{VAR Support Service Formula Rate} = \frac{\text{Annual Revenue Requirement for VAR Support Service}}{\text{Transmission Transactions Requiring VAR Support Service (kW)}}$$

The annual revenue requirement for VAR Support Service equals revenue requirement for generation × % of resource capacity used for VAR Support Service (1 minus power factor) plus other resources, *e.g.,* energy and transmission costs for condensing Federal generating units minus applicable revenue credits related to WACM providing service.

The transmission transactions requiring VAR Support Service equals the transmission capacity use of the Federal transmission systems; including Point-to-Point and Network Transmission Services on LAP and CRSP transmission systems.

The unit charge is applicable to all LAP and CRSP transmission transactions in excess of any Federal Entitlements and to any non-Federal Transmission Service Providers for which WACM provides service. WACM will charge based on the rate applicable under L–AS2 and any resulting revenue will be treated as a revenue credit within the L–AS2 rate design. Federal Entitlements pay the same unit charge for this service, but the charge remains bundled in the LAP and CRSP FES rates.

WAPA–RMR is eliminating previously granted LAP and CRSP transmission service VAR Support Service charge exemptions, unless the Federal transmission customer has generating resources capable of providing VARs directly connected to a Federal transmission facility owned and operated by CRSP and/or LAP and has executed a contract stipulating all the provisions of their self-supply. Including the previously exempted capacity in the VAR Support Service denominator puts downward pressure on the VAR Support Service rate, which will benefit the Federal transmission customers who are currently paying a higher rate. Customers who have previously received an exemption will now pay for VAR Support Service, but their rate will be significantly lower than those who have paid for the service to date.

Regulation and Frequency Response Service

The formula rate for Regulation Service, under Rate Schedule L–AS3, has been modified so the denominator includes wind and solar capacity multipliers that will be applied to the installed nameplate capacity value of wind and solar generators. The basis for application of the multiplier is the growth WACM has seen in VERs, requiring WAPA–RMR to purchase additional regulation and frequency

response services. WAPA–RMR developed a ''Regulation Analysis'' tool that allows WAPA–RMR to see the hourly impacts of both load and traditional generation and VERs on WACM and determine the amount of regulation and following resource consumption. For the period of July 2014–June 2015, the tool indicated that wind VERs required 225% more regulation and frequency response services than load and traditional generation require. WACM does not have a significant amount of solar generation impacting its Balancing Authority area and, therefore, does not have sufficient solar generation data available to perform a thorough analysis at this time. Therefore, WAPA–RMR will identify a solar capacity multiplier of 100% until such a time a different value is warranted, *i.e.,* if and when solar VERs become more prevalent in the WACM footprint.

The Provisional Formula Rate for Regulation Service is as follows:

$$\text{Regulation Service Formula Rate} = \frac{\text{Total Annual Revenue Requirement for Regulation Service}}{\begin{array}{c}\text{Load inside WACM Requiring Regulation Service (kW)} \\ + \\ (\text{Installed Nameplate Capacity of Wind Generators Serving Load inside WACM} \\ \text{X} \\ \text{Wind Capacity Multiplier) (kW)} \\ + \\ (\text{Installed Nameplate Capacity of Solar Generators Serving Load inside WACM} \\ \text{X} \\ \text{Solar Capacity Multiplier) (kW)}\end{array}}$$

The total annual revenue requirement for Regulation Service includes such costs as LAP and CRSP plant costs, purchases of regulation products, purchases of power in support of the generating units' ability to regulate, purchases of transmission for regulating units who are trapped geographically inside another Balancing Authority area, purchases of transmission required to relocate energy due to regulation/load following issues, and lost on-peak sales opportunities resulting from the requirement to generate at night to permit units to have 'down' regulating capability.

The total load for Regulation Service equals load inside WACM requiring Regulation Service, plus the installed nameplate capacity of wind generators serving load inside WACM times the wind capacity multiplier, plus the installed nameplate capacity of solar generators serving load inside WACM times the solar capacity multiplier. The capacity multipliers will be updated yearly to coincide with the normal annual formula rate updates (each October 1).

The capacity required for regulation is subject to re-evaluation every year. Historically, the regulation requirement from Federal generators had been 75 MW (55 MW from LAP and 20 MW from CRSP). Starting in the FY 2014 rate design, following the CRSP transmission system being reconfigured into WACM, WAPA–RMR and WAPA–CRSP agreed to assign the regulation requirement to LAP and CRSP based on a ratio of LAP, CRSP, and WACM individual contract requirements to the total of all requirements. Using this ratio share methodology, to annually update the ratio shares, allows LAP and CRSP to each supply resources sufficient to cover their own requirement (FES and transmission sales), plus a portion of WACM's requirement (Balancing Authority agreements), with LAP being capped at 55 MW and CRSP being capped at 40 MW—the historical commitment from each Project. In addition, WAPA–RMR made changes within the rate design to assign only the proper share of each Project's plant costs, and any applicable purchases and transmission costs, to the LAP and CRSP Federal Entitlements. This change ensures the Federal Entitlements are not being improperly assigned costs related to WAPA–RMR's purchase of additional regulation and frequency response services needed for VERs or increased sales of transmission service. The methodology for determining annual plant costs is unchanged. First, the annual costs for Federal plants used to regulate is calculated by multiplying the net plant costs by the annual fixed charge rate for generation. Then, the annual cost per unit of capacity for regulating plants is calculated by dividing the annual costs for regulating plants by the capacity of those plants. Next, the portion of the total annual plant costs to be recovered in the Regulation Service rate is calculated by multiplying the annual unit cost by the amount of capacity required for regulation from those Federal plants.

The analysis to determine the capacity multipliers will be completed on a monthly basis for WAPA–RMR to determine a 12-month average. WAPA–RMR will use the most current analysis data available, typically July of the prior year to June of the current year, for the annual formula rate updates. The capacity multipliers will be posted to the Web sites along with the annual charges.

The formula rate for Regulation Service has two different applications:

1. *Load-based Assessment:* The charge is assessed on an entity's auxiliary load (total metered load less applicable Federal Entitlements) and on the amount stated in any Balancing Authority or other transmission service agreements. The charge is also applied to the installed nameplate capacity of all VER, including wind and solar generators, serving load inside the WACM Control Area, multiplied by the applicable annually-calculated capacity multiplier.

2. *Self-provision Assessment:* WAPA–RMR allows entities with AGC to self-provide for all or a portion of their loads. Entities with AGC are known as sub-Balancing Authorities and must meet various criteria, as listed in the rate schedule.

WACM does not regulate for the difference between the output of a variable generator located inside the WACM Control Area and a delivery schedule from a generator serving load located outside the WACM Control Area. In addition, WACM may allow entities to self- or third-party supply

their regulation requirement. As such, Rate Schedule L–AS3 will continue to include the following ''alternative arrangements'':

Exporting Variable Generator Requirement

WACM does not provide Regulation Service to variable resources inside the WACM Control Area which are not used to serve load inside the WACM Control Area. An entity that exports the output from a variable generator to another Balancing Authority will be required to dynamically meter or dynamically schedule that resource out of WACM to another Balancing Authority unless arrangements, satisfactory to WACM, are made for that entity to acquire this service from a third party or self-supply (as outlined below).

Self- or Third-Party Supply

WACM may allow an entity to supply some or all of its required regulation, or contract with a third party to do so. This entity must have revenue quality metering at every load and generation point, accurate as defined by North American Electric Reliability Corporation (NERC), to include MW flow data availability at 6-second (or smaller) intervals. WACM will evaluate the entity's metering, telecommunications, and regulating resource, as well as the required level of regulation, and determine whether the entity qualifies to self-supply under this provision. If approved, the entity is required to enter into a separate contract with WACM which will specify the terms of the self-supply agreement.

Imbalance Services

WAPA–RMR has made no changes to the Energy Imbalance Service or Generator Imbalance Service formula rates, under Rate Schedules L–AS4 and L–AS9.

Energy Imbalance

WAPA–RMR calculates energy imbalances and assesses penalties based on a three deviation band structure as follows:

1. An imbalance of less than or equal to 1.5 percent of metered load (or 4 MW, whichever is greater) for any hour is settled financially at 100 percent of the WACM weighted average hourly energy price for that hour.

2. An imbalance between 1.5 percent and 7.5 percent of metered load (or 4 to 10 MW, whichever is greater) for any hour is settled financially at 90 percent of the WACM weighted average hourly energy price when net energy scheduled exceeds metered load or 110 percent of the WACM weighted average hourly energy price when net energy scheduled is less than metered load.

3. An imbalance greater than 7.5 percent of metered load (or 10 MW, whichever is greater) for any hour is settled financially at 75 percent of the WACM weighted average hourly energy price when net energy scheduled exceeds metered load or 125 percent of the WACM weighted average hourly energy price when net energy scheduled is less than metered load.

The term ''metered load'' is defined to be ''metered load adjusted for losses.'' Also, each hour stands on its own; there is no monthly netting. Hourly accounting encourages the customer to more closely follow its load.

Generator Imbalance

Generator Imbalance Service applies to all:

1. Jointly-owned generators (unless arrangements are made to allocate actual generation to each individual owner),

2. Variable generators (unless arrangements are made to assess the variable generator under Rate Schedule L–AS4), and

3. Non-variable generators serving load outside the WACM Control Area.

An entity's solely-owned non-variable generator inside the WACM Control Area will be included in the entity's Energy Imbalance Service calculation.

The formula rate and pricing for Generator Imbalance Service will be identical to the formula rate for Energy Imbalance Service, with the following exceptions:

1. Bandwidths will be calculated as a percentage of metered generation, since there is no load.

2. Variable generators will be exempt from the outer bandwidth. All imbalances greater than 1.5 percent of metered generation are subject only to a 10 percent penalty.

Penalty Elimination

In any hour, WAPA–RMR may charge a customer a penalty for either Generator Imbalance Service or Energy Imbalance Service, but not both.

Minimum Bandwidth

WAPA–RMR has concluded that strict imposition of FERC Order 890 parameters for minimum bandwidth (2 MW) is unnecessarily restrictive to small customers. LAP's Federal Entitlement may be the only resource a small customer has available for following load and staying within prescribed bandwidths. WAPA–RMR requires customers to schedule their Federal Entitlements 48-hours in advance, which is unique in the industry. With weekends and holidays, this schedule may have to be submitted several days in advance. This situation is exacerbated by the requirement scheduling be done in whole MWs, while loads (and imbalance) are measured to the kilowatt. Due to these circumstances, WAPA–RMR will not start assessing penalties after a 2 MW deviation and will continue to employ a 4 MW minimum bandwidth. No costs are being passed to customers with larger loads due to the larger minimum bandwidth. WAPA–RMR has employed this practice, with FERC approval, since March 2004.[1]

Settlement and Pricing

All imbalances will be settled financially using WACM pricing for each hour. The imbalance for each applicable entity shall be totaled and netted to determine WACM's aggregate energy condition. The sign of the aggregate energy condition for WACM will determine whether sale or purchase pricing will be used in all bandwidths (surplus hours will use sale pricing, and deficit hours will use purchase pricing).

Expansion of the Bandwidth

Expansion of the bandwidth may be allowed during the following instances: 1) response to the loss of a physical resource and 2) during transition of large base-load thermal resources (capacity greater than 200 MW) between off-line and on-line following a reserve sharing group response, when the unit generates less than the predetermined minimum scheduling level. Details are as follows:

1. WAPA–RMR will expand the bandwidth during an event established by a WAPA-recognized reserve-sharing group, such as the Rocky Mountain Reserve Group. A response made by a member of the reserve group will be accounted for by an after-the-fact schedule. Normally, these events are 1–2 hours in duration. Since such events are accounted for by after-the-fact schedules, no expansion will be necessary for the entity receiving the response. The expanded bandwidth will apply to the customer who increased generation in response to the event and will be based on the magnitude of that customer's generation response.

2. During transition of large base-load thermal resources (capacity greater than 200 MW) between off-line and on-line following a reserve sharing group response, WAPA–RMR may expand the bandwidth (eliminate all penalties)

[1] FERC's initial confirmation and approval was in Docket No. EF04–5182–000. *See United States Department of Energy, Western Area Power Administration,* 110 FERC ¶ 62,084 (January 31 2005).

during hours in which the unit generates less than the predetermined minimum scheduling level. WAPA–RMR may not have access to information necessary to determine these hours for some generators and will not have access to information on events for reserve sharing groups outside WACM. Customers should request bandwidth expansion in hours in which they believe it to be warranted. WAPA–RMR may request additional information for its decision whether to grant the request. Bandwidth will not be expanded when the customer's ramping services have been acquired by another entity.

Balancing Authority Operating Constraints

WAPA–RMR reserves the right to offer no credit for Imbalance Service over-deliveries during times of WACM operating constraints, such as ''must-run'' hydrologic conditions, or times when WACM cannot dispose of surplus energy. Due to the unpredictable nature of hour-to-hour energy imbalances and the very short notice for disposition of over deliveries, WACM may experience some hours of zero value sales and may eliminate credits in these hours.

If WACM is unable to dispose of the entire net over-delivery and the operating criteria for the balancing authority are not met, reliability oversight agencies, such as the NERC or the Western Electricity Coordinating Council may charge WACM with violating applicable standards. In these cases, WAPA–RMR reserves the right to eliminate credit to customers and require customers to share in any costs incurred as a result of such violations. Also, there may be conditions under which customers who under-deliver may share in any costs incurred by WAPA–RMR as a result of violations asserted by reliability oversight agencies.

Operating Reserves—Spinning and Supplemental Reserve Services

WAPA–RMR has made no changes to the Operating Reserve Services formula rates, under Rate Schedules L–AS5 and L–AS6. LAPT and WACM have no Reserves available for sale. At a customer's request, WAPA–RMR will purchase and pass-through the cost of Operating Reserves, plus the cost of any activation energy, plus a fee for administration. The customer will be responsible for providing the transmission to deliver the Operating Reserves purchased.

Transmission Losses Service Discussion

WAPA–RMR has made no changes to the Transmission Losses Service formula rate, under Rate Schedule L–AS7. WACM provides Transmission Losses Service to all Transmission Service Providers who market transmission inside the WACM Control Area. Transmission losses are assessed for all real-time and prescheduled transactions on transmission facilities inside the WACM Control Area. Customers may settle financially or with energy. The pricing for this service will be the WACM weighted average hourly purchase price.

LAP Marketing Service Discussion

WAPA–RMR has implemented a new LAP Marketing rate schedule, L–M1, applicable to the sale of LAP surplus energy and capacity products. The schedule includes reserves, regulation, and frequency response. If LAP surplus products are available, the charge will be determined based on market rates, plus administrative costs. The customer will be responsible for acquiring transmission service necessary to deliver the product(s). This rate schedule is not applicable to transmission service and therefore, is not provided through WAPA's OATT.

Rate Schedule Discussion

Editorial changes have been made to the rate schedules for better clarification and to ensure greater consistency between WAPA's regions and the OATT, as applicable. In addition, the rate schedules will no longer include the unit charge(s) and be updated each year. Annual charges will instead be posted on WAPA's Web sites listed above under ''Provisional Formula Rates'' and on the LAPT and CRCM OASIS Web sites.

Comments

WAPA–RMR received multiple comments during the public consultation and comment period. Comments have been paraphrased where appropriate, without compromising the meaning of the comments.

Comment 1: Customer commented they are supportive of the following proposals: (1) Leave unchanged the existing formula rate for calculating the ATRR; (2) shorten the forward-looking transmission rate projection period; (3) incorporate minor edits to the network formula rate schedule; (4) modify the denominator for Firm and Non-firm Point-to-Point transmission service; (5) incorporate minor edits to the Transmission Losses Service formula rate schedule; (6) not modify the Unreserved Use formula rate and to make minor edits to the formula rate schedule; (7) not modify the SSCD Service formula rate and to make minor edits to the formula rate schedule; and (8) leave unchanged the Energy Imbalance, Generator Imbalance, and Spinning and Supplemental Reserve Services formula rates.

Response 1: WAPA–RMR acknowledges the Customer's support of these proposals.

Comment 2: Customer commented they support WAPA–RMR's proposal regarding the Transmission Losses Service rate; however, customer recommends WAPA–RMR perform a transmission loss study if the latest loss study was performed more than five years ago. Customer also recommends WAPA–RMR perform any loss study through a formal public process.

Response 2: This comment regarding the loss study is outside the scope of this rate process, considering WAPA–RMR's formula rate schedule does not address the method for calculating the loss rate or the process for determining the loss rate, but rather only the method in which WACM is to be compensated for providing the losses. However, WAPA–RMR does perform loss studies periodically. In fact, several months ahead of this rate process, due to various changes within the WACM Control Area, WAPA–RMR began conducting a loss study to determine the appropriate loss rate to be in effect starting October 1, 2016. WAPA–RMR has shared the methodology and the result of this loss study with its customers; however, WAPA–RMR no plans to conduct formal public processes in order to conduct loss studies and implement loss rates.

Comment 3: Customer commented they do not support WAPA–RMR's proposed changes to the VAR Support Service rate, as WAPA–RMR has not provided the underlying data to support the rate. They would like details of the costs and the methodology to which those costs are assigned to WAPA–RMR's FES customers and to WAPA–RMR's transmission customers. Specifically, the customer asked whether: (1) The denominator includes all, or a portion of, CRSP long-term point-to-point reservations supporting hydropower, Customer Displacement Power (CDP), and Western Replacement Power (WRP) deliveries; (2) the annual maximum Contract Rate of Delivery (CROD) for LAP FES deliveries is a component of the VAR Support Service denominator; and (3) whether the Network Service load will be derived from prior year actuals or will it be derived from a forecast of the rate year?

Response 3: Since WAPA–RMR is seeking approval of formula rates for services previously approved, with the exception of the new LAP Marketing formula rate for the Sales of Surplus Products, WAPA–RMR focused on highlighting the proposed changes to the formulas of those previously approved formula rates. Also, since WAPA–RMR did not have all the applicable annual data necessary to update the formulas until the June-July timeframe for the upcoming fiscal year rate, WAPA–RMR was not able to include data for the FY 2017 rates in the proposed formulas during the rate process. In order to provide the Customer with the requested details, WAPA–RMR has prepared the table below using the FY 2016 rate data, since data for the FY 2017 rate was not yet available, with modifications to the numerator to include the addition of the ''Other Resources'' and to the denominator in order to demonstrate how the elimination of the exemptions will impact the rate, as proposed.

REACTIVE SUPPLY AND VOLTAGE CONTROL FROM GENERATION AND OTHER SOURCES SERVICE

[Example FY 2017 rate design using FY 2016 rate data]

	FY 17 example	FY 16	% change
Revenue Requirement			
LAP Annual Fixed Charge Rate	17.425%	17.425%	0
Total Net LAP Generation Plant Costs	$344,385,364	$344,385,364	0
Annual Cost of LAP Generation	$60,010,711	$60,010,711	0
LAP Capacity Used for VAR (1 minus power factor)	5.984%	5.984%	0
LAP Plant Costs for VAR	$3,590,825	$3,590,825	0
SLCA/IP Annual Fixed Charge Rate	24.84%	24.84%	0
Total Net SLCA/IP Generation Plant Costs	$177,435,000	$177,435,000	0
Annual Cost of SLCA/IP Generation	$44,072,729	$44,072,729	0
SLCA/IP Capability Used for VAR (1 minus power factor)	5.670%	5.670%	0
SLCA/IP Plant Costs for VAR	$2,498,924	$2,498,924	0
Other Resources: Condensing *NEW	$446	$0	100
Revenue from VAR Support for FY 2014 non-firm PTP	−$842,233	−$842,233	0
Revenue from WACM Transactions *NEW	−$0	−$0	0
Annual VAR Support Revenue Requirement	$5,247,962	$5,247,516	0.01
Transmission Transactions Requiring VAR Support (kW)			
LAP FES (12-mo avg of CROD)	582,231	582,231	0
LAPT	670,622	314,744	113
CRSP FES (CDP, WRP, merchant)	4,758,030	880,507	440
CRCM	1,025,188	903,188	14
Total Transmission Transactions Requiring VAR Support (kW), *INCLUDING ELIMINATED EXEMPTIONS	7,036,071	2,680,670	163
Rate			
Monthly Rate/kW-mo	$0.066	$0.163	−62

Based on customer feedback, and to avoid confusion, rather than including the non-Federal Transmission Service Provider's capacity usage as another component of the denominator as WAPA–RMR proposed, if WACM, as the Control Area operator, supplies any VAR Support on behalf of a non-Federal Transmission Service Provider, WACM will assess charges based on the unit rate applicable under L–AS2 and the resulting revenue will instead be treated as a revenue credit within the L–AS2 rate design in a subsequent year. As such, WAPA–RMR has changed the denominator to now read ''Transmission Transactions that Require VAR Support Service (kW).'' The denominator will continue to include only LAPT and CRCM's transmission transactions, both point-to-point and Network Service, including CRSP's FES, CDP, and WRP deliveries and LAP's FES deliveries. It will continue to be based on LAPT and CRCM's Network 12-month coincident peak (12cp) values from the most recent billing month available (normally May), and LAPT and CRCM's total point-to-point reservations expected to be in place during the rate year.

Comment 4: Customer recommends WAPA–RMR provide additional information and an example regarding the component in the denominator ''Transmission Capacity Usage by Other Transmission Service Providers inside WACM.'' Customer seeks to better understand how third party Transmission Service Providers are a part of the VAR Support Service rate for a service WAPA–RMR proposes they are providing only for the LAPT and CRCM transmission systems located within the WACM Control Area. Customer also requests additional information regarding how WACM may assess VAR Support Service charges to Transmission Service Providers located in the Control Area found to not be providing sufficient VAR support.

Response 4: As discussed in the Proposed FRN and in the Customer Brochure, WACM, as the Control Area operator, is not currently charging any non-Federal Transmission Service Providers for VAR Support Service, so the proposed capacity component is 0 MW at this time. WACM had previously determined that the non-Federal Transmission Service Providers within the WACM Control Area have adequate non-Federal generation resources and/or other VAR compensating devices connected to their transmission systems to self-provide VAR support for the transactions on their systems. The potential exists, however, where WACM, using facilities under its control, could be providing VAR

support on behalf of a non-Federal Transmission Service Provider (directly or indirectly). As such, language in L–AS2 has been revised to clarify how the formula rate applies to CRCM and LAPT as Transmission Service Providers and to WACM as the Control Area operator. If and when deemed necessary, WACM will assess charges to Transmission Service Providers using the unit rate applicable under L–AS2 against either the Transmission Service Provider's reserved capacity or the tagged megawatt usage of the Transmission Service Provider's transmission customers.

As stated above, WAPA–RMR is removing this proposed capacity component from the denominator and is instead going to treat any future revenue from these potential WACM transactions as revenue credits within the numerator of the VAR Support Service rate design.

Comment 5: Customer requests additional information regarding the entity from which a transmission customer will be obtaining VAR Support Service as part of the use of transmission located within the WACM Control Area. It is not clear if the WACM Control Area is the provider of VAR Support Services and LAPT and CRCM Transmission Service Providers are providing VAR support on behalf of the WACM Control Area or if individual Transmission Service Providers within the WACM Control Area are independently providing VAR support. Customer also seeks to better understand the role and contribution of non-Federal generation resources located inside the WACM Control Area and how those contributions support VAR requirements, as these activities are primarily performed on a local basis and not necessarily separated by Transmission Service Provider ownership within the Control Area boundaries.

Response 5: According to WAPA's OATT, VAR Support Service can be provided directly by the Transmission Service Provider if the Transmission Service Provider is the Control Area operator or indirectly by the Transmission Service Provider making arrangements with the Control Area operator performing this service for the Transmission Service Provider's system. As such, CRCM and LAPT provide VAR Support Service directly to the LAP and CRSP transmission systems. CRCM and LAPT assess charges to their transmission customers using a rate design that includes only the portion of the Federal generation costs applicable to VAR support.

WACM, as the Control Area operator, through coordinated efforts with the Transmission Service Providers, performs this service for the non-Federal Transmission Service Providers within the Control Area. As previously discussed, WACM had previously determined that the non-Federal Transmission Service Providers within the WACM Control Area have adequate non-Federal generation resources and/or other VAR compensating devices connected to their transmission systems to self-provide VAR support for their systems. In these cases, WACM is not the provider of VAR support and therefore does not charge the non-Federal Transmission Service Providers for performing this service on their behalf. If WACM determines a Transmission Service Provider does not have adequate VAR resources, WACM may assess charges to the Transmission Service Provider under L–AS2.

Comment 6: Customer recommends WAPA–RMR provide a list of generators and other transmission equipment providing VAR support for the LAP and CRSP transmission systems located within the WACM Control Area.

Response 6: The generators providing VAR support for LAP and CRSP transmission systems and whose costs are included in the L–AS2 rate design are: Alcova, Big Thompson, Blue Mesa, Boysen, Crystal, Estes, Flaming Gorge, Flatiron, Fontenelle, Fremont Canyon, Glen Canyon, Glendo, Green Mountain, Guernsey, Heart Mountain, Kortes, Morrow Point, Mary's Lake, Molina, Mt. Elbert, Polehill, Seminoe, Towaoc, Willow Creek, and Yellowtail. The costs for the transmission equipment (*i.e.,* reactors and shunt capacitors) providing VAR support for the LAP and CRSP transmission systems are not included in the L–AS2 rate design, but are instead included in each Project's respective transmission rate.

Comment 7: Customer requests additional information regarding the process in which WAPA–RMR may exclude charges for VAR Support Service for a transmission customer. Customer seeks to better understand the application and the governing agreement used to qualify a transmission customer for exemption, *i.e.,* is the exclusion an all or nothing election or is there a pro-rated off-set or credit for eligibility exemption?

Response 7: According to WAPA's OATT, VAR Support Service is a service Transmission Service Providers must offer for each transaction on its transmission system and the transmission customers must purchase. As discussed in the Customer Brochure, LAPT and CRCM may allow a LAP or CRSP transmission customer who requests an exemption to receive an exemption from VAR Support Service charges related to its LAP or CRSP transmission service if they have a generating plant directly connected to the LAP or CRSP transmission system. The generator must have the capability to provide VARs and the transmission customer must execute a contract with WAPA–RMR stipulating all the provisions of their VAR support self-supply. WAPA–RMR will work with customers to evaluate their particular circumstances.

Comment 8: Customer commented they are generally supportive of the concept to more accurately allocate costs based on cost causation principals by applying a cost multiplier; however, Customer has concerns regarding how WAPA–RMR plans to assess Regulation Service charges under its proposal for three example scenarios: (1) A distribution cooperative purchases the output of a 2 MW wind farm connected to a 34.5–kV distribution system from a third party. The distribution system is connected to a 34.5/115–kV transformer and is metered on the low side of the transformer. The maximum output of the wind farm is less than the local load served through the 34.5/115–kV transformer connected off the transmission system; (2) A retail customer of a distribution cooperative with a load of 15 MW installs a 10 MW wind farm behind its retail revenue meter to self-supply a portion of its load requirements; and (3) A transmission customer purchases the output of a solar facility located physically outside of the WACM Control Area and the transmission customer requests to dynamically meter the solar facility into the WACM Control Area and WACM approves the request.

With respect to scenarios 1 and 2, Customer considers them to not be subject to Regulation Service VER charges from WAPA–RMR for several reasons. First, Customer does not own, control, or lease the resources. Second, Customer cannot designate these resources as Network resources. Third, the VER is located on the underlying distribution system or behind a retail customer's revenue meter, and the resources do not utilize transmission located inside the WACM Control Area. Fourth, local load self-supply by Customer's member owners allows for member owners to serve up to five percent of their load by non-customer owned, controlled, or leased resources. Customer is responsible for delivering resources it owns, controls, or leases to the remaining load not self-provided by its members. Customer supports cost

causation principles to allocate regulation costs, however, Customer does not support costs shifted to it as a transmission customer of WAPA–RMR for resources for which Customer has no responsibility and over which Customer has no control. Customer believes they should be subject only to Regulation Service VER charges for VER they own, control, or lease and which is located within the WACM Control Area.

Customer requests WAPA–RMR to identify the entity responsible for specific eligible charges for Regulation Service for VER located in the WACM Control Area. Are these resources subject to Regulation Service charges under WAPA's OATT? Customer requests WAPA–RMR provide the supporting OATT language of WAPA–RMR's determination of the responsible entity.

Response 8: The application of the load-based assessment to the installed nameplate of VER serving load inside the WACM Control Area has been in place since June 2006. WAPA–RMR did not propose a change to the assessment. WAPA–RMR proposed to include only the ''variable capacity multipliers'' to the assessment.

All loads inside the Control Area consume regulation; therefore, WACM, by default, provides Regulation Service to all loads inside the Control Area. As such, WAPA–RMR's Regulation Service formula rate schedule L–AS3 is a combined rate schedule applicable to CRCM and LAPT as Transmission Service Providers and to WACM as the Control Area operator.

WAPA–RMR's OATT is applicable to Federal transmission service, not to services provided by the WACM Control Area. WAPA–RMR establishes Business Practices to document policies/practices applicable to the Control Areas. WAPA's OATT does not specifically address how Regulation Service is to be charged under these scenarios, but WAPA–RMR has posted a Business Practice that specifically addresses behind the meter generation. Based on customer feedback, WAPA–RMR will pursue providing more specific details related to these types of scenarios in a new Business Practice.

Since 2006, L–AS3 has been applicable to all variable generators inside the WACM Control Area. WACM does not differentiate where the variable resource is connected to any elements of the transmission system, *e.g.,* directly connected to a transmission line, direct interconnection to a substation, or connected to the distribution system behind the customer's meter. The Regulation Service provided by WACM for the variable resource is to mitigate the minute-to-minute variation of the generator output. The Regulation need is the same no matter where the variable resource is connected. WAPA–RMR acknowledges any resource behind the customer's meter reduces the customer's energy requirements, but the transmission service and ancillary services for said load is not decreased by the variable resource behind the customer's meter. Variable resource, by definition, is intermittent, non-dispatchable, and has a unique energy profile whether it is netted to load or sent elsewhere.

When a Federal transmission customer or a WACM customer purchases the output of a variable resource located outside the WACM Control Area, and statically schedules it into WACM, the application of the load-based assessment on the VER nameplate is not applicable since the regulation service for the resource is being provided by the host or native Balancing Authority (where the VER resides). If a Federal transmission customer or a WACM customer requests to dynamically transfer the output of a VER that resides in another Balancing Authority to the WACM Control Area, WACM will work with the customer to dynamically transfer the VER from the native Balancing Authority to the WACM Control Area. Under this condition, and with installation of proper telemetry and inclusion of the variable resource in its AGC, WACM will be providing the Regulation Service for the VER generator and the application of the load-based assessment on the VER nameplate is applicable.

Comment 9: Customer recommends WAPA–RMR provide the quantity of renewable resources comprised of solar generation located within the WACM Control Area that would result in WAPA–RMR applying a capacity multiplier other than 1.00.

Response 9: As stated in the Proposed FRN, WACM does not have a significant amount of solar generation impacting its Control Area; therefore, does not have sufficient solar generation data available to perform a thorough analysis to determine a more specific solar multiplier at this time. The multipliers are determined based on the size of the resource, as well as the behavior and diversity of those resources and how they impact the Control Area, so a specific quantity of solar generation which would result in changing the multiplier is unknown at this time.

Comment 10: Customer recommends in lieu of an annual update to the variable capacity multiplier, if the annual update calculation results in a multiplier change of .25 or more (higher or lower) from the previous multiplier, then an update to the multiplier would be appropriate. Customer also recommends WAPA–RMR update the multiplier in increments of 0.25.

Response 10: WAPA–RMR conducted an analysis which shows allowing a difference in the multiplier up to 0.24 would result in a cost shift in the rate design of approximately 3–4% between the VER and non-VER customers. WAPA–RMR has determined that this cost shift is not warranted because the correct multiplier will be known at the time the annual rate design is updated.

Comment 11: Customer asked if WAPA–RMR anticipates the total revenue collection for regulation will increase due to the rate proposal.

Response 11: The only proposed change to the Regulation Service formula rate was to implement the ''variable capacity multipliers.'' This change will impact the denominator of the rate and will change how much of the revenue requirement is collected from customers with VER and from customers without VER, but it has no impact on the total revenue collected because it has no impact on the revenue requirement.

Comment 12: Customer commented they do not support WAPA–RMR's current proposal to develop a new rate schedule for LAP Marketing to sell surplus products as they believe it, as currently written, provides very little detail and it is unclear how the proposal will be used by WAPA–RMR in its management of delivery of hydropower to FES customers as well as the marketing of excess non-firm transmission to transmission customers available after meeting FES delivery obligations. The new rate schedule appears to support the marketing of available products and resources to wholesale electricity market participants at market-based rates in lieu of offering products to FES customers on a cost-based basis. They recommend WAPA–RMR not pursue development of the proposed L–M1 rate schedule at this time, even though they agree WAPA–RMR should have a more formal level of documentation of new products it may have available to offer to its FES customers and agrees this should be supported through the formal public process.

If WAPA–RMR moves forward with the proposal, Customer recommends if excess products are available for sale (regardless of duration) the FES customers are provided first opportunity to purchase excess products from WAPA–RMR on a cost-based delivery basis and not at prevailing market

prices. Customer also recommends WAPA–RMR provide to its FES customers the supporting rate sheet data for products offered to FES customers so they can better understand the cost drivers for a product.

Response 12: WAPA–RMR intends to use this rate schedule to offer products to FES and other customers. LAP cannot always sell these surplus products at cost to FES or other customers due to more competitive market options; therefore, the rates have been discounted to make the sales possible. As such, WAPA–RMR is not able to provide specific rate sheet data for these types of transactions. The revenue LAP receives from these surplus sales offsets expenses, which is a benefit to the LAP power rate and all FES customers.

Availability of Information

All brochures, studies, comments, letters, memorandums, or other documents used by WAPA–RMR to develop the Provisional Formula Rates are available for inspection and copying at the Rocky Mountain Regional Office, 5555 East Crossroads Boulevard, Loveland, Colorado. Many of these documents are also available on WAPA–RMR's Web site located at *https://www.wapa.gov/regions/RM/rates/Pages/2017-rate-adjustment.aspx.*

Ratemaking Procedure Requirements

Environmental Compliance

In compliance with the National Environmental Policy Act (NEPA) of 1969, 42 U.S.C. 4321–4347; the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500–1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021), WAPA has determined this action is categorically excluded from the preparation of an environmental assessment or an environmental impact statement. A copy of the categorical exclusion determination is available on WAPA–RMR's Web site located at *https://www.wapa.gov/regions/RM/environment/Pages/CX2016.aspx.* Look for file entitled, ''2016–077 Prop Formula Rate Adjust for Transmission Ancillary Services and Sale of Surplus Prods 031016.''

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Submission to the Federal Energy Regulatory Commission

The formula rates herein confirmed, approved, and placed into effect on an interim basis, together with supporting documents, will be submitted to FERC for confirmation and final approval.

ORDER

In view of the foregoing, and under the authority delegated to me, I confirm and approve on an interim basis, effective the first full billing period on or after October 1, 2016, formula rates for LAP Transmission; CRSP, LAP, and WACM Ancillary Services; WACM Transmission Losses, and LAP Marketing Sales of Surplus Products under Rate Schedules L–NT1, L–FPT1, L–NFPT1, L–UU1, L–AS1, L–AS2, L–AS3, L–AS4, L–AS5, L–AS6, L–AS7, L–AS9, and L–M1. These rate schedules shall remain in effect on an interim basis, pending FERC's confirmation and approval of them, or substitute formula rates, on a final basis through September 30, 2021.

Dated: August 12, 2016

Elizabeth Sherwood-Randall
Deputy Secretary of Energy

Rate Schedule L–NT1

ATTACHMENT H to OATT

(Supersedes Rate Schedule L–NT1 dated October 1, 2011, through September 30, 2016)

UNITED STATES DEPARTMENT OF ENERGY

WESTERN AREA POWER ADMINISTRATION

ROCKY MOUNTAIN REGION

Loveland Area Projects

NETWORK INTEGRATION TRANSMISSION SERVICE

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

The Transmission Customer will compensate the Loveland Area Projects Transmission Service Provider (LAPT) each month for Network Integration Transmission Service under the applicable Network Integration Transmission Service Agreement and the Annual Transmission Revenue Requirement described herein.

Formula Rate

$$\text{Monthly Charge} = \frac{\text{Annual Transmission Revenue Requirement (\$)}}{12} \times \text{Network Service Customer's Load Ratio Share}$$

A calculated Annual Transmission Revenue Requirement will go into effect every October 1 based on updated financial projections and the true-up of previous projections. The Annual Transmission Revenue Requirement will be posted on the LAPT Open Access Same-Time Information System Web site.

Rate Schedule L–FPT1

SCHEDULE 7 to OATT

(Supersedes Rate Schedule L–FPT1 dated October 1, 2011, through September 30, 2016)

UNITED STATES DEPARTMENT OF ENERGY

WESTERN AREA POWER ADMINISTRATION

ROCKY MOUNTAIN REGION

Loveland Area Projects

LONG-TERM FIRM AND SHORT-TERM FIRM POINT-TO-POINT TRANSMISSION SERVICE

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

The Transmission Customer shall compensate the Loveland Area Projects Transmission Service Provider (LAPT) each month for reserved capacity under the applicable Firm Point-to-Point Transmission Service Agreement and the formula rate described herein.

Formula Rate

$$\text{Firm Point-to-Point Transmission Service Formula Rate} = \frac{\text{Annual Transmission Revenue Requirement (\$)}}{\text{Firm Transmission Capacity Reservations (kW) plus Network Integration Transmission Service Capacity (kW)}}$$

A calculated charge will go into effect every October 1 based on the formula above, updated financial and load projections, and the true-up of previous projections. The annual charge will be posted on the LAPT Open Access Same-Time Information System (OASIS) Web site.

Discounts

Three principal requirements apply to discounts for transmission service as follows: (1) Any offer of a discount made by LAPT must be announced to all eligible customers solely by posting on the LAPT OASIS Web site; (2) any customer-initiated requests for discounts, including requests for use by LAP Marketing, must occur solely by posting on the LAPT OASIS Web site; and (3) once a discount is negotiated, details must be immediately posted on the LAPT OASIS Web site. For any discount agreed upon for service on a path, from Point(s) of Receipt to Point(s) of Delivery, LAPT must offer the same discounted transmission service rate for the same time period to all eligible customers on all unconstrained transmission paths that go to the same point(s) of delivery on the transmission system.

Rate Schedule L–NFPT1

SCHEDULE 8 to OATT

(Supersedes Rate Schedule L–NFPT1 dated October 1, 2011, through September 30, 2016)

UNITED STATES DEPARTMENT OF ENERGY

WESTERN POWER AREA ADMINISTRATION

ROCKY MOUNTAIN REGION

Loveland Area Projects

NON-FIRM POINT-TO-POINT TRANSMISSION SERVICE

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

The Transmission Customer will compensate the Loveland Area Projects Transmission Service Provider (LAPT) for Non-Firm Point-to-Point Transmission Service under the applicable Non-Firm Point-to-Point Transmission Service Agreement and the formula rate described herein.

Formula Rate

$$\text{Maximum Non-Firm Point-to-Point Transmission Service Formula Rate} = \text{Firm Point-to-Point Transmission Service Formula Rate}$$

A calculated charge will go into effect every October 1 based on the formula above, updated financial and load projections, and the true-up of previous projections. The annual charge will be posted on the LAPT Open Access Same-Time Information System (OASIS) Web site.

Discounts

Three principal requirements apply to discounts for transmission service as follows: (1) any offer of a discount made by LAPT must be announced to all eligible customers solely by posting on the LAPT OASIS Web site; (2) any customer-initiated requests for discounts, including requests for use by

LAP Marketing, must occur solely by posting on the LAPT OASIS; and (3) once a discount is negotiated, details must be immediately posted on the LAPT OASIS. For any discount agreed upon for service on a path, from Point(s) of Receipt to Point(s) of Delivery, LAPT must offer the same discounted transmission service charge for the same time period to all eligible customers on all unconstrained transmission paths that go to the same point(s) of delivery on the transmission system.

Rate Schedule L–UU1

SCHEDULE 10 to OATT

(Supersedes Rate Schedule L–UU1 dated October 1, 2011, through September 30, 2016)

UNITED STATES DEPARTMENT OF ENERGY

WESTERN AREA POWER ADMINISTRATION

ROCKY MOUNTAIN REGION

Loveland Area Projects

UNRESERVED USE PENALTIES

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

The Transmission Customer shall compensate the Loveland Area Projects Transmission Service Provider (LAPT) each month for any unreserved use of the transmission system (Unreserved Use) under the applicable transmission service formula rates as described herein. Unreserved Use occurs when an eligible customer uses transmission service it has not reserved or a Transmission Customer uses transmission service in excess of its reserved capacity. Unreserved Use may also include a Transmission Customer's failure to curtail transmission when requested, a Network Integration Transmission Service (Network) Customer's scheduled delivery of off-system non-designated purchases using transmission capacity reserved for designated Network resources, and a Network Customer's use of Network service or secondary service to facilitate a wholesale sale that does not serve a Network load.

Penalty Rate

The penalty charge for a Transmission Customer who engages in Unreserved Use is 200 percent of the Loveland Area Project's approved formula rate for Firm Point-to-Point Transmission Service assessed as follows: the Unreserved Use Penalty for a single hour of Unreserved Use is based upon the charge for daily Firm Point-to-Point Transmission Service. The Unreserved Use Penalty for more than one assessment for a given duration (*e.g.,* daily) increases to the next longest duration (*e.g.,* weekly). The Unreserved Use Penalty for multiple instances of Unreserved Use (*e.g.,* more than one hour) within a day is based on the charge for daily Firm Point-to-Point Transmission Service. The Unreserved Use Penalty for multiple instances of Unreserved Use isolated to one calendar week is based on the charge for weekly Firm Point-to-Point Transmission Service. The Unreserved Use Penalty for multiple instances of Unreserved Use during more than one week in a calendar month is based on the charge for monthly Firm Point-to-Point Transmission Service.

A Transmission Customer who exceeds their reserved capacity at any point of receipt or point of delivery, or an eligible customer who uses transmission service at a point of receipt or point of delivery it has not reserved, is required to pay for all ancillary services provided by LAPT and associated with the Unreserved Use. The Transmission Customer will pay for ancillary services based on the amount of transmission service it used and did not reserve.

Rate Schedule L–AS1

SCHEDULE 1 to OATT

(Supersedes Rate Schedule SP–SD4 and Rate Schedule L–AS1 dated October 1, 2011, through September 30, 2016)

UNITED STATES DEPARTMENT OF ENERGY

WESTERN AREA POWER ADMINISTRATION

ROCKY MOUNTAIN REGION

Colorado River Storage Project

Loveland Area Projects

Western Area Colorado Missouri Balancing Authority

SCHEDULING, SYSTEM CONTROL, AND DISPATCH SERVICE

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

This rate schedule applies to Colorado River Storage Project Transmission (CRCM) and Loveland Area Projects Transmission (LAPT) as Transmission Service Providers (TSPs) and to Western Area Colorado Missouri Balancing Authority (WACM) as the Control Area operator. Scheduling, System Control, and Dispatch Service is required to schedule the movement of power through, out of, within, or into WACM. This service can be provided only by the operator of the Control Area in which the transmission facilities used for transmission service are located.

The CRCM and LAPT TSPs must offer this service and the Federal Transmission Customers must purchase this service from the CRCM and LAPT TSPs. WACM provides this service on behalf of all TSPs within WACM and those TSPs must purchase this service from WACM.

The charge will be applied to all schedules, except those for the delivery of transmission losses to WACM. WACM will accept any number of scheduling changes over the course of the day without any additional charge. Unless other arrangements are made with WACM, the charge will be allocated equally among all TSPs, both Federal and non-Federal, listed on the schedule who are inside WACM. The Federal transmission segments of the schedule are exempt from invoicing, as costs for these segments are included in the CRCM and LAPT transmission service rates.

Formula Rate

$$\text{Charge per Schedule} = \frac{\text{Annual Cost of Scheduling Personnel and Related Costs (\$)}}{\text{Number of Schedules per Year, excluding schedules for Delivery of Losses to WACM}}$$

The annual cost of scheduling personnel and related costs includes annual costs associated with transmission scheduling (*i.e.,* personnel, facilities, equipment and software, as well as credits representing fees for agent services).

The number of schedules per year is the yearly total of daily tags which result in a schedule, excluding loss schedules.

A calculated charge will go into effect every October 1 based on the formula above and updated financial and schedule data. The annual charge will be posted on the CRCM and LAPT Open Access Same-Time Information System Web sites.

Rate Schedule L–AS2

SCHEDULE 2 to OATT

(Supersedes Rate Schedule SP–RS4 and Rate Schedule L–AS2 dated October 1, 2011, through September 30, 2016)

UNITED STATES DEPARTMENT OF ENERGY

WESTERN AREA POWER ADMINISTRATION

ROCKY MOUNTAIN REGION

Colorado River Storage Project

Loveland Area Projects

Western Area Colorado Missouri Balancing Authority

REACTIVE SUPPLY AND VOLTAGE CONTROL FROM GENERATION OR OTHER SOURCES SERVICE

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs first.

Applicable

This rate schedule applies to Colorado River Storage Project (CRCM) and Loveland Area Projects (LAPT) as Transmission Service Providers (TSPs) and to Western Area Colorado Missouri Balancing Authority (WACM) as the Control Area operator. Reactive Supply and Voltage Control from Generation or Other Sources Services (VAR Support Service) is required to maintain transmission voltages on the TSPs transmission facilities within acceptable limits, using generation facilities and non-generation resources capable of providing this service to produce or absorb reactive power. Thus, VAR Support Service must be provided for each transaction on the transmission facilities within the Control Area. The amount of VAR Support Service supplied to the transmission transactions will be based on the VAR Support Service necessary to maintain transmission voltages within limits generally accepted in the region and consistently adhered to by WACM.

The CRCM and LAPT TSPs must offer this service for each transaction and the Federal Transmission Customers must purchase this service from the CRCM and LAPT TSPs, unless the Transmission Customer has generating resources capable of providing VARs directly connected to a Federal transmission facility owned and operated by CRCM and/or LAPT and has executed a contract stipulating all the provisions of their self-supply. If WACM provides VAR Support Service on behalf of any non-Federal TSP, VAR Support Service will be assessed based on either the TSP's reserved capacity or the tagged megawatt usage of the TSP's Transmission Customers.

Formula Rate

$$\text{VAR Support Service Formula Rate} = \frac{\text{Annual Revenue Requirement for VAR Support Service (\$)}}{\text{Transmission Transactions Requiring VAR Support Service (kW)}}$$

The annual revenue requirement for VAR Support Service equals the revenue requirement for Federal generation times the % of resource capacity used for VAR Support Service (1 minus power factor) plus other resources, *e.g.,* energy and transmission costs for condensing Federal generating units minus applicable revenue credits related to WACM providing service.

The transmission transactions requiring VAR Support Service equals transmission capacity use of the Federal transmission systems; including point-to-point and network service on LAPT and CRCM transmission systems.

A calculated charge will go into effect every October 1 based on the formula above and updated financial and capacity data. The annual charge will be posted on the CRCM and LAPT Open Access Same-Time Information System Web sites.

Rate Schedule L–AS3

SCHEDULE 3 to OATT

(Supersedes Rate Schedule SP–FR4 and Rate Schedule L–AS3 dated October 1, 2011, through September 30, 2016)

UNITED STATES DEPARTMENT OF ENERGY

WESTERN AREA POWER ADMINISTRATION

ROCKY MOUNTAIN REGION

Colorado River Storage Project

Loveland Area Projects

Western Area Colorado Missouri Balancing Authority

REGULATION AND FREQUENCY RESPONSE SERVICE

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

This rate schedule applies to Colorado River Storage Project (CRCM) and Loveland Area Projects (LAPT) as Transmission Service Providers (TSPs) and to Western Area Colorado Missouri Balancing Authority (WACM) as the Control Area operator. Regulation and Frequency Response Service (Regulation Service) is necessary to provide for the continuous balancing of resources, generation, and interchange with load and for maintaining scheduled interconnection frequency at sixty cycles per second (60 Hz). Regulation Service is accomplished by committing on-line generation whose output is raised or lowered, predominantly through the use of automatic generation control (AGC) equipment as necessary, to follow the moment-by-moment changes in load. All loads inside the Control Area consume regulation; therefore, WACM, by default, provides Regulation Service to all loads inside the Control Area.

The CRCM and LAPT TSPs offer this service when transmission service is used to serve load within WACM and the Federal Transmission Customers must purchase this service from the CRCM and LAPT TSPs or make alternative comparable arrangements with WACM to satisfy their regulation obligations. For the Load Serving Entities (LSEs) who are not taking transmission service from CRCM and LAPT, WACM will assess Regulation Service charges for their load and for their variable resources inside WACM.

The formula rate will be assessed to all applicable Federal Transmission Customers and to all applicable non-Federal LSEs serving load inside WACM.

Formula Rate

$$\text{Regulation Service Formula Rate} = \frac{\text{Total Annual Revenue Requirement for Regulation Service (\$)}}{\text{Load inside WACM Requiring Regulation Service (kW)} + (\text{Installed Nameplate Capacity of Wind Generators Serving Load inside WACM} \times \text{Wind Capacity Multiplier}) \text{ (kW)} + (\text{Installed Nameplate Capacity of Solar Generators Serving Load inside WACM} \times \text{Solar Capacity Multiplier}) \text{ (kW)}}$$

The total annual revenue requirement for Regulation Service includes such costs as LAP and CRSP plant costs, purchases of regulation products, purchases of power in support of the generating units' ability to regulate, purchases of transmission for regulating units trapped geographically inside another balancing authority, purchases of transmission required to relocate energy due to regulation/load following issues, and lost on-peak sales opportunities resulting from the requirement to generate at night to permit units to have ''down'' regulating capability.

The total load for Regulation Service equals load inside WACM requiring Regulation Service, plus the installed nameplate capacity of wind generators serving load inside WACM times the wind capacity multiplier, plus the installed nameplate capacity of solar generators serving load inside WACM times the solar capacity multiplier.

A calculated charge will go into effect every October 1 based on the formula above and updated financial, load, and capacity multiplier data. The annual charge and multipliers will be posted on the CRCM and LAPT Open Access Same-Time Information System Web sites.

Types

There are two different applications of this Formula Rate:

1. Load-based Assessment: The charge is assessed on an entity's auxiliary load (total metered load less applicable Federal entitlements) and on the amount stated in any BA or transmission service agreements. The charge is also applied to the installed nameplate capacity of all variable energy resources, including wind and solar generators, serving load inside WACM multiplied by the applicable annually calculated Capacity Multiplier.

2. Self-provision Assessment: WACM allows entities with AGC to self-provide for all or a portion of their loads. Entities with AGC are known as Sub-Balancing Authorities (SBA) and must meet all of the following criteria:

a. Have a well-defined boundary, with WACM-approved revenue-quality metering, accurate as defined by the North American Electric Reliability Corporation (NERC), to include Megawatt flow data availability at 6-second or smaller intervals;

b. Have AGC responsive unit(s);

c. Demonstrate Regulation Service capability; and

d. Execute a contract with WACM in which entities agree to:

i. Provide all requested data to WACM.

ii. Meet SBA error criteria as described below.

Self-provision is measured by use of the entity's 1-minute average Area Control Error (ACE) to determine the amount of self-provision. The ACE is used to calculate the Regulation Service charges every hour as follows:

a. If the entity's 1-minute average ACE for the hour is less than or equal to 0.5 percent of its hourly average load, no Regulation Service charge is assessed for that hour.

b. If the entity's 1-minute average ACE for the hour is greater than or equal to 1.5 percent of its hourly average load, WACM assesses Regulation Service charges to the entity's entire auxiliary load, using the hourly Load-based Assessment applied to the entity's auxiliary 12-cp load for that month.

c. If the entity's 1-minute average ACE for the hour is greater than 0.5 percent of its hourly average load, but less than 1.5 percent of its hourly average load, WACM assesses Regulation Service charges based on linear interpolation of zero charge and full charge, using the hourly Load-based Assessment applied to the entity's auxiliary 12-cp load for that month.

d. WACM monitors the entity's Self-provision on a regular basis. If WACM determines the entity has not been attempting to self-regulate, WACM will, upon notification, employ the Load-based Assessment described in No. 1, above.

Alternative Arrangements

Exporting Variable Resource Requirement: WACM does not provide Regulation Service to variable resources inside the WACM Control Area which are not used to serve load inside the WACM Control Area. An entity that exports the output from a variable generator to another Control Area will be required to dynamically meter or dynamically schedule the resource out of the WACM Control Area to another Control Area unless arrangements, satisfactory to WACM, are made for the entity to acquire this service from a third party or self-supply (as outlined below). A variable generator is one whose output is volatile and variable due to factors beyond direct operational control and, therefore, is not dispatchable.

Self- or Third-party supply: WACM may allow an entity to supply some or all of its required regulation, or contract with a third party to do so. This entity must have revenue quality metering at every load and generation point, accurate as defined by NERC, to include MW flow data availability at 6-second or smaller intervals. WACM will evaluate the entity's metering, telecommunications and regulating resource, as well as the required level of regulation, and determine whether the entity qualifies to self-supply under this provision. If approved, the entity is required to enter into a separate agreement with WACM which will specify the terms of the self-supply application.

Customer Accommodation

For entities unwilling to take Regulation Service, self-provide as described above, or acquire the service from a third party, WACM will assist the entity in dynamically metering its loads/resources to another Control Area. Until such time as meter configuration is accomplished, the entity will be responsible for charges assessed under the formula rate in effect.

Rate Schedule L–AS4

SCHEDULE 4 to OATT

(Supersedes Rate Schedule L–AS4 dated October 1, 2011, through September 30, 2016)

UNITED STATES DEPARTMENT OF ENERGY WESTERN AREA POWER ADMINISTRATION

ROCKY MOUNTAIN REGION

Loveland Area Projects

Western Area Colorado Missouri Balancing Authority

ENERGY IMBALANCE SERVICE

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

This rate schedule applies to Loveland Area Projects (LAPT) as the Transmission Service Provider (TSP) and to Western Area Colorado Missouri Balancing Authority (WACM) as the Control Area operator. WACM provides Energy Imbalance Service when a difference occurs between the scheduled and the actual delivery of energy to a load located within the Control Area over a single hour. Energy Imbalance Service is calculated as resources minus obligations (adjusted for transmission and transformer losses) for any combination of generation, scheduled transfers, transactions, or actual load integrated over each hour.

The LAPT TSP must offer this service when the transmission service is used to serve load within WACM and the Federal Transmission Customers must purchase this service from the LAPT TSP or make alternative comparable arrangements with WACM to satisfy their Energy Imbalance obligations. By default, WACM, as the Control Area operator, provides Energy

Imbalance Service to all entities within its Control Area footprint. All entities who serve load inside WACM must enter into separate agreements with WACM which will specify the terms of the Energy Imbalance Service.

Formula Rate

Imbalances are calculated in three deviation bands as follows. The term ''metered load'' is defined to be ''metered load adjusted for losses.''

1. An imbalance of less than or equal to 1.5 percent of metered load (or 4 MW, whichever is greater) for any hour is settled financially at 100 percent of the

WACM weighted average hourly energy price.

2. An imbalance between 1.5 percent and 7.5 percent of metered load (or 4 to 10 MW, whichever is greater) for any hour is settled financially at 90 percent of the WACM weighted average hourly energy price when net energy scheduled exceeds metered load or 110 percent of the WACM weighted average hourly energy price when net energy scheduled is less than metered load.

3. An imbalance greater than 7.5 percent of metered load (or 10 MW, whichever is greater) for any hour is settled financially at 75 percent of the WACM weighted average hourly energy price when net energy scheduled exceeds metered load or 125 percent of the WACM weighted average hourly energy price when net energy scheduled is less than metered load.

Pricing:

All Energy Imbalance Service provided by WACM is accounted for hourly and settled financially. The WACM aggregate imbalance determines the energy pricing used in all deviation bands. A surplus dictates the use of sale pricing; a deficit dictates the use of purchase pricing. When no hourly data is available, the pricing defaults for sales and purchase pricing are applied in the following order:

1. Weighted average sale or purchase pricing for the day (on- and off-peak).

2. Weighted average sale or purchase pricing for the month (on- and off-peak).

3. Weighted average sale or purchase pricing for the prior month (on- and off-peak).

4. Weighted average sale or purchase pricing for the month prior to the prior month (and continuing until sale or purchase pricing is located) (on- and off-peak).

Expansion of the bandwidth may be allowed during the following instances:

1. Response to the loss of a physical resource.

2. During transition of large base-load thermal resources (capacity greater than 200 MW) between off-line and on-line following a reserve sharing group response, when the unit generates less than the predetermined minimum scheduling level.

During periods of Balancing Authority operating constraints, WACM reserves the right to eliminate credits for over-deliveries. The cost to WACM of any charge assessed by a reliability oversight agency due to a violation of operating standards resulting from under-delivery or over-delivery of energy may be passed through to Energy Imbalance Service Customers.

Rate Schedule L–AS9

SCHEDULE 9 to OATT

(Supersedes Rate Schedule L–AS9 dated October 1, 2011, through September 30, 2016)

UNITED STATES DEPARTMENT OF ENERGY

WESTERN AREA POWER ADMINISTRATION

ROCKY MOUNTAIN REGION

Loveland Area Projects and

Western Area Colorado Missouri Balancing Authority

GENERATOR IMBALANCE SERVICE

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

This rate schedule applies to Loveland Area Projects (LAPT) as the Transmission Service Provider (TSP) and to Western Area Colorado Missouri Balancing Authority (WACM) as the Control Area operator. WACM provides Generator Imbalance Service when there is a difference between actual generation and scheduled generation for each hour.

The LAPT TSP must offer this service when transmission service is used to deliver energy to serve load within WACM and the Federal Transmission Customers must purchase this service from the LAPT TSP or make alternative comparable arrangements with WACM to satisfy their Generator Imbalance obligations. By default, WACM, as the Control Area operator, provides Generator Imbalance Service to all entities within its Control Area footprint. All entities who have generation inside WACM must enter into separate agreements with WACM which will specify the terms of the Generator Imbalance Service.

This formula rate applies to all jointly-owned generators (unless arrangements are made to allocate actual generation to each individual owner), variable generators (unless arrangements are made to assess the variable generator under Rate Schedule L–AS4), and any non-variable generators without associated load inside the WACM Control Area.

Formula Rate

Imbalances are calculated in three deviation bands as follows:

1. An imbalance of less than or equal to 1.5 percent of metered generation (or 4 MW, whichever is greater) for any hour is settled financially at 100 percent of the WACM weighted average hourly energy price.

2. An imbalance between 1.5 percent and 7.5 percent of metered generation (or 4 to 10 MW, whichever is greater) for any hour is settled financially at 90 percent of the WACM weighted average hourly energy price when actual generation exceeds scheduled generation or 110 percent of the WACM weighted average hourly energy price when actual generation is less than scheduled generation.

3. An imbalance greater than 7.5 percent of metered generation (or 10 MW, whichever is greater) for any hour is settled financially at 75 percent of the WACM weighted average hourly energy price when actual generation exceeds scheduled generation or 125 percent of the WACM weighted average hourly energy price when actual generation is less than scheduled generation.

Variable generators are exempt from 25 percent penalties. All imbalances greater than 1.5 percent of metered generation are subject only to a 10 percent penalty.

Pricing:

All Generator Imbalance Service provided by WACM is accounted for hourly and settled financially. The WACM aggregate imbalance determines the energy pricing used in all deviation bands. A surplus dictates the use of sale pricing; a deficit dictates the use of purchase pricing. When no hourly data is available, the pricing defaults for sales and purchase pricing are applied in the following order:

1. Weighted average sale or purchase pricing for the day (on- and off-peak).

2. Weighted average sale or purchase pricing for the current month (on- and off-peak).

3. Weighted average sale or purchase pricing for the prior month (on- and off-peak).

4. Weighted average sale or purchase pricing for the month prior to the prior month (and continuing until sale or purchase pricing is located) (on- and off-peak).

Expansion of the bandwidth may be allowed during the following instances:

1. Response to the loss of a physical resource.

2. During transition of large base-load thermal resources (capacity greater than 200 MW) between off-line and on-line following a reserve sharing group response, when the unit generates less than the predetermined minimum scheduling level.

During periods of Balancing Authority operating constraints, WACM reserves

the right to eliminate credits for over-deliveries. The cost to WACM of any charge assessed by a reliability oversight agency due to a violation of operating standards resulting from under-delivery or over-delivery of energy may be passed through to Generator Imbalance Service Customers.

Rate Schedule L–AS5

SCHEDULE 5 to OATT

(Supersedes Rate Schedule L–AS5 dated October 1, 2011, through September 30, 2016)

UNITED STATES DEPARTMENT OF ENERGY

WESTERN AREA POWER ADMINISTRATION

ROCKY MOUNTAIN REGION

Loveland Area Projects and

Western Area Colorado Missouri Balancing Authority

OPERATING RESERVE—SPINNING RESERVE SERVICE

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

This rate schedule applies to Loveland Area Projects (LAPT) as the Transmission Service Provider (TSP) and to Western Area Colorado Missouri Balancing Authority (WACM) as the Control Area operator. Spinning Reserve Service is needed to serve load immediately in the event of a system contingency. Spinning Reserve Service may be provided by generating units that are on-line and loaded at less than maximum output.

The LAPT TSP must offer this service when transmission service is used to serve load within WACM and the Federal Transmission Customers must purchase this service from the LAPT TSP or make alternative comparable arrangements with WACM to satisfy their Spinning Reserve obligations. WACM may be willing to provide Spinning Reserves to other entities, providing the entities enter into separate agreements with WACM which will specify the terms of the Spinning Reserve Service.

Formula Rate

The LAPT TSP and WACM have no Spinning Reserves available for sale. At a customer's request, the Rocky Mountain Region will purchase Spinning Reserves and pass through the cost and any activation energy, plus a fee for administration. The customer will be responsible for providing the transmission to deliver the Spinning Reserves purchased.

Rate Schedule L–AS6

SCHEDULE 6 to OATT

(Supersedes Rate Schedule L–AS6 dated October 1, 2011, through September 30, 2016)

UNITED STATES DEPARTMENT OF ENERGY

WESTERN AREA POWER ADMINISTRATION

ROCKY MOUNTAIN REGION

Loveland Area Projects and

Western Area Colorado Missouri Balancing Authority

OPERATING RESERVE—SUPPLEMENTAL RESERVE SERVICE

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

This rate schedule applies to the Loveland Area Projects (LAPT) as the Transmission Service Provider (TSP) and the Western Area Colorado Missouri Balancing Authority (WACM) as the Control Area operator. Supplemental Reserve Service is needed to serve load in the event of a system contingency; however, it is not available immediately to serve load but rather within a short period of time. Supplemental Reserve Service may be provided by generating units that are on-line but unloaded, by quick-start generation, or by interruptible load.

The LAPT TSP must offer this service when the transmission service is used to serve load within WACM and the Federal Transmission Customers must purchase this service from the LAPT TSP or make alternative comparable arrangements with WACM to satisfy their Supplemental Reserve obligations. WACM may be willing to provide Supplemental Reserves to other entities, providing the entities enter into separate agreements with WACM which will specify the terms of the Supplemental Reserve Service.

Formula Rate

The LAPT TSP and WACM have no Supplemental Reserves available for sale. At a customer's request, the Rocky Mountain Region will purchase Supplemental Reserves and pass through the cost and any activation energy, plus a fee for administration. The customer will be responsible for providing the transmission to deliver the Supplemental Reserves purchased.

Rate Schedule L–AS7

(Supersedes Rate Schedule L–AS7 dated October 1, 2011, through September 30, 2016)

UNITED STATES DEPARTMENT OF ENERGY

WESTERN AREA POWER ADMINISTRATION

ROCKY MOUNTAIN REGION

Western Area Colorado Missouri Balancing Authority

TRANSMISSION LOSSES SERVICE

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

The Western Area Colorado Missouri Balancing Authority (WACM) provides Transmission Losses Service (Losses) to all Transmission Service Providers (TSPs) who market transmission inside the WACM Control Area (Customers). Transmission Losses are assessed for all real-time and prescheduled transactions on transmission facilities inside the WACM Control Area. For transactions (schedules) which involve more than one TSP inside the WACM Control Area, the loss obligation falls on the last TSP listed on the schedule. This prevents double and triple assessment of the losses for schedules which involve more than one TSP. The Customer is allowed the option of energy repayment or financial repayment. Customers must declare annually their preferred methodology of energy payback. Energy repayment may be either concurrently or seven days later, to be delivered using the same profile as the related transmission transaction. The Losses applicable to the Colorado River Storage Project (CRCM) and Loveland Area Projects (LAPT) TSPs will be passed directly to the CRCM and LAPT Transmission Customers.

Formula Rate

The loss factor currently in effect is posted on WACM's Business Practices which is posted on the CRCM and LAPT Open Access Same-Time Information System Web sites.

When a transmission loss energy obligation is not provided (or is under-

provided) by a Customer for a transmission transaction, the energy owed for Transmission Losses Service is calculated and a charge is assessed to the Customer based on the WACM weighted average hourly purchase price.

Pricing for loss energy due 7 days later, and not received by WACM, will be priced at the 7-day-later-price based on the WACM weighted average hourly purchase price.

There will be no financial compensation or energy return to Customers for over-delivery of Transmission Losses Service, as there should be no condition beyond the control of the Customer that results in overpayment.

Customers may settle financially or with energy. The pricing for this service will be the WACM weighted average hourly purchase price. When no hourly data is available, pricing defaults will be applied in the following order:

1. Weighted average purchase pricing for the day (on- and off-peak).
2. Weighted average purchase pricing for the current month (on- and off-peak).
3. Weighted average purchase pricing for the prior month (on- and off-peak).
4. Weighted average purchase pricing for the month prior to the prior month (and continuing until purchase pricing is located (on- and off-peak).

Rate Schedule L–M1

UNITED STATES DEPARTMENT OF ENERGY

WESTERN AREA POWER ADMINISTRATION

ROCKY MOUNTAIN REGION

Loveland Area Projects

SALES OF SURPLUS PRODUCTS

Effective

The first day of the first full billing period beginning on or after October 1, 2016, and extending through September 30, 2021, or until superseded by another rate schedule, whichever occurs earlier.

Applicable

This rate schedule applies to Loveland Area Projects (LAP) Marketing and is applicable to the sale of the following LAP surplus energy and capacity products: reserves, regulation, and frequency response. If any of the above LAP surplus products are available, LAP can make the product(s) available for sale, providing entities enter into separate agreement(s) with LAP Marketing which will specify the terms of sale(s).

Formula Rate

The charge for each product will be determined at the time of the sale based on market rates, plus administrative costs. The customer will be responsible for acquiring transmission service necessary to deliver the product(s).

[FR Doc. 2016–19973 Filed 8–19–16; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9951–03–Region 4; CERCLA–04–2016–3754]

Forshaw Chemicals Superfund Site Charlotte, Mecklenburg County, North Carolina; Notice of Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Settlement.

SUMMARY: Under 122(h) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the United States Environmental Protection Agency (EPA) has entered into a settlement with Thomas Forshaw III, Forshaw Industries, Inc., Forshaw Chemicals Incorporated, Forshaw Distribution, Inc., and Bess C. Forshaw, concerning the Forshaw Chemicals Superfund Site located in Charlotte, Mecklenburg County, North Carolina. The settlement addresses recovery of CERCLA costs for a cleanup action performed by the EPA at the Site.

DATES: The Agency will consider public comments on the settlement until September 21, 2016. The Agency will consider all comments received and may modify or withdraw its consent to the proposed settlement if comments received disclose facts or considerations which indicate that the proposed settlement is inappropriate, improper, or inadequate.

ADDRESSES: Copies of the settlement are available from the Agency by contacting Ms. Paula V. Painter, Program Analyst, using the contact information provided in this notice. Comments may also be submitted by referencing the Site's name through one of the following methods:

Internet: https://www.epa.gov/aboutepa/about-epa-region-4-southeast#r4-public-notices.

- *U.S. Mail:* U.S. Environmental Protection Agency, Superfund Division, Attn: Paula V. Painter, 61 Forsyth Street, SW., Atlanta, Georgia 30303.
- *Email: Painter.Paula@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Paula V. Painter at 404/562–8887.

Dated: July 28, 2016.

Greg Armstrong,

Acting Chief, Enforcement and Community Engagement Branch, Superfund Division.

[FR Doc. 2016–20027 Filed 8–19–16; 8:45 am]

BILLING CODE 6560–50–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Agency Information Collection Activities; Comment Request

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final notice of information collection under review; ADEA waivers.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Commission gives notice that it has submitted to the Office of Management and Budget (OMB) a request for an extension without change of the existing collection requirements under 29 CFR 1625.22, Waivers of rights and claims under the Age Discrimination in Employment Act (ADEA). No public comments were received in response to the EEOC's May 27, 2016 60-Day notice soliciting comments on the proposed extension of this collection.

DATES: Written comments on this notice must be submitted on or before September 21, 2016.

ADDRESSES: Comments on this final notice must be submitted to Joseph B. Nye, Policy Analyst, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, email *oira_submission@omb.eop.gov.* Commenters are also encouraged to send comments to the EEOC online at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions on the Web site for submitting comments. In addition, the EEOC's Executive Secretariat will accept comments in hard copy by delivery by COB on September 21, 2016. Hard copy comments should be sent to Bernadette Wilson, Acting Executive Officer, EEOC, 131 M Street NE., Washington, DC 20507. Finally, the Executive Secretariat will accept comments totaling six or fewer pages by facsimile (''fax'') machine before the same deadline at (202) 663–4114. (This is not a toll-free number.) Receipt of fax transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–4070 (voice) or (202) 663–4074 (TTY). (These are not toll-free telephone numbers.) The EEOC will post online at *http://www.regulations.gov* all comments

submitted via this Web site, in hard copy, or by fax to the Executive Secretariat. These comments will be posted without change, including any personal information you provide. However, the EEOC reserves the right to refrain from posting libelous or otherwise inappropriate comments including those that contain obscene, indecent, or profane language; that contain threats or defamatory statements; that contain hate speech directed at race, color, sex, national origin, age, religion, disability, or genetic information; or that promote or endorse services or products.

All comments received, including any personal information provided, also will be available for public inspection during normal business hours by appointment only at the EEOC Headquarters' Library, 131 M Street NE., Washington, DC 20507. Upon request, individuals who require assistance viewing comments will be provided appropriate aids such as readers or print magnifiers. To schedule an appointment, contact EEOC Library staff at (202) 663–4630 (voice) or (202) 663–4641 (TTY). (These are not toll-free numbers.)

FOR FURTHER INFORMATION CONTACT: Thomas J. Schlageter, Assistant Legal Counsel, (202) 663–4668, or Savannah E. Marion, General Attorney, (202) 663–4909, Office of Legal Counsel, 131 M Street NE., Washington, DC 20507. Copies of this notice are available in the following alternate formats: large print, braille, electronic computer disk, and audio-tape. Requests for this notice in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 663–4191 (voice) or (202) 663–4494 (TTY).

SUPPLEMENTARY INFORMATION:

Overview of This Information Collection

Collection Title: Informational requirements under Title II of the Older Workers Benefit Protection Act of 1990 (OWBPA), 29 § CFR 1625.22.

OMB Number: 3046–0042.

Type of Respondent: Business, State or local governments, not for profit institutions.

Description of Affected Public: Any employer with 20 or more employees that seeks waiver agreements in connection with an exit incentive or other employment termination program.

Number of Responses: 17,350.

Reporting Hours: 26,025.

Number of Forms: None.

Burden Statement: The only paperwork burden involved is the inclusion of the relevant data in requests for waiver agreements under the OWBPA.

Abstract: The EEOC enforces the ADEA which prohibits discrimination against employees and applicants for employment who are age 40 or older. The OWBPA, enacted in 1990, amended the ADEA to require employers to disclose certain information to employees (but not to EEOC) in writing when they ask employees to waive their rights under the ADEA in connection with an exit incentive program or other employment termination program. The regulation at 29 § CFR 1625.22 reiterates those disclosure requirements. The EEOC seeks an extension without change for the third-party disclosure requirements contained in this regulation.

On May 27, 2016, the Commission published a 60-Day Notice informing the public of its intent to request an extension of the information collection requirements from the Office of Management and Budget. 81 FR 33670–33671 (May 27, 2016). No comments were received.

For the Commission.

Dated: August 16, 2016

Jenny R. Yang,

Chair.

[FR Doc. 2016–19941 Filed 8–19–16; 8:45 am]

BILLING CODE 6570–01–P

FEDERAL MARITIME COMMISSION

[Petition No. P2–16]

Petition of Direct Chassislink, Inc., Flexi-Van Leasing, Inc., and Trac Intermodal for an Order To Show Cause; Notice of Filing and Request for Comments

Notice is hereby given that Direct ChassisLink, Inc., Flexi-Van Leasing, Inc., and TRAC Intermodal (Petitioners), have petitioned the Commission pursuant to 46 CFR 502.76 of the Commission's Rules of Practice and Procedure, for an Order to Show Cause to be issued under 46 CFR 502.73. Petitioners ''own and lease/rent chassis to ocean common carriers, motor carriers, cargo interests and others on a short and long term basis.''

Petitioner requests the Commission ''issue an Order to Show Cause to the West Coast MTO Agreement and its individual members participating in WCMTOA Marine Terminal Operator Schedule No. 1. . . .'' Petitioners allege that ''WCMTOA and its members have violated the Shipping Act of 1984 . . . with respect to the publication in WCMTOA Terminal Schedule No. 1 of Rule 15 establishing a Chassis Services Fee in an amount that would cumulatively cost the Petitioners an estimated $28 million annually.''

In order for the Commission to make a thorough evaluation of the Petition, interested persons are requested to submit views or arguments in reply to the Petition no later than August 26, 2016. Replies shall consist of an original and 5 copies, be directed to the Secretary, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573–0001, and be served on Petitioner's counsel, Neal M. Mayer, Esq., and Paul D. Coleman, Esq., Hoppel, Mayer & Coleman, 5th Floor, 1050 Connecticut Avenue NW., Washington, DC 20036. A PDF copy of the reply must also be sent to *secretary@fmc.gov*. Include in the email subject line ''Petition No. P2–16.''

Replies containing confidential information should not be submitted by email. The Commission will provide confidential treatment for identified confidential information to the extent allowed by law. A reply containing confidential information must include:

- A transmittal letter requesting confidential treatment that identifies the specific information in the reply for which protection is sought and demonstrates that the information is a trade secret or other confidential research, development, or commercial information.
- A confidential copy of the reply, clearly marked ''Confidential-Restricted'', with the confidential material clearly marked on each page.
- A public version of your reply with the confidential information excluded or redacted, marked ''Public Version—confidential materials excluded.''

The Petition will be posted on the Commission's Web site at *http://www.fmc.gov/P2–16*. Replies filed in response to this Petition also will be posted on the Commission's Web site at this location.

Parties participating in this proceeding may elect to receive service of the Commission's issuances in this proceeding through email in lieu of service by U.S. mail. A party opting for electronic service shall advise the Office of the Secretary in writing and provide an email address where service can be made.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–20026 Filed 8–19–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 16, 2016.

A. Federal Reserve Bank of St. Louis (David L. Hubbard, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *Central Bancompany, Inc., Jefferson City, Missouri;* to acquire 100 percent of Bank Star One, Fulton, Missouri.

Board of Governors of the Federal Reserve System, August 17, 2016.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2016–19958 Filed 8–19–16; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2430–N]

Medicaid Program; Connecting Kids to Coverage Outreach and Enrollment Cooperative Agreement

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

ACTION: Notice.

SUMMARY: The purpose of this notice is to announce a single source emergency cooperative agreement funding opportunity available solely to the Greater Flint Health Coalition to reduce the number of children in Flint, Michigan who are eligible for Medicaid and CHIP, but are not enrolled, and improve retention of children enrolled.

DATES: 3 years, composed of three 12-month budget periods. The maximum funding amount for the first 12-month budget period is $100,000. The Greater Flint Health Coalition will be eligible to receive an additional $100,000 per year for the second and third 12-month budget periods.

FOR FURTHER INFORMATION CONTACT: Patrick M. Edwards, Project Officer, 410–786–4463.

SUPPLEMENTARY INFORMATION:

I. Background

On January 16, 2016, President Obama declared an emergency in the State of Michigan and ordered federal aid to supplement state and local efforts in response to the lead exposure related to the Flint, Michigan water system. On March 3, 2016, we approved the State of Michigan's 1115 demonstration, which (along with associated state plan amendments) extended Medicaid coverage and services to children up to age 21 years and to pregnant women with incomes up to and including 400 percent of the federal poverty level (FPL) who were served by the Flint water system from April 2014 through a state-specified date. To maximize outreach efforts to the significant number of children newly eligible for coverage, the Secretary for the Department of Health and Human Services (DHHS) has expressed interest in utilizing $300,000 of outreach funding available under the Medicare Access and CHIP Reauthorization Act (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) to support and coordinate outreach and enrollment efforts in Flint, Michigan to address the urgent health coverage needs of children exposed to lead related to the Flint water system. The MACRA funds will be used to support the immediate need for an outreach and enrollment coordinator to educate current beneficiaries and applicants about the availability of important Medicaid benefits for children impacted by the lead exposure that began in April 2014 and continues to pose a risk. This exposure can cause negative developmental neurocognitive effects. Funds will be used for activities aimed at educating families about the availability of free or low-cost health coverage under Medicaid and CHIP,[1] identifying children likely to be eligible for these programs, assisting families with the application, as well as supporting the renewal of children in Medicaid and CHIP.

II. Provisions of the Notice

The purpose of this notice is to announce a single source emergency cooperative agreement funding opportunity available solely to the Greater Flint Health Coalition to reduce the number of children in Flint, Michigan who are eligible for Medicaid and CHIP, but are not enrolled, and improve retention of children enrolled. A single-source award to the Greater Flint Health Coalition will enable CMS to expeditiously provide emergency assistance to Flint, Michigan for the following purposes: To coordinate and promote activities aimed at educating families about the availability of free or low-cost health coverage under Medicaid and CHIP, identify children likely to be eligible for these programs, assist families with the application and renewal process, instruct current beneficiaries and applicants about the evaluation of potential lead exposure in the homes, communicate other benefits available to individuals eligible for services through the Flint demonstration, and ensure that such communication with individuals with disabilities and with individuals who are limited English proficient are in compliance with applicable civil rights laws, including Section 504 of the Rehabilitation Act and Title VI of the Civil Rights Act of 1964.

To provide these essential services as quickly as possible to reduce the

[1] On January 1, 2016, Michigan transitioned most of the children in its separate CHIP to a Medicaid expansion CHIP. The only children remaining in the separate CHIP are children from conception to birth, as defined in 42 CFR 457.10, with family income up to and including 195 percent of the Federal Poverty Level. Outreach and enrollment efforts will be directed to children who are eligible for Medicaid, as well as this CHIP population, to address the urgent health coverage needs of children exposed to lead contaminated water.

potential long term effects caused by lead exposure, this single source emergency funding opportunity must solely be available to the Greater Flint Health Coalition (GFHC) which is uniquely positioned to meet the goals of the emergency cooperative agreement based on the organization's location, capacity, partnerships, resources, prior experience, and ability to begin implementing the project immediately. Prior to the water crisis in Flint, the GFHC worked to significantly improve the health status of Flint residents by establishing a common health agenda and instituting a shared measurement system among local hospitals with mutually reinforcing health activities. In addition, this organization currently administers programs that involve a variety of constituents important to reaching and enrolling children in Medicaid and CHIP, such as schools, health homes, safety net providers, and various government organizations. The GFHC's presence in the greater Flint community enabled them to become an early leader in alerting the public about the lead exposure related to the Flint water system.

Utilizing the funding under this single-source award, the GFHC will be able to immediately hire an outreach and enrollment coordinator to educate beneficiaries about Medicaid and CHIP services available to affected children and families in Flint, Michigan and to coordinate community-based activities designed to support Medicaid enrollment for eligible children. More broadly, this funding will enable the GFHC to address the lead exposure related to the Flint water system by promoting critical public health, medical, and community-based services and interventions that address and mitigate the detrimental short and long term impacts of lead. Due to these reasons and the GFHC's cross sector collaboration with Genesee County's public health leadership, physicians, hospitals, and health insurers, GFHC has the full capacity to begin implementation of the project tasks immediately.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: August 16, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–19999 Filed 8–19–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.583]

Announcement of the Award of Single-Source Grants Under the Wilson-Fish Alternative Program (W–F)

AGENCY: Office of Refugee Resettlement, ACF, HHS.

ACTION: Announcement of 13 single-source awards under the Wilson-Fish (W–F) Alternative Program.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), announces the award of 13 single-source grants for a total of $35,513,938 under the W–F Alternative Program.

DATES: September 30, 2015 through September 29, 2016.

FOR FURTHER INFORMATION CONTACT: Colleen Mahar-Piersma, Program Analyst, Office of Refugee Resettlement, Aerospace Building, 8th Floor West, 901 D Street SW., Washington, DC 20447. Telephone: 202–401–6891; Email: *colleen.mahar-piersma@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Wilson-Fish Alternative Program is intended to be an alternative to state-administered refugee assistance program that ensures that refugee assistance programs exist in every state where refugees are resettled. The W–F Alternative Program provides integrated assistance (cash and medical) and services (employment, case management, English language instruction, and other social services) to eligible clients in order to increase their prospects for early employment and self-sufficiency, reduce their level of welfare dependence, and promote coordination among voluntary resettlement agencies and service providers. W–F Alternative Program eligible clients include refugees, asylees, Amerasian Immigrants, Cuban and Haitian Entrants, Trafficking Victims, and Iraqi/Afghani Special Immigrant Visa holders.

The W–F Alternative Program, which operates in 13 states, is one of three models outlined in the ORR regulations for the purpose of providing refugee cash assistance (RCA) to new arrivals. The W–F Alternative Program utilizes a ''one stop shop'' model in which services and assistance are administered by a single agency.

Grant awards were made to 12 statewide W–F Alternative Programs in Alabama, Alaska, Colorado, Idaho, Kentucky, Louisiana, Massachusetts, Nevada, North Dakota, South Dakota, Tennessee, and Vermont. An award was also made to one countywide program in San Diego County, CA.

The W–F grant recipients are:

Grantee name	Location	Award amounts
Catholic Social Services	Mobile, AL	$414,037
Catholic Social Services	Anchorage, AK	718,916
Colorado Department of Human Services	Denver, CO	2,955,177
Jannus Inc.—Idaho Office for Refugees	Boise, ID	2,304,414
Catholic Charities—Louisville	Louisville, KY	4,856,018
Catholic Charities Diocese of Baton Rouge	Baton Rouge, LA	1,463,000
Massachusetts Office of Refugees & Immigrants	Boston, MA	3,814,588
Catholic Charities of Southern Nevada	Las Vegas, NV	4,349,921
Lutheran Social Services of North Dakota	Fargo, ND	1,378,169
Catholic Charities Diocese of San Diego	San Diego, CA	3,534,100
Lutheran Social Services of South Dakota	Sioux Falls, SD	841,890
Catholic Charities of Tennessee, Inc.	Nashville, TN	8,299,523
US Committee for Refugees & Immigrants	Burlington, VT	584,185

It is expected that ORR will continue to provide awards to the listed grantees for a 4-year project period. Grantees will be required to submit applications for noncompetitive awards for the subsequent years of the project period. Future noncompetitive awards will be based on the grantee's performance, the availability of funds, and the best interest of the Federal Government.

Statutory Authority: The Refugee Act of 1980 as amended, Wilson-Fish Amendment, Public Law 98–473, 8 U.S.C. 1522(e)(7); section 412(e)(7)(A) of the Immigration and Nationality Act.

Mary M. Wayland,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2016–19923 Filed 8–19–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1021]

Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2016 Proposed Guidance Development; Correction

AGENCY: Food and Drug Administration, HHS

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2016 Proposed Guidance Development'' that appeared in the **Federal Register** of December 29, 2016 (80 FR 81335). The document announced the Web site location where the Agency will post two lists of guidance documents that the Center for Devices and Radiological Health (CDRH or the Center) intends to publish in Fiscal Year (FY) 2016. The document was published with the incorrect number of years in which CDRH committed to finalize, withdraw, re-open the comment period, or issue another draft guidance on the topic for 80 percent of the documents. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, December 29, 2015, in FR Doc. 2015–32726, the following correction is made:

1. On page 81336, in the third column, in the 13th sentence of the second paragraph under section II. *CDRH Guidance Development Initiative,* ''2 years'' is corrected to read ''3 years''.

Dated: August 16, 2016.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2016–19874 Filed 8–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2473]

Adapting Regulatory Oversight of Next Generation Sequencing-Based Tests; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Adapting Regulatory Oversight of Next Generation Sequencing-Based Tests.'' The purpose of this workshop is to obtain feedback on two FDA draft guidances, ''Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases'' and ''Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics'' that describes new approaches to regulate NGS-based tests.

DATES: The public workshop will be held on September 23, 2016, from 9 a.m.to 3 p.m. Submit either electronic or written comments on the public workshop by October 6, 2016.

ADDRESSES: The workshop will be held in Masur Auditorium at the NIH Campus, 9000 Rockville Pike, Bldg. 10, Bethesda, MD 20814. For parking and security information, please refer to the NIH Campus Visitor Information: *http://www.nih.gov/icd/od/ocpl/VIC/index.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2473 for ''Adapting Regulatory Oversight of Next Generation Sequencing-Based Tests.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: David Litwack, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4548, Silver Spring, MD 20993, 301–796–6206, *ernest.litwack@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In Vitro diagnostic devices that utilize NGS technology to generate information on an individual's genome are rapidly transforming healthcare. As part of the Precision Medicine Initiative,[1] FDA is developing and implementing a novel framework for NGS test regulation that can accelerate innovation while assuring NGS-based test safety and effectiveness. To advance this effort, FDA published two draft guidances on July 8, 2016. The first, entitled ''Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics'', describes how publicly accessible databases of human genetic variants can serve as sources of valid scientific evidence to support the clinical validity of genotype-phenotype relationships in FDA's regulatory review of NGS-based tests. This draft guidance further outlines the process by which administrators of genetic variant databases could voluntarily apply to FDA for recognition, and how FDA would review such applications and periodically reevaluate recognized databases.

The second draft guidance document, entitled ''Use of Standards in the Food and Drug Administration's Regulatory Oversight of Next Generation Sequencing-Based In Vitro Diagnostics Used for Diagnosing Germline Diseases'', addresses DNA sequencing and whole exome sequencing NGS-based tests intended to aid in the diagnosis of individuals with suspected germline diseases or other conditions. This document provides recommendations for designing, developing, and validating NGS-based tests for germline diseases, and also discusses possible use of FDA-recognized standards for regulatory oversight of these tests. These recommendations are based on FDA's understanding of the tools and processes needed to run an NGS-based test along with the design and analytical validation considerations appropriate for such tests.

Neither draft guidance is final nor in effect at this time. The workshop announced in this document seeks to obtain public input on the proposals contained in the two draft guidances. Workshop material, including the draft guidances, can be accessed from the workshop Web site: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

II. Topics for Discussion at the Public Workshop

This public workshop will consist of presentations that will frame the goals of the workshop followed by moderated discussions via panel sessions. The presentations and discussions will focus on the content of the draft guidances, as well as on additional questions that were posed in the Notices of Availability published in the **Federal Register** on July 8, 2016. These notices can be found at *https://federalregister.gov/a/2016-1233* and *https://federalregister.gov/a/2016-1270.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by September 13, 2016, at 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, 301–796–5661, *susan.monahan@fda.hhs.gov,* no later than September 12, 2016.

To register for the public workshop, please visit FDA's Medical Devices News, Events, Workshops, and Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact David Litwack to register (see **FOR FURTHER INFORMATION CONTACT**). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. The Webcast link will be available on the registration Web site after September 13, 2016. To view the registration Web site, please visit FDA's Medical Devices News, Events, Workshops, and Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* Select this public workshop from the posted events list. FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Requests for Oral Presentations: This public workshop includes a public comment session. During online registration you may indicate if you wish to present during a public comment session, and which topics you wish to address. In addition to the subjects discussed in the two draft guidances, FDA has posed supplemental topics in the Notices of Availability for the draft guidances (see Supplementary Information). FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments, and request time for joint comments, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin,

[1] The Precision Medicine Initiative found on the White House's Web site at: *https://www.whitehouse.gov/precision-medicine.*

and will select and notify participants by September 14, 2016. All requests to make oral presentations must be received by September 13, 2016. If selected for presentation, any presentation materials must be emailed to David Litwack (see **FOR FURTHER INFORMATION CONTACT**) no later than September 16, 2016, at 5 p.m. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

FDA is holding this public workshop to obtain feedback on its recently released draft guidance documents: ''Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing-Based In Vitro Diagnostics'' and ''Use of Standards in the Food and Drug Administration's Regulatory Oversight of Next Generation Sequencing-Based In Vitro Diagnostics Used for Diagnosing Germline Diseases''. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is October 6, 2016.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

Dated: August 17, 2016.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2016–19939 Filed 8–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

National Mammography Quality Assurance Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the National Mammography Quality Assurance Advisory Committee. This meeting was announced in the **Federal Register** of August 5, 2016. The amendment is being made to reflect a change in the **ADDRESSES** portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: S.J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1552, Silver Spring, MD 20993–0002, *Sara.Anderson@fda.hhs.gov,* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code MA. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 5, 2016 (81 FR 51918), FDA announced that a meeting of the National Mammography Quality Assurance Advisory Committee would be held on September 15, 2016. On page 51919, in the first column, in the **ADDRESSES** portion: Hilton Washington, DC/North, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900, is changed to read as follows: Gaithersburg Holiday Inn—Grand Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20878. The hotel's telephone number is 301–948–8900.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: August 17, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–19957 Filed 8–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2474]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting associated with designation under the Minor Use and Minor Species Animal Health Act of 2004.

DATES: Submit either electronic or written comments on the collection of information by October 21, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the

public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2474 for ''Reporting Associated with Designated New Animal Drugs for Minor Use and Minor Species.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species; 21 CFR Part 516 OMB Control Number 0910–0605—Extension

The Minor Use and Minor Species (MUMS) Animal Health Act of 2004 (Pub. L. 108–282) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species as well as uncommon diseases in major animal species. This legislation provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing limited-demand animal drugs. These incentives are only available to sponsors whose drugs are ''MUMS-designated'' by FDA. Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys, dogs, and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas. Minor species are all animals other than the major species; for example, zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish, and honeybees. Participation in the MUMS program is completely optional for drug sponsors so the associated reporting only applies to those sponsors who request and are subsequently granted ''MUMS designation.''

Our regulations in 21 CFR part 516 specify the criteria and procedures for requesting MUMS designation as well as the annual reporting requirements for MUMS designees. Section 516.20 provides requirements on the content and format of a request for MUMS-drug designation; § 516.26 provides requirements for amending MUMS-drug designation; § 516.27 provides for change in sponsorship of MUMS-drug designation; § 516.29 provides for termination of MUMS-drug designation; § 516.30 contains the requirements for annual reports from sponsor(s) of MUMS-designated drugs; and § 516.36 sets forth consequences for insufficient quantities of MUMS-designated drugs.

Description of Respondents: The respondents to this information collection are pharmaceutical companies that sponsor new animal drugs.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
516.20; content and format of MUMS request	15	5	75	16	1200
516.26; requirements for amending MUMS designation	3	1	3	2	6
516.27; change in sponsorship	1	1	1	1	1
516.29; termination of MUMS designation	2	1	2	1	2
516.30; requirements of annual reports	15	5	75	2	150
516.36; insufficient quantities	1	1	1	3	3
Total					1,362

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

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the investigational new animal drug/new animal drug application reporting requirements for similar actions by this same segment of the regulated industry and from previous interactions with the minor use/minor species community.

Dated: August 16, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016–19919 Filed 8–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Changes to the Black Lung Clinics Program

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

ACTION: Request for Public Comment on Proposed Changes to the Black Lung Clinics Program for Consideration for the FY 2017 Funding Opportunity Announcement Development.

SUMMARY: This notice seeks comments on a range of issues pertaining to the Black Lung Clinics Program (BLCP), which will be competitive in Fiscal Year (FY) 2017. HRSA's Federal Office of Rural Health Policy allocates funds for state, public, or private entities that provide medical, educational, and outreach services to active, inactive, and retired coal miners with disabilities. Funding allocations take into account the number of miners to be served; their medical, outreach, and educational needs; and the quality and breadth of services that are provided. HRSA requests feedback on how to best determine the needs of coal miners and their families, given the available data, and how to better equip future BLCP grantees to meet those needs.

DATES: Submit written comments no later than September 21, 2016.

ADDRESSES: Written comments should be submitted to *Blacklung@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Allison Hutchings, Program Coordinator, Black Lung Clinics Program, Federal Office of Rural Health Policy, Health Resources and Services Administration, *Blacklung@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

a. Authorizing Legislation and Program Regulations

BLCP is authorized by Section 427(a) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 937(a)), as amended, and accompanying regulations found at 42 CFR part 55a (''BLCP regulations''). HRSA began administering the program in FY 1979, when $7.5 million was appropriated. HRSA awarded approximately $6.5 million to clinics in FY 2015.

The primary goal of the BLCP is to reduce the morbidity and mortality associated with occupationally-related coal mine dust lung disease. The BLCP regulations (42 CFR part 55a) state that BLCP grantees must provide for the following services to active and inactive miners, in consultation with a physician with special training or experience in the diagnosis and treatment of respiratory diseases: primary care; patient and family education and counseling; outreach; patient care coordination; antismoking advice; and other symptomatic treatments. Additionally, BLCP grantees must serve as payers of last resort and be able to administer, or provide referrals for, U.S. Department of Labor (DOL) disability examinations.

b. Eligibility and Funding Criteria

The BLCP funding opportunity is open to any state or public or private entity that meets the requirements of the BLCP as described above. These entities include faith-based and community-based organizations, as well as federally recognized Tribes and Tribal organizations.

The BLCP regulations state that the funding criteria for applicants should take into account: *(1) The number of miners to be served and their needs; and (2) the quality and breadth of services to be provided.* The regulations also state that ''the Secretary will give preference to a State, which meets the requirement of this part and applies for a grant under this part, over other applications in that State''.

c. Application Cycle

HRSA administers the BLCP over 3-year grant cycles. The program was last competitive in FY 2014, and current BLCP grantees finished their second year of the cycle on June 30, 2016. The program will be competitive again in FY 2017.

II. Current Challenges

a. Growing Need for Black Lung Services

In FY 2000, surveillance data from the Centers for Disease Control and Prevention's National Institute of Occupational Safety and Health (NIOSH) showed an unexpected increase in the national prevalence of coal workers' pneumoconiosis (CWP), also known as black lung disease, after nearly three decades of steady decline following the enactment of the Federal Coal Mine Health and Safety Act of 1969. The overall CWP prevalence among U.S. coal workers declined from 11 percent in 1970 to 2 percent in 1999. However, since 2000, the prevalence of CWP has increased to 3 percent and continues to rise. According to NIOSH surveillance data, the rise in CWP has been the most severe among coal miners

in Kentucky, Virginia, and West Virginia. Compared with coal miners in other states, these miners tend to be younger, with fewer years of work experience in underground mines. Investigators from NIOSH reported that the prevalence of progressive massive fibrosis (PMF), the most severe form of black lung disease, increased 900 percent between 2000 and 2012, affecting over 3 percent of miners with over 25 years of work. This level of prevalence of PMF has not been seen since the 1970s. Additionally, NIOSH has reported that coal miners are developing severe CWP at relatively young ages.

Finally, the U.S. coal industry is currently experiencing a downturn. Industry analysts estimate that nearly 50 coal companies have sought bankruptcy court protection since 2012, resulting in layoffs and, in some cases, lost retirement benefits for coal miners. According to a 2016 report by the Appalachian Regional Commission, Appalachian Kentucky experienced a coal mining job decline of 56 percent between 2011 and 2015, while Tennessee and Virginia both experienced declines of approximately 40 percent during the same time period. The West Virginia Office of Miners Health Safety and Training has estimated that there are currently 12,000 coal miners employed in the state, down from 22,000 in 2011. Widespread coal mining job losses have also been reported in other states such as Pennsylvania, Ohio, and Alabama. These trends have the potential to affect coal miners' economic welfare and, by extension, their ability to access or afford health care. Indeed, some current BLCP grantees have noted in their annual progress reports to HRSA, submitted April 2016, and in written email communication ahead of the March 2016 HRSA BLCP Grantee Workshop, that they have witnessed a recent uptick in the number of coal miners visiting their clinics, which some attribute to industry layoffs.

b. Ongoing Challenges in Meeting Those Needs

Current BLCP grantees reported facing several challenges in meeting the needs of coal miners in their service areas during a March 2016 BLCP Grantee Workshop hosted by HRSA. First, recruitment, training, and retention of qualified clinical and benefits counseling staff remain difficult, particularly in rural areas. Second, coal miners often face transportation and other barriers to accessing health services, which is problematic given that many suffer from chronic conditions that require regular management and treatment. Third, BLCP grantees have indicated that some miners, including those who have been laid off or are not part of a union, are difficult to locate, which can complicate outreach and service delivery efforts. Finally, there continues to be a shortage of clinicians willing and able to perform exams related to the emerging DOL standards for x-rays, pulmonary testing, and medical documentation, particularly in rural areas.

c. Limited Available Data

Overarching these challenges is the lack of a single, comprehensive, national dataset that contains information on active, inactive and retired, and disabled U.S. coal miners who have worked in surface and underground mines. DOL's Office of Workers' Compensation Programs and Mine Safety and Health Administration, along with NIOSH's Coal Workers' Health Surveillance Program, each regularly collect health and safety data on coal miners, but these data address specific and separate aspects of this population. HRSA also collects yearly performance data from BLCP grantees, but these data are in aggregate form making it problematic to analyze patient-level data or link to DOL or NIOSH's datasets. As a result, it is difficult to ascertain both the total number of active, inactive and retired, and coal miners with disabilities in a given service area, as well as the complete health and wellness profile of U.S. coal miners. This makes it difficult for HRSA to assess where U.S. coal miners reside and what their needs are. Per statute, HRSA is required to allocate BLCP grant funds based in part on ''the number of miners to be served and their needs.'' Additionally, the lack of comprehensive data on coal miners is a challenge to current BLCP grantees that use BLCP funds to target and deliver services to miners.

III. FY 2014 Funding Approach and Current BLCP Cohort

a. Overview of FY 2014 Funding Approach

In FY 2014, HRSA tested a new funding approach that aimed to respond to the growing national need for BLCP services, as well as the BLCP regulations' requirement to allocate BLCP grant funds according to: *(1) The number of miners to be served and their needs; and (2) the quality and breadth of services to be provided.* The new funding approach enabled individual applicants to apply for a specific tier of funding, depending on the level of services they intended to provide (see pp. 6–9 of the FY 2014 Funding Opportunity Announcement). Historically, the mix of BLCP grantees and applicants has been broad in terms of those who are very clinically focused and those who are more geared towards outreach, education, and counseling. The tiered-based funding approach was designed, in part, to account for these differences. Additionally, the funding methodology took into account available data on the number of coal miners and coal mines in a service area, as reported by the U.S. Department of Energy's Energy Information Administration (EIA) *and other national, state, and local resources.*

b. Current BLCP Cohort

Following a competitive application process, HRSA allocated approximately $6.5 million among 15 BLCP grantees. These grantees provided medical, outreach, educational, and counseling services to 11,843 miners across 14 states in FY 2014.

c. Black Lung Center of Excellence

HRSA also funded one Black Lung Center of Excellence (BLCE) through a cooperative agreement in FY 2014 to strengthen the quality of the BLCP and respond to some of the challenges faced by BLCP grantees and the program as a whole, including around the emerging clinical requirements related to DOL's black lung claims process.

IV. Request for Public Comment on Next Funding Opportunity Announcement (FOA)

a. Background

The BLCP will be competitive again in FY 2017, and HRSA is seeking public comment on issues pertaining to the program, including:

b. Funding Approach

Following the release of the new funding approach in FY 2014, some stakeholders expressed concern that the funding tiers increased the administrative burden on applicants and, in some cases, reduced funding for applicants that experienced a high demand for black lung services in their service areas. With this request, HRSA invites public comment on the FY 2014 funding approach and suggestions for other funding methodologies that will allocate BLCP grant funds based on the healthcare needs of coal miners and the ability of applicants to meet those needs, while minimizing service disruption, aligning with the program's statutory and regulatory requirements, and taking into account the amount of available funding.

One approach HRSA would like to seek feedback on includes a service area competition whereby HRSA allocates funds to states based on the need for services (which includes the number of miners in the state) and the implications of taking into account historical funding amounts in administering the program.

c. Determining Need

HRSA's FY 2014 funding methodology aimed to better align the BLCP with the regulations, which require HRSA to allocate funds based on: *(1) The number of miners to be served and their needs; and (2) the quality and breadth of services to be provided.* To that end, the FY 2014 funding methodology took into account the number of coal miners and coal mines in a service area, as reported by EIA and other national, state, and local resources, as well as the level of services an applicant intended to provide. HRSA recognizes that these data do not necessarily encapsulate important factors like disease severity and comorbidity, disability, and employment status, all of which could affect the time and resources grantees must devote to delivering health and social services to coal miners. With the recent downturn of the U.S. coal industry, and the corresponding layoffs of coal miners, the numbers of active coal miners and coal mines in a service area may not be the most accurate indicators of need for services. Therefore, HRSA invites public comment on how to better define and measure the diverse needs of coal miners based on publicly available data to ensure that HRSA allocates BLCP grant funds to areas of the country where they are most needed.

d. Data Collection

Currently, BLCP grantees report performance data on the number of coal miners they serve and the number and type of services they provide to HRSA. These aggregated data provide little insight into the quality of services clinics provide, nor relevant factors such as comorbid conditions, smoking history, and insurance coverage. Requiring BLCP grantees to collect and report on patient-level data would strengthen the quality of the BLCP by enabling HRSA to better understand coal miners' needs, the ability of BLCP grantees to meet those needs, and, importantly, how to better allocate BLCP grant funds. Additionally, given that the majority of coal miners served by BLCP grantees are retired, collecting patient-level data would enable HRSA to add to the limited body of knowledge on this population.

However, despite the benefits of patient-level data collection, HRSA recognizes that this process may be administratively and financially burdensome for BLCP grantees. Therefore, HRSA invites public comment on whether it should require grantees to collect and report patient-level data, either through the current performance measurement system or a separate black lung clinical database.

e. The Black Lung Center of Excellence (BLCE)

In FY 2014, HRSA funded one BLCE through a cooperative agreement to focus on the quality aspect of the BLCP. The current BLCE grantee, with assistance from HRSA, has implemented a number of activities aimed at achieving HRSA's goals around quality, including:

- Developing and launching the BLCE Web site to provide BLCP grantees, miners, and others who provide services to miners with educational expertise and resources on coal mine dust lung disease;
- Creating four training modules in collaboration with the DOL, Division of Coal Mine Workers Compensation, for medical providers and Black Lung examiners that provide in-depth information on screening, diagnosis, and treatment of coal mine lung dust disease;
- Providing technical assistance to BLCP grantees; and
- Developing and piloting the Black Lung Clinical Research Database (REDCap) to standardize clinical data collection and performance data submission by HRSA BLCP grantees.

HRSA invites public comment on how HRSA can better leverage the BLCE's expertise and quantify the BLCE's impact on BLCP grantees and the coal miners they serve through performance measures.

f. Timeliness and Quality of DOL Exams

One of the goals of the BLCP, as outlined in the FY 2014 funding opportunity announcement, is to ''provide well-reasoned medical opinions and timely scheduling/completion of DOL medical exams to facilitate the filing of Federal Black Lung Benefits claims.'' HRSA proposes to work with DOL's Office of Workers' Compensation Programs (OWCP) to hold BLCP grantees to standards for medical exam timeliness. In particular, these standards would require clinicians performing 413(b) examinations, who are affiliated with BLCP clinics, to complete initial 413(b) requests within 90 days and 413(b) supplemental medical evidence development within 60 days. Additionally, to strengthen the quality of services provided by BLCP grantees, HRSA proposes requiring medical and non-medical personnel from all BLCP clinics to complete the OWCP-sponsored training modules entitled ''Black Lung Disability Evaluation and Claims Training for Medical Examiners'' prior to applying for BLCP grant funds. HRSA invites public comment on whether these requirements are reasonable and attentive approaches to strengthening the quality of medical services provided by BLCP grantees.

g. Grantee Collaboration

The current BLCP grantees and applicants are mixed in terms of those who are clinically focused and those who are service focused. Encouraging grantees to share best practices and provide technical assistance to one another could help strengthen the quality of the BLCP. Proposed mechanisms for achieving greater collaboration include allowing grantees to allocate a portion of their award towards providing on-site or remote technical assistance to other clinics and/or encouraging grantees to participate in a yearly peer learning workshop hosted by HRSA. HRSA invites public comment on these strategies as well as how the BLCE can play a role in facilitating grantee collaboration.

h. Pulmonary Rehabilitation

The current BLCP grant guidance requires grantees to provide for accredited pulmonary rehabilitation services. The first two funding tiers require BLCP grantees to provide ''on-site or contracted accredited Phase II or Phase III rehabilitation services,'' while the third and highest funding tier requires BLCP grantees to provide an ''on-site'' and ''American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR)-certified'' pulmonary rehabilitation program. Current BLCP grantees have expressed concerns that these standards are difficult to meet, particularly in rural areas where miners have to travel long distances to attend multiple sessions a week. Thus, HRSA invites public comment on how to revise the BLCP requirements around pulmonary rehabilitation such that they are feasible but still ensure that miners receive a variation of this beneficial service.

Dated: August 15, 2016.

James Macrae,

Acting Administrator.

[FR Doc. 2016–19938 Filed 8–19–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 21, 2016.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Building Futures: Supporting Youth Living with HIV.

OMB No.: 0915–xxxx–New.

Abstract: The Ryan White HIV/AIDS Program (RWHAP), administered by the HRSA HIV/AIDS Bureau (HRSA/HAB), provides HIV-related services in the United States for people living with HIV (PLWH) who do not have sufficient health care coverage or financial resources to pay for HIV-related services. In 2014, 5.8 percent of the approximately 512,000 RWHAP clients served were young adults between the ages of 13–24.[1] HRSA/HAB awarded a contract, *Building Futures: Supporting Youth Living with HIV,* to identify and document best-practices and challenges associated with providing HIV care to youth living with HIV. Information learned from RWHAP sites serving youth living with HIV (aged 13–24 years) will help identify effective strategies and barriers for helping this population reach viral load suppression. The sites will be chosen from RWHAP-funded providers based on data from the 2014 Ryan White HIV/AIDS Services Report. Information gathered at these visits will help inform best practices and the development of technical assistance (TA) to conduct at sites looking to improve their outcomes along the HIV care continuum. It will also inform additional TA products that will be made available to other RWHAP providers to improve health outcomes for young PLWH.

Need and Proposed Use of the Information: Youth (defined for the purposes of this project as age 13 through 24) in the United States are disproportionately impacted by HIV. In 2014, 9,731 (22 percent) of the 44,073 new HIV diagnoses in the U.S. were among youth between the ages of 13 and 24, with a large majority (81 percent) of these youth diagnoses among older youth aged 20–24.[2] Young PLWH also experience disparities in outcomes along the HIV care continuum.[3] Among RWHAP clients in 2014, older youth aged 20–24 had the lowest rates of retention in care and both 15–19 year olds and 20–24 year olds had notably lower rates of viral load suppression as compared to other age groups. Additionally, certain subpopulations such as young men who have sex with men (MSM) of color, lesbian, gay, bisexual, transgender and questioning youth (LGBTQ), and young women of color bear a disproportionate share of the disease burden and have poorer outcomes in the areas of retention in care and viral suppression.[4] [5]

The Building Futures: Supporting Youth Living with HIV project aims to strengthen RWHAP engagement with young people aged 13–24 living with HIV to improve their health outcomes. Through this project, HRSA/HAB will systematically document strategies used by providers funded by the RWHAP to achieve high rates of youth retention in care and viral load suppression. HRSA/HAB will also learn about gaps and challenges from providers that have demonstrated poorer outcomes in these areas.

Specialized Site Visits will be conducted with 10 RWHAP providers with youth patients with strong outcomes in the areas of patient retention and viral suppression to identify, understand, and document replicable evidence-based best practices and models of care. Interviews will be conducted with program support and clinical staff, in addition to HIV-positive youth patients. HIV-positive youth leaders will be engaged as consultants to the site visit team to pretest instruments, review site visit conclusions with the project team, and offer a perspective of youth living with HIV on the data gathered from sites. TA, including implementation of changes to improve performance among youth-serving RWHAP providers, will be developed from information gathered through the site visits.

Performance Improvement Site Visits will be conducted with 16 additional RWHAP providers to better understand the gaps and challenges to providing RWHAP care to youth, share best practices and lessons learned from other providers, and provide action-oriented TA to overcome barriers and improve outcomes along the HIV care continuum. Youth consultants will co-lead a panel/advisory board of young people living with HIV and a planning session to better understand technical assistance implementation issues.

Sampled providers will be selected based on viral load suppression and retention in care rates and the diversity of client populations, as identified in 2014 Ryan White HIV/AIDS Services Report data.

Likely Respondents: Clinics funded by the Ryan White HIV/AIDS Program.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden

[1] Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2014. *http://hab.hrsa.gov/data/servicesdelivered/2014RWHAPDataReport.pdf.* Published December 2015. Accessed 1/29/2016.

[2] Centers for Disease Control and Prevention, ''Diagnoses of HIV Infection in the United States and Dependent Areas, 2014,'' HIV Surveillance Supplemental Report; Vol 26, November 2015, *http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf.*

[3] ''HIV/AIDS Care Continuum,'' accessed January 26, 2016, *https://www.aids.gov/federal-resources/policies/care-continuum/.*

[4] Centers for Disease Control and Prevention, ''HIV Among Youth,'' *HIV Among Youth,* June 30, 2015, *http://www.cdc.gov/hiv/group/age/youth/index.html.*

[5] ''Youth and Young Adults in the Ryan White HIV/AIDS Program,'' September 2015, *http://hab.hrsa.gov/data/reports/youthdatareport2015.pdf.*

hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden—523.

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (hours)	Total burden hours
Online questionnaire	26	1	26	0.5	13
Onsite Observational Tool	26	1	26	0.5	13
Program Manager and Clinical Director Interview Guide (Specialized)	20	1	20	1.5	30
Program Manager and Clinical Director Interview Guide (Performance Improvement)	32	1	32	1.5	48
Program and Administrative Staff Interview Guide (Specialized)	50	1	50	1	50
Program and Administrative Staff Interview Guide (Performance Improvement)	80	1	80	1	80
Youth Focus Group	156	1	156	1	156
Youth Interview	26	1	26	0.5	13
Panel/advisory board of young people living with HIV (Performance Improvement)	80	1	80	1.5	120
Total	496	.....	496	.....	523

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–19931 Filed 8–19–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Data Collection Tool for State Offices of Rural Health Grant Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 21, 2016.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Data Collection Tool for State Offices of Rural Health Grant Program

OMB No. 0915–0322—Extension

Abstract: The mission of the Federal Office of Rural Health Policy (FORHP) is to sustain and improve access to quality care services for rural communities. In its authorizing language (Section 711 of the Social Security Act *[42 U.S.C. 912]),* Congress charged FORHP with administering grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas. In accordance with the Public Health Service Act, Section 338J (42 U.S.C. 254r), HRSA proposes to continue the State Offices of Rural Health (SORH) Grant Program—Funding Opportunity Announcement (FOA) and Forms for the Application. The FOA is used by 50 states in preparing applications for grants under the SORH Grant Program of the Public Health Service Act, and in preparing the required report.

Need and Proposed Use of the Information: FORHP seeks to continue gathering information from grantees on their efforts to provide technical assistance to clients within their states. SORH grantees submit a Technical Assistance Report that includes: (1) The total number of technical assistance encounters provided directly by the grantee; and (2) the total number of unduplicated clients that received direct technical assistance from the grantee. The Technical Assistance Report is submitted via the HRSA Electronic Handbook no later than 30 days after the end of each 12-month budget period.

A 60-day Federal Register Notice was published in the **Federal Register** on June 22, 2016 (81 FR 40704). There were no public comments.

Likely Respondents: Fifty State Offices of Rural Health.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Technical Assistance Report	50	1	50	12.5	625
Total	50		50		625

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–19924 Filed 8–19–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From Area IV of the Santa Susana Field Laboratory in California, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: NIOSH gives notice of a decision to evaluate a petition to designate a class of employees from Area IV of the Santa Susana Field Laboratory in California, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

SUPPLEMENTARY INFORMATION:

Authority: 42 CFR 83.9–83.12. Pursuant to 42 CFR 83.12, the initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Area IV of the Santa Susana Field Laboratory.

Location: California.

Job Titles and/or Job Duties: ''All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked in any area of Area IV of the Santa Susana Field Laboratory from January 1, 1965 through December 31, 1988, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.''

Period of Employment: January 1, 1965 through December 31, 1988.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2016–19198 Filed 8–19–16; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. A portion of this meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review and discussion of grant applications. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

Name of Committee: National Advisory Child Health and Human Development Council.

Date: September 21, 2016.

Open: September 21, 2016.

Time: 8:00 a.m. to 12:30 p.m.

Agenda: The agenda will include opening remarks, administrative matters, Director's Report, Division of Extramural Research Report and, other business of the Council.

Place: National Institutes of Health, Building 31, C-Wing, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

Closed: September 21, 2016.

Time: 1:30 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C-Wing, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Della Hann, Ph.D., Director, Division of Extramural Research, *Eunice Kenney Shriver* National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Room 2314, MSC 7002, Bethesda, MD 20892, (301) 496–8535.

Any interested person may file written comments with the committee by forwarding the statement to the contact person listed on this notice. The statement should include the name, address, telephone number, and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

In order to facilitate public attendance at the open session of Council in the main meeting room, Conference Room 6, please contact Ms. Lisa Kaeser, Program and Public Liaison Office, NICHD, at 301–496–0536 to make your reservation, additional seating will be available in the meeting overflow rooms, Conference Rooms 7 and 8. Individuals will also be able to view the meeting via NIH Videocast. Please go to the following link for Videocast access instructions at: *http://www.nichd.nih.gov/about/advisory/nachhd/Pages/virtual-meeting.aspx.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS).

Dated: August 16, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19883 Filed 8–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Reproductive Health Epidemiology.

Date: September 1, 2016.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Valerie Durrant, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, (301) 827–6390, *durrantv@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 16, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19884 Filed 8–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Sickle Cell Disease Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Sickle Cell Disease Advisory Committee.

Date: September 23, 2016.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: Discussion of Programs.

Place: National Institutes of Health, 6701 Rockledge Drive, 9th Floor, Room 9112/9116, Bethesda, MD 20892.

Contact Person: W. Keith Hoots, MD, Director, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Suite 9030, Bethesda, MD 20892, 301–435–0080, *hootswk@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 16, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19881 Filed 8–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Center for Scientific Review Advisory Council.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Center for Scientific Review Advisory Council.

Date: September 26, 2016.

Time: 8:30 a.m. to 3:30 p.m.

Agenda: Provide advice to the Director, Center for Scientific Review (CSR), on matters related to planning, execution, conduct, support, review, evaluation, and receipt and referral of grant applications at CSR.

Place: Bethesda Marriott, Congressional Ballroom, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Rene Etcheberrigaray, MD, Deputy Director, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3030, MSC 7776, Bethesda, MD 20892, (301) 435–1111, *etcheber@csr.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://public.csr.nih.gov/aboutcsr/CSROrganization/Pages/CSRAC.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 16, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19886 Filed 8–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Genetic Basis of Monogenic Diseases.

Date: September 15, 2016.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michael P. Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room

7200, Bethesda, MD 20892, 301–496–9659, *reillymp@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 16, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19882 Filed 8–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Materials To Support NIH Serving as an Institutional Review Board (IRB) of Record or a Single IRB for Outside Institutions

SUMMARY: To provide the opportunity for public comment on proposed data collection projects, the Office of Human Subjects Research Protections (OHSRP), Office of the Director, National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received with 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Julia Slutsman, Health Science Policy Analyst, Office of Human Subjects Research Protections (OHSRP), IRP, OD, NIH, Building 10, Room 1C154, 10 Center Drive, Bethesda, MD 20892, or call non-toll-free number (301) 402–3444 or Email your request, including your address to: *PHERRB@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: In compliance with the requirement of Section 350(c)(2)(A) of the Paperwork Reduction Act of 1995, written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

PROPOSED COLLECTION: Materials to support the NIH Serving As an Institutional Review Board (IRB) of Record or a Single IRB for Outside Institutions, 0925—New, Office of Human Subjects Research Protections (OHSRP), Office of the Director, National Institutes of Health (NIH).

Need and Use of Information Collection: The NIH Human Research Protections Program (HRPP) is preparing to implement the recent ''NIH Policy on the Use of a Single Institutional Review Board (sIRB) of Record for Multi-Site Research,'' which requires the use of a single IRB of record for human subject protections review of certain multisite studies. Additionally, the NIH and HHS have recently established the Public Health Emergency Research Review Board (PHERRB) mechanism, for human subject protections review of certain—typically multi-site—public health emergency research studies. Any of the 12 NIH intramural IRBs can be designated to serve as the PHERRB for review of a public health emergency research protocol. Finally, proposed changes to federal human subject protections regulations, if finalized, will require the use of single IRB review for the majority of HHS funded, multi-site studies.

To meet all of these needs, and support efficient single IRB review, researchers at outside institutions will need to provide information to the NIH HRPP, which includes the NIH intramural IRBs, using materials developed by the NIH Office of Human Subject Protections. The required materials which include: The Application for PHERRB Review (APR); the Initial Review Local Context Worksheet (IRLCW); and the Continuing Review Local Context Worksheet (CRLCW). This information collection is intended to provide the NIH HRPP and the NIH IRBs with information necessary for the NIH to maintain regulatory compliance in its conduct of human subject protections review when an NIH IRB serves an IRB of record for multi-site research and to provide high quality and timely human subject protections reviews.

When an NIH IRB serves as the PHERRB, investigators seeking PHERRB human subject protections review will need to submit their request using the ''Application for PHERRB Review (APR).'' This application will be used to collect information to allow the NIH to evaluate public health emergency research protocol submissions' suitability for review by the PHERRB. The form will collect the investigator's name, work address, phone, fax and email, the curriculum vitae of the principal investigator and all co-investigators on the research study, and a detailed description of the proposed research study including the funding source for the study. The APR will facilitate the timely review of public health emergency protocols for human subjects protections review by the PHERRB for protocols meeting PHERRB review eligibility criteria.

As part of meeting regulatory requirements for IRB review of protocols and ensuring the welfare and safety of human subjects, IRBs need to consider local context considerations, that is the sum of state and local laws related to the conduct of human subjects research, relevant institutional policies and resources, research team qualifications and contextual considerations particular to the site where research is taking place. When an NIH IRB serves as the IRB of record for institutions participating in a multisite study, it is necessary for IRBS to have a systematic way of collecting information about local context.

To facilitate local context information collection, the NIH has developed two forms: The Initial Review Local Context Worksheet (IRLCW) and the Continuing Review Local Context Worksheet (CRLCW). The IRLCW will be submitted by investigators at each institution participating in a multi-site study for which an NIH IRB is the IRB of record at the time of submission of the research protocol. The CRLCW will be submitted at the time of continuing review of the protocol. These forms asks principal investigators to PIs to provide their name and the name of the institution with which they are affiliated, as well as names of regulatory points of contact and information about institutional policies and state and local laws on issues related to informed consent, legally authorized representative designation procedures and other relevant laws. This data collection is authorized pursuant to sections 301, 307, 465, and 478A of the Public Health Service Act [42 U.S.C. 241, 242l, 286

and 286d]. OHSRP has as part of its mission a commitment to provide high quality human subject protections review to all research reviewed by NIH IRBs.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annual burden hours are 790.

ESTIMATED ANNUALIZED BURDEN HOURS

Data collection activity	Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average time per response (in hours)	Estimated total annual burden hours
APR	Principal Investigator (M.D. or Ph.D.)	20	1	2	40
IRLCW	Principal Investigator (M.D. or Ph.D. degree) or Research Coordinator (RN, BA, MA degree) or Regulatory Staff (BA degree).	250	1	2	500
CRLCW	Principal Investigator (M.D. or Ph.D. degree) or Research Coordinator (RN, BA, MA degree) or Regulatory Staff (BA degree).	250	1	1	250
Total		520	520		790

Dated: August 13, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–19829 Filed 8–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–15–276: Turkey-US Collaborative Program for Affordable Medical Technologies (R01).

Date: September 16, 2016.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@csr.nih.gov*.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Lung Injury, Repair, and Remodeling Study Section.

Date: September 19–20, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, 240–498–7546, *diramig@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 16, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19885 Filed 8–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; A National Survey of Nurse Coaches (CC)

SUMMARY: To provide opportunity for public comment on proposed data collection projects, the National Institutes of Health Clinical Center (CC) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Alyson Ross, Nurse Researcher, Department of Nursing Research and Translational Science, NIH Clinical Center, Building 10, Room 2B07, MSC–1151, Bethesda, Maryland, 20892 or call non-toll-free number (301) 451–8338 or Email your request, including your address to: *Alyson.ross@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology.

Proposed Collection: Title: A National Survey of Nurse Coaches, 0925—NEW, National Institutes of Health Clinical Center (CC), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this survey is to describe the role of Certified Nurse Coaches in order to gain insight into their clinical practice including: The settings in which they work, the types of clients/health conditions they see, the types of client records maintained and outcomes followed, as well as the personal benefits experienced by nurse coaches as a result of becoming a nurse coach. It provides information regarding two areas of interest to the CC Department of Nursing Research and Translational Science: The collection of patient-reported outcomes in novel clinical practice areas and the physical and psychosocial benefits of an intervention in nurses, a professional caregiver population. This study will provide preliminary data and guidance in: 1. Developing recommendations for collecting outcomes to longitudinally assess the effectiveness nurse coaching, and 2. developing an intervention to improve patient care targeting the nursing staff at the NIH Clinical Center.

OMB approval is requested for 1 year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 104.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Certified nurse coaches	250	1	25/60	104
Total	250	250		104

Dated: August 15, 2016.

Laura M. Lee,

Project Clearance Liaison, NIH Clinical Center, National Institutes of Health.

[FR Doc. 2016–19823 Filed 8–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Pretesting of Substance Abuse Prevention and Treatment and Mental Health Services Communication Messages—(OMB No. 0930–0196)—Extension

As the Federal agency responsible for developing and disseminating authoritative knowledge about substance abuse prevention, addiction treatment, and mental health services and for mobilizing consumer support and increasing public understanding to overcome the stigma attached to addiction and mental illness, the Substance Abuse and Mental Health Services Administration (SAMHSA) is responsible for development and dissemination of a wide range of education and information materials for both the general public and the professional communities. This submission is for generic approval and will provide for formative and qualitative evaluation activities to (1) assess audience knowledge, attitudes, behavior and other characteristics for the planning and development of messages, communication strategies and public information programs; and (2) test these messages, strategies and program components in developmental form to assess audience comprehension, reactions and perceptions. Information obtained from testing can then be used to improve materials and strategies while revisions are still affordable and possible. The annual burden associated with these activities is summarized below.

Activity	Number of respondents	Responses/ respondent	Hours per response	Total hours
Individual In-depth Interviews:				
General Public	400	1	.75	300
Service Providers	200	1	.75	150
Focus Group Interviews:				
General Public	3,000	1	1.5	4,500
Service Providers	1,500	1	1.5	2,250
Telephone Interviews:				
General Public	335	1	.08	27
Service Providers	165	1	.08	13
Self-Administered Questionnaires:				
General Public	2,680	1	.25	670
Service Providers	1,320	1	.25	330
Gatekeeper Reviews:				
General Public	1,200	1	.50	600
Service Providers	900	1	.50	450
Total	11,700			9,290

Written comments and recommendations concerning the proposed information collection should be sent by September 21, 2016 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov*. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2016–19959 Filed 8–19–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Addiction Technology Transfer Centers (ATTC) Network Program Monitoring (OMB No. 0930–0216)—Extension

The Substance Abuse and Mental Health Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) will continue to monitor program performance of its Addiction Technology Transfer Centers (ATTCs). The ATTCs disseminate current health services research from the National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, National Institute of Mental Health, Agency for Health Care Policy and Research, National Institute of Justice, and other sources, as well as other SAMHSA programs. To accomplish this, the ATTCs develop and update state-of-the-art, research-based curricula and professional development training.

CSAT monitors the performance of ATTC events. The ATTCs hold three types of events: Technical assistance events, meetings, and trainings. An ATTC technical assistance event is defined as a jointly planned consultation generally involving a series of contacts between the ATTC and an outside organization/institution during which the ATTC provides expertise and gives direction toward resolving a problem or improving conditions. An ATTC meeting is defined as an ATTC sponsored or co-sponsored events in which a group of people representing one or more agencies other than the ATTC work cooperatively on a project, problem, and/or a policy. An ATTC training is defined as an ATTC sponsored or co-sponsored event of at least three hours that focuses on the enhancement of knowledge and/or skills. Higher education classes are included in this definition with each course considered as one training event.

CSAT currently uses seven (7) instruments to monitor the performance and improve the quality of ATTC events. Two (2) of these forms, the Meeting Follow-up Form and the Technical Assistance Follow-up Form, are currently approved by the Office of Management and Budget (OMB) through approval for CSAT Government Performance and Results Act (GPRA) Customer Satisfaction instruments (OMB No. 0930–0197). CSAT is not seeking any action related to these two forms at this time. They are merely referenced here to provide clarity and context to the description of the forms CSAT uses to monitor the performance of the ATTCs.

The remaining five (5) instruments for program monitoring and quality improvement of ATTC events are currently approved by the OMB (OMB No. 0930–0216) for use through April 30, 2013. These five forms are as follows: Event Description Form; Training Post Event Form; Training Follow-up Form; Meeting Post Event Form; and Technical Assistance Post Event Form. Sixty percent of the forms are administered in person to participants at educational and training events, who complete the forms by paper and pencil. Ten percent of the training courses are online, and thus, those forms are administered online. The remaining thirty percent is made up of 30-day follow-up forms that are distributed to consenting participants via electronic mail using an online survey tool. At this time, CSAT is requesting approval to extend the use of these five forms as is, with no revisions. A description of each of these forms follows.

(1) Event Description Form (EDF). The EDF collects descriptive information about each of the events of the ATTC Network. This instrument asks approximately 10 questions of ATTC faculty/staff relating to the event focus and format, as well as publications to be used during the event. It allows the ATTC Network and CSAT to track the number and types of events held. There are no revisions to the form. CSAT is proposing to continue to use the form as is.

(2) Training Post Event Form. This form is distributed to training participants at the end of the training activity, and collected from them before they leave. For training events which take place over an extended period of time, this form is completed after the final session of training. The form asks approximately 30 questions of each individual that participated in the training. Training participants are asked to report demographic information, education, profession, field of study, status of certification or licensure, workplace role, employment setting, satisfaction with the quality of the training and training materials, and to assess their level of skills in the topic area. There are no revisions to the form. CSAT is proposing to continue to use the form as is.

(3) Training Follow-up Form. The Training Follow-up form, which is administered 30-days after the event to 25% of consenting participants, asks about 25 questions. The form asks participants to report demographic information, satisfaction with the quality of the training and training materials, and to assess their level of skills in the topic area. No revisions are being made to the form. CSAT is proposing to continue to use the form as is.

(4) Meeting Post Event Form. This form is distributed to meeting participants at the end of the meeting, and collected from them before they leave. This form asks approximately 30 questions of each individual that participated in the meeting. Meeting participants are asked to report demographic information, education, profession, field of study, status of certification or licensure, workplace role, employment setting, and satisfaction with the quality of the event and event materials, and to assess their level of skills in the topic area. No revisions are being made to the form. CSAT is proposing to continue to use the form as is.

(5) Technical Assistance (TA) Post Event form. This form is distributed to technical assistance participants at the end of the TA event. This form asks approximately 30 questions of each individual that participated in the TA event. TA participants are asked to report demographic information, education, profession, field of study, status of certification or licensure, workplace role, employment setting, and satisfaction with the quality of the event and event materials, and to assess their level of skills in the topic area. No revisions are being made to the form. CSAT is proposing to continue to use the form as is.

The information collected on the ATTC forms will assist CSAT in documenting the numbers and types of participants in ATTC events, describing the extent to which participants report improvement in their clinical competency, and which method is most effective in disseminating knowledge to various audiences. This type of information is crucial to support CSAT in complying with GPRA reporting requirements and will inform future development of knowledge dissemination activities.

The chart below summarizes the annualized burden for this project.

Type of respondent	Number of respondents	Responses per respondent	Total responses	Hours per response	Total annual burden hours	Hourly wage cost	Total hour cost
ATTC Faculty/Staff: Event Description Form	250	1	250	.25	62.50	$20.64	$1,290
Meeting and Technical Assistance Participants: Post-Event Form	5,000	1	5,000	.12	600	20.64	12,384
Follow-up Form	Covered under CSAT Government Performance and Results Act (GPRA) Customer Satisfaction form (OMB # 0930–0197)						
Training Participants: Post-Event Form	30,000	1	30,000	.16	4,800	20.64	99,072
Follow-up Form	7,500	1	7,500	.16	1,200	20.64	24,768
Total	42,750		42,750		6,662.50		137,514

Written comments and recommendations concerning the proposed information collection should be sent by September 21, 2016 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2016–19926 Filed 8–19–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) National Advisory Council will meet on August 23, 2016, 4:30 p.m.–5:00 p.m., in Rockville, MD.

The meeting will include the review, discussion, and evaluation of grant applications reviewed by the Initial Review Group, and involve an examination of confidential financial and business information as well as personal information concerning the applicants. Therefore, these meetings will be closed to the public as determined by the SAMHSA Administrator, in accordance with Title 5 U.S.C. 552b(c)(4) and (c)(6); and 5 U.S.C. App. 2, Section 10(d).

This notice is published less than 15 days prior to the start of the announced meeting, in accordance with 41 CFR 102–3.150(b), in order to enable the review of an additional Strategic Prevention Framework Partnerships for Success grant application, and applications for SAMSHA's Tribal Behavioral Health Grants program. These grant applications were not ready for discussion during the July 25th NAC Review, and both grant programs use Fiscal Year 2016 annual appropriations. Therefore, it is necessary to review these grant programs as soon as possible so that SAMSHA can award grant funds to successful applicants prior to the end of the Fiscal Year.

Committee name: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention National Advisory Council.

Date/time/type: August 23, 2016, 4:30 p.m.–5:00 p.m. (CLOSED).

Place: SAMHSA Building, 5600 Fishers Lane, Rockville, MD 20857.

Contact: Matthew J. Aumen, Designated Federal Officer, SAMHSA/CSAP National Advisory Council, 5600 Fishers Lane, Rockville, MD 20857, Email: *Matthew.Aumen@samhsa.hhs.gov.*

Charles LoDico,

Senior Chemist/Toxicologist, SAMHSA.

[FR Doc. 2016–19989 Filed 8–19–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Registration for Behavioral Health Web Site and Resources (OMB No. 0930–0313)—Extension

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting OMB approval for an extension to the Behavioral Health Web site and Resources data collection. SAMHSA is authorized under section 501(d)(16) of the Public Health Service Act (42 U.S.C. 290aa(d)(16)) to develop and distribute materials for the prevention, treatment, and recovery from substance abuse and mental health disorders. To improve customer service and lessen the burden on the public to locate and obtain these materials, SAMHSA has developed a Web site that includes more than 1,400 free publications from SAMHSA and its component Agencies: The Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, the Center for Mental Health Services, the Center for Behavioral Health Statistics and Quality, and other SAMHSA partners, such as the Office of National Drug Control Policy. These products are available to the public for ordering and download. When a member of the public chooses to order hard-copy publications, it is necessary for SAMHSA to collect certain customer information in order to fulfill the request. To further lessen the burden on the public and provide the level of customer service that the public has come to expect from product Web sites, SAMHSA has developed a voluntary registration process for its publication Web site that allows customers to create accounts. Through these accounts, SAMHSA customers are able to access their order histories and save their shipping addresses. This reduces the burden on customers of having to re-identify materials they ordered in the past and to re-enter their shipping information each time they place an order with SAMHSA. During the Web site registration process, SAMHSA also asks customers to provide optional demographic information that helps SAMHSA evaluate the use and distribution of its publications and improve services to the public.

SAMHSA is employing a web-based form for information collection to avoid duplication and unnecessary burden on customers who register both for an account on the product Web site and for email updates. The Web technology allows SAMHSA to integrate the email update subscription process into the Web site account registration process. Customers who register for an account on the product Web site are given the option of being enrolled automatically to receive SAMHSA email updates. Any optional questions answered by the customer during the Web site registration process automatically are mapped to the profile generated for the email update system, thereby reducing the collection of duplicate information.

SAMHSA collects all customer information submitted for Web site registration and email update subscriptions electronically via a series of Web forms on the *samhsa.gov* domain. Customers can submit the Web forms at their leisure, or call SAMHSA's toll-free Call Center and an information specialist will submit the forms on their behalf. The electronic collection of information reduces the burden on the respondent and streamlines the data-capturing process. SAMHSA places Web site registration information into a Knowledge Management database and places email subscription information into a database maintained by a third-party vendor that serves multiple Federal agencies and the White House. Customers can change, add, or delete their information from either system at any time.

The respondents are behavioral health professionals, researchers, parents, caregivers, and the general public.

There are no changes to the burden or the forms.

SAMHSA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Web site Registration	38,605	1	38,605	.033 (2 min.)	1,286
Email Update Subscription	21,138	1	21,138	.017 (1 min.)	359
Total	59,743		59,743		1,645

Written comments and recommendations concerning the proposed information collection should be sent by September 21, 2016 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2016–19927 Filed 8–19–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C.

Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: SAMHSA Application for Peer Grant Reviewers (OMB No. 0930–0255)—Extension

Section 501(h) of the Public Health Service (PHS) Act (42 U.S.C. 290aa) directs the Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA) to establish such peer review groups as are needed to carry out the requirements of Title V of the PHS Act. SAMHSA administers a large discretionary grants program under authorization of Title V, and, for many years, SAMHSA has funded grants to provide prevention and treatment services related to substance abuse and mental health.

In support of its grant peer review efforts, SAMHSA desires to continue to expand the number and types of reviewers it uses on these grant review committees. To accomplish that end, SAMHSA has determined that it is important to proactively seek the inclusion of new and qualified representatives on its peer review groups. Accordingly SAMHSA has developed an application form for use by individuals who wish to apply to serve as peer reviewers.

The application form has been developed to capture the essential information about the individual applicants. Although consideration was given to requesting a resume from interested individuals, it is essential to have specific information from all applicants about their qualifications. The most consistent method to accomplish this is through completion of a standard form by all interested persons which captures information about knowledge, education, and experience in a consistent manner from all interested applicants. SAMHSA will use the information provided on the applications to identify appropriate peer grant reviewers. Depending on their experience and qualifications, applicants may be invited to serve as either grant reviewers or review group chairpersons.

The following table shows the annual response burden estimate.

Number of respondents	Responses/respondent	Burden/responses (hours)	Total burden hours
500	1	1.5	750

Written comments and recommendations concerning the proposed information collection should be sent by September 21, 2016 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2016–19960 Filed 8–19–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of October 6, 2016 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: August 3, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Henry County, Georgia, and Incorporated Areas Docket No.: FEMA–B–1521	
City of Hampton	City Hall, 17 East Main Street South, Hampton, GA 30228.
City of Locust Grove	City Hall, 3644 Highway 42, Locust Grove, GA 30248.
City of McDonough	City Hall, 136 Keys Ferry Street, McDonough, GA 30253.
City of Stockbridge	City Hall, 4640 North Henry Boulevard, Stockbridge, GA 30281.
Unincorporated Areas of Henry County	Henry County Courthouse, 140 Henry Parkway, McDonough, GA 30253.

[FR Doc. 2016–19909 Filed 8–19–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of August 3, 2016 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: August 3, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Non-watershed-based studies:

Community	Community map repository address
Napa County, California, and Incorporated Areas Docket No.: FEMA–B–1502	
City of American Canyon	Community Development Department, 4381 Broadway Street, Suite 201, American Canyon, CA 94503.
City of Napa	Public Works Department, 1600 1st Street, Napa, CA 94559.
Unincorporated Areas of Napa County	Public Works Department, 1195 3rd Street, Suite 201, Napa, CA 94559.

Community	Community map repository address
Solano County, California, and Incorporated Areas Docket No.: FEMA–B–1502	
City of Benicia	Public Works Division, 250 East L Street, Benicia, CA 94510.
City of Fairfield	Public Works, Engineering Division, 1000 Webster Street, Fairfield, CA 94533.
City of Suisun City	Public Works Department, 701 Civic Center Boulevard, Suisun City, CA 94585.
City of Vallejo	Public Works, 555 Santa Clara Street, Vallejo, CA 94590.
Unincorporated Areas of Solano County	Public Works Department, 675 Texas Street, Suite 5500, Fairfield, CA 94553.
Saunders County, Nebraska, and Incorporated Areas Docket No.: FEMA–B–1511	
City of Wahoo	City Hall, 605 North Broadway Street, Wahoo, NE 68066.
Unincorporated Areas of Saunders County	Saunders County Courthouse, 433 North Chestnut Street, Wahoo, NE 68066.

[FR Doc. 2016–19907 Filed 8–19–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2016–0020; OMB No. 1660–0113]

Agency Information Collection Activities: Proposed Collection; Comment Request; FEMA Preparedness Grants: Tribal Homeland Security Grant Program (THSGP).

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the FEMA Preparedness Grants: Tribal Homeland Security Grant Program (THSGP). The THSGP investment justification allows Native American Indian Tribes to apply for Federal funding to support efforts to build and sustain core capabilities across the Prevention, Protection, Mitigation, Response, and Recovery mission areas to protect the homeland.

DATES: Comments must be submitted on or before October 21, 2016.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2016–0020. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW., 8NE, Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Cornelius Jackson, Program Analyst, DHS FEMA, Grant Programs Directorate, (202) 786–9508. You may contact the Records Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the THSGP to make grants available to Federally-recognized ''directly eligible tribes'' to provide tribes with the ability to develop and deliver core capabilities using the combined efforts of the whole community, rather than the exclusive effort of any single organization or level of government. The THSGP's allowable costs support efforts of tribes to build and sustain core capabilities across the prevention, protection, mitigation, response, and recovery mission areas. The THSGP also plays an important role in the implementation of the National Preparedness System by supporting the building, sustainment, and delivery of core capabilities essential to achieving DHS FEMA's National Preparedness Goal of a secure and resilient Nation. Federally-recognized tribes are those tribes appearing on the list published by the Secretary of the Interior pursuant to the Federally Recognized Indian Tribe List Act of 1994 (Pub. L. 103–454) (25 U.S.C. 479a–1). ''Directly eligible tribes'' are defined in Section 2001 of the Homeland Security Act of 2002, as amended (Pub. L. 107–296) (6 U.S.C. 601).

Collection of Information

Title: FEMA Preparedness Grants: Tribal Homeland Security Grant Program (THSGP).

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0113.

FEMA Forms: FEMA Form 089–22, THSGP—Tribal Investment Justification Template.

Abstract: The THSGP provides supplemental funding to directly eligible Tribes to help strengthen the nation against risks associated with potential terrorist attacks. This program provides funds to build capabilities at the State & local levels and implement goals and objectives included in state homeland security strategies.

Affected Public: State, Local, or Tribal Government.

Number of Respondents: 60.

Number of Responses: 60.

Estimated Total Annual Burden Hours: 18,010 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $701,129.30. There are no annual

costs to respondents operations and maintenance costs for technical services. There is no annual start-up or capital costs. The cost to the Federal Government is $399,576.50.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Dated: August 11, 2016.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–19892 Filed 8–19–16; 8:45 am]

BILLING CODE 9111–46–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1638]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before November 21, 2016.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1638, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: August 3, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Watershed-based studies:

Community	Community map repository address
Lower Kentucky Watershed	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Anderson County, Kentucky and Incorporated Areas	
City of Lawrenceburg	City Hall, 100 North Main Street, Lawrenceburg, KY 40342.
Unincorporated Areas of Anderson County	Anderson County Planning and Zoning Office, 139 South Main Street, Lawrenceburg, KY 40342.
Carroll County, Kentucky and Incorporated Areas	
City of Carrollton	Carroll County Emergency Operations Center, 829 Polk Street, Carrollton, KY 41008.
City of Prestonville	Carroll County Emergency Operations Center, 829 Polk Street, Carrollton, KY 41008.
City of Worthville	Carroll County Emergency Operations Center, 829 Polk Street, Carrollton, KY 41008.
Unincorporated Areas of Carroll County	Carroll County Emergency Operations Center, 829 Polk Street, Carrollton, KY 41008.
Clark County, Kentucky and Incorporated Areas	
Unincorporated Areas of Clark County	Clark County Courthouse, 34 South Main Street, Winchester, KY 40391.
Franklin County, Kentucky and Incorporated Areas	
City of Frankfort	Planning and Building Codes Department, 315 West Second Street, Frankfort, KY 40601.
Unincorporated Areas of Franklin County	Franklin County Fiscal Court, 321 West Main Street, Frankfort, KY 40601.
Garrard County, Kentucky and Incorporated Areas	
Unincorporated Areas of Garrard County	Garrard County Courthouse, 15 Public Square, Lancaster, KY 40444.
Henry County, Kentucky and Incorporated Areas	
Unincorporated Areas of Henry County	Henry County Courthouse Annex, 19 South Property Road, New Castle, KY 40050.
Jessamine County, Kentucky and Incorporated Areas	
City of Nicholasville	City Hall, 517 North Main Street, Nicholasville, KY 40356.
City of Wilmore	City Hall, 335 East Main Street, Wilmore, KY 40390.
Unincorporated Areas of Jessamine County	Jessamine County Courthouse, 101 North Main Street, Nicholasville, KY 40356.
Lexington-Fayette Urban County Government, Kentucky (All Jurisdictions)	
Lexington-Fayette Urban County Government	Lexington-Fayette Urban County Government Center, 200 East Main Street, 12th Floor, Lexington, KY 40507.
Madison County, Kentucky and Incorporated Areas	
City of Berea	City Hall, 212 Chestnut Street, Berea, KY 40403.
City of Richmond	City Hall, 239 West Main Street, Richmond, KY 40475.
Unincorporated Areas of Madison County	Madison County Courthouse, 101 West Main Street, Richmond, KY 40475.
Mercer County, Kentucky and Incorporated Areas	
Unincorporated Areas of Mercer County	The Greater Harrodsburg/Mercer County Planning and Zoning Commission, 109 Short Street, Harrodsburg, KY 40330.
Owen County, Kentucky and Incorporated Areas	
City of Gratz	City Hall, 583 Crittenden Street, Gratz, KY 40359.
City of Monterey	City Hall, 35 Worth Street, Monterey, KY 40359.
Unincorporated Areas of Owen County	Owen County Courthouse, 100 North Thomas Street, Owenton, KY 40359.

Community	Community map repository address
Scott County, Kentucky and Incorporated Areas	
City of Georgetown	Georgetown-Scott County Planning Commission, 230 East Main Street, Georgetown, KY 40324.
Unincorporated Areas of Scott County	Georgetown-Scott County Planning Commission, 230 East Main Street, Georgetown, KY 40324.
Woodford County, Kentucky and Incorporated Areas	
City of Midway	City Hall, 101 East Main Street, Midway, KY 40347.
City of Versailles	City Hall, 196 South Main Street, Versailles, KY 40383.
Unincorporated Areas of Woodford County	Woodford County Courthouse, 103 South Main Street, Versailles, KY 40383.
Lower North Canadian Watershed	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Lincoln County, Oklahoma and Incorporated Areas	
Kickapoo Tribe of Oklahoma	Kickapoo Tribe of Oklahoma, Secondary Administration Building, 400 North Highway 102, McLoud, OK 74851.
Unincorporated Areas of Lincoln County	Lincoln County Courthouse, 811 Manvel Avenue, Suite 4, Chandler, OK 74834.

II. Non-watershed-based studies:

Community	Community map repository address
Arapahoe County, Colorado and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–08–1412S Preliminary Date: March 10, 2016	
City of Littleton	Public Works Department, 2255 West Berry Avenue, Littleton, CO 80120.
Town of Columbine Valley	Town Hall, 2 Middlefield Road, Columbine Valley, CO 80123.
Unincorporated Areas of Arapahoe County	Arapahoe County Public Works and Development Department, 6924 South Lima Street, Centennial, CO 80112.
City and County of Denver, Colorado	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–08–1412S Preliminary Date: March 10, 2016	
City and County of Denver	Public Works Department, 201 West Colfax Avenue, Department 507, Denver, CO 80202.
Morgan County, Utah and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 12–08–0134S Preliminary Date: March 25, 2016	
City of Morgan City	Building Department, 90 West Young Street, Morgan City, UT 84050.
Unincorporated Areas of Morgan County	Morgan County Community Development Department, 48 West Young Street, Morgan City, UT 84050.

[FR Doc. 2016–19905 Filed 8–19–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2016–0021; OMB No. 1660–0110]

Agency Information Collection Activities: Proposed Collection; Comment Request; FEMA Preparedness Grants: Urban Areas Security Initiative (UASI) Nonprofit Security Grant Program (NSGP)

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the information collection activities for the Urban Areas Security Initiative (UASI) Nonprofit Security Grant Program (NSGP).

DATES: Comments must be submitted on or before October 21, 2016.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2016–0021. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW., 8NE, Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Samrawit Aragie, Program Analyst, FEMA, Grant Programs Directorate, Preparedness Grants Division, Program Development and Support Branch at (202) 257–2518. You may contact the Records Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: FEMA's Urban Areas Security Initiative (UASI) Nonprofit Security Grant Program (NSGP) provides funding support for target hardening activities to nonprofit organizations that are determined by the Secretary of Homeland Security to be at high risk of terrorist attack. The collection of information for the UASI Nonprofit Security Grant Program is mandated by section 2003 of the Homeland Security Act of 2002, 6 U.S.C. 604, as amended by section 101, title I of the Implementing Recommendations of the 9/11 Commission Act of 2007, Public Law 110–53.

Collection of Information

Title: FEMA Preparedness Grants: Urban Areas Security Initiative (UASI) Nonprofit Security Grant Program (NSGP).

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0110.

FEMA Forms: FEMA Form 089–25, NSGP Investment Justification Template; FEMA Form 089–24, NSGP Prioritization of the Investment Justifications.

Abstract: The NSGP is an important tool among a comprehensive set of measures to help strengthen the Nation against risks associated with potential terrorist attacks. FEMA uses the information to evaluate applicants' familiarity with the national preparedness architecture and identify how elements of this architecture have been incorporated into regional/state/local planning, operations, and investments. Information collected provides narrative details on proposed activities (Investments) that will be accomplished with grant funds and prioritizes the list of applicants from each requesting State. This program is designed to promote coordination and collaboration in emergency preparedness activities among public and private community representatives, State and local government agencies, and Citizen Corps Councils.

Affected Public: Not-for-profit Institutions; State, Local or Tribal Government.

Number of Respondents: 1,129.

Number of Responses: 1,129.

Estimated Total Annual Burden Hours: 94,575 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $3,380,775. There are no annual costs to respondents operations and maintenance costs for technical services. There is no annual start-up or capital costs. The cost to the Federal Government is $258,006.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Dated: August 11, 2016.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–19893 Filed 8–19–16; 8:45 am]

BILLING CODE 9111–46–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1643]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment

regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before November 21, 2016.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1643, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: August 3, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Non-watershed-based studies:

Community	Community map repository address
Perry County, Indiana and Incorporated Areas	
Maps Available for Inspection Online at: *www.fema.gov/preliminaryfloodhazarddata*	
Project: 12–05–8922S Preliminary Date: December 18, 2015	
City of Tell City	Tell City Planning and Zoning, City Hall, 700 Main Street, Tell City, IN 47586.

[FR Doc. 2016–19906 Filed 8–19–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports

have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of September 30, 2016 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: August 3, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Athens-Clarke County, Georgia (All Jurisdictions) Docket No.: FEMA–B–1523	
Athens-Clarke County	120 West Dougherty Street, Athens, GA 30601.
New Orleans/Orleans Parish, Louisiana Docket No.: FEMA–B–1301	
New Orleans/Orleans Parish	Public Library, Archives Division, 219 Loyola Avenue, 3rd Floor, New Orleans, LA 70112.
Rogers County, Oklahoma, and Incorporated Areas Docket No.: FEMA–B–1521	
City of Catoosa	City Hall, 214 South Cherokee Street, Catoosa, OK 74015.
City of Tulsa	Stormwater Design Office, 2317 South Jackson Street, Suite 302, Tulsa, OK 74103.
Town of Fair Oaks	Robson Ranch Office/Fair Oaks Town Hall, 23515 East 31st Street, Catoosa, OK 74015.
Unincorporated Areas of Rogers County	Rogers County Courthouse, 200 South Lynn Riggs Boulevard, Claremore, OK 74017.
Tulsa County, Oklahoma, and Incorporated Areas Docket No.: FEMA–B–1521	
City of Broken Arrow	Operations Building, 485 North Poplar Avenue, Broken Arrow, OK 74012.
City of Tulsa	Stormwater Design Office, 2317 South Jackson Street, Suite 302, Tulsa, OK 74103.
Unincorporated Areas of Tulsa County	Tulsa County Annex Building, 633 West 3rd Street, Room 140, Tulsa, OK 74127.
Wagoner County, Oklahoma, and Incorporated Areas Docket No.: FEMA–B–1521	
City of Broken Arrow	Operations Building, 485 North Poplar Avenue, Broken Arrow, OK 74012.
City of Catoosa	City Hall, 214 South Cherokee Street, Catoosa, OK 74015.
City of Coweta	City Hall, 310 South Broadway Street, Coweta, OK 74429.
City of Tulsa	Stormwater Design Office, 2317 South Jackson Street, Suite 302, Tulsa, OK 74103.

Community	Community map repository address
Town of Fair Oaks	Robson Ranch Office/Fair Oaks Town Hall, 23515 East 31st Street, Catoosa, OK 74015.
Unincorporated Areas of Wagoner County	Wagoner County Courthouse, 307 East Cherokee Street, Wagoner, OK 74467.

[FR Doc. 2016–19908 Filed 8–19–16; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0018]

FEMA Directive 108–1 and FEMA Instruction 108–1–1

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of availability.

SUMMARY: This document provides notice of availability of final FEMA Directive 108–1 and FEMA Instruction 108–1–1 (referred to as Directive and Instruction). Together, this Directive and Instruction serve as FEMA's supplemental instructions for Environmental Planning and Historic Preservation (EHP), in accordance with the Department of Homeland Security's (DHS) Directive 023–01, Rev. 01 and Instruction Manual 023–01–001–01, Rev. 01, Implementation of the National Environmental Policy Act (NEPA).

DATES: This final Directive and Instruction are effective August 22, 2016.

ADDRESSES: The final Directive and Instruction are available online at *http://www.regulations.gov* (docket ID FEMA–2016–0018) and on FEMA's Web site at *https://www.fema.gov/media-library/assets/documents/118323.* You may also view a hard copy of the final Directive and Instruction at the Office of Chief Counsel, Federal Emergency Management Agency, Room 835, 500 C Street SW., Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Katherine Zeringue, Environmental Officer, Federal Emergency Management Agency, 400 C Street SW., Suite 313, Washington, DC 20472–3020; 202–212–2282, or *Katherine.Zeringue@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: On November 26, 2014, DHS issued revised NEPA implementing procedures, applicable to all DHS components, via Directive 023–01 and Instruction 023–01–001–01, which went into effect on March 26, 2015 (79 FR 70538). The EHP Directive and Instruction operate jointly to constitute FEMA's supplemental EHP procedures in accordance with the DHS Directive and Instruction. The Directive establishes FEMA's policies, roles, responsibilities, and procedures for delegations of authority concerning EHP. The Instruction provides guidance and policy direction for implementation of NEPA and other EHP requirements across FEMA.

The EHP Directive and Instruction replace 44 CFR part 10: Environmental Considerations. The EHP Instruction also replaces the following policy memoranda:

A. Environmental Policy Memo 108.024.2: Other Federal Agency Clearance for Environmental Assessments (December 18, 2013).

B. Environmental Policy Memo 108.024.4: Projects Initiated Without Environmental Review Required by the National Environmental Policy Act (December 18, 2013).

Authority: The Directive and Instruction are consistent with the DHS Directive 023–01 and Instruction 023–01–001–01 for implementation of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), as amended, and the Council on Environmental Quality (CEQ) regulations for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508).

Dated: August 2, 2016.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–19534 Filed 8–19–16; 8:45 am]
BILLING CODE 9110–A6–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1639]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before November 21, 2016.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1639, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at

www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: August 3, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Watershed-based studies:

Community	Community map repository address
Ventura River Watershed	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Ventura County, California and Incorporated Areas	
City of Ojai	Ojai Public Works Department, 408 South Signal Street, Ojai, CA 93023.
City of San Buenaventura	San Buenaventura City Hall, 501 Poli Street, Ventura, CA 93001.
Unincorporated Areas of Ventura County	Ventura County Public Works Agency, 800 South Victoria Avenue, Ventura, CA 93009.

II. Non-watershed-based studies:

Community	Community map repository address
Yavapai County, Arizona and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–09–1692S Preliminary Date: January 29, 2016	
Unincorporated Areas of Yavapai County	Yavapai County Flood Control District Office, 1120 Commerce Drive, Prescott, AZ 86305.

[FR Doc. 2016–19911 Filed 8–19–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5921–N–13]

Implementation of the Privacy Act of 1974, as Amended; Notice To Amend Systems of Records, Integrated Real Estate Management System, Development Application Processing System, Tenant Rental Assistance Certification System

AGENCY: Office of Multifamily Housing, HUD.

ACTION: Notice to amend systems of records.

SUMMARY: In accordance with requirements Privacy Act of 1974, as amended, 5 U.S.C. 552a, the U.S. Department of Housing and Urban Development (HUD), Office of Multifamily Housing gives notice of its intent to amend three system of records notices (SORNS): Integrated Real Estate Management System, published in the **Federal Register** on August 14, 2007 at 72 FR 45442–45443, Development Application Processing System, published in the **Federal Register** on August 1, 2007 at 72 FR 42101–42102, Tenant Housing Assistance and Contract Verification Data, published in the FR on March 13, 1997 62 FR 11909–11910.'' This notice proposal renames the ''Tenant Housing Assistance and Contract Verification Data'' systems of records to ''Tenant Rental Assistance Certification System (TRACS)'', makes administrative updates to the systems of records location, authority, purpose, and records retention statements, refines previously published information about each notice in a clear and easy to read format, and implements a new coding structure to make it easier to differentiate a system of records from other program specific SORNs. A more detailed description of the present systems status is republished under this notice. This notice supersedes and replaces the former notice publications. The amended systems of records and their new/prior coding structures are identified below.

New coding structure	Systems of records name/prior coding structure
1. HSNG.MF/HTS.01	Integrated Real Estate Management System (iREMS) (Previously coded HUD/MFH–10).
2. HSNG.MF.HTS.02	Tenant Rental Assistance Certification System (TRACS) (Previously coded HUD/H–11).
3. HSNG.MF/HTHE.01	Development Application Processing System (DAPS) (Previously coded HUD/MFH–08).

DATES: *Effective Date:* This action will be effective without further notice, August 22, 2016.

Comments Due Date: September 21, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10276, Washington, DC 20410. Communications should refer to the above docket number and title. Faxed comments are not accepted. A copy of each communication submitted will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Helen Goff Foster, Chief Privacy Officer/Senior Agency Official for Privacy, 451 Seventh Street SW., Room 10139, Washington, DC 20410, telephone number 202–402–6836 (this is not a toll-free number). Individuals who are hearing- and speech-impaired may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: This notice satisfies the Privacy Act requirement that an agency must publish a system of records in the **Federal Register** when there are additional changes to a notice. The amended notices are set out in their entirety and described in detail following this section. The amended notices reflect administrative changes, as well as make minor clarification and/or editorial changes to the name and location of the record system, the authority for and manner of its operations, the categories of individuals that it covers, the type of records that it contains, and the records source sections. The notice also includes the current business address of the HUD officials who will inform interested persons of how they may gain access to and/or request amendments to records pertaining to the records themselves. The existing scope, objectives, business processes, and uses being made of the data by the Department for each notice remain unchanged.

Publication of this notice allows the Department to maintain current information about its notices in a clear and cohesive format. The Privacy Act places on Federal agencies principal responsibility for compliance with its provisions, by requiring Federal agencies to safeguard an individual's records against an invasion of personal privacy; protect the records contained in an agency system of records from unauthorized disclosure; ensure that the records collected are relevant, necessary, current, and collected only for their intended use; and adequately safeguard the records to prevent misuse of such information. In addition, this notice demonstrates the Department's focus on industry best practices and laws that protect interest such as personal privacy and privacy protect records from inappropriate release.

Pursuant to the Privacy Act and the Office of Management and Budget (OMB) guidelines, the amended notices do not meet threshold requirements for having to transmit a report to OMB, the Senate Committee on Homeland Security and Governmental Affairs, and the House Committee on Oversight and Government Reform, as instructed by paragraph 4c of Appendix l to OMB Circular No. A–130, ''Federal Agencies Responsibilities for Maintaining Records About Individuals,'' November 28, 2000.

Authority: 5 U.S.C. 552a; 88 Stat. 1896; 42 U.S.C. 3535(d).

Dated: August 16, 2016.

Helen Goff Foster,

Chief Privacy Officer/Senior Agency Official for Privacy.

SYSTEM OF RECORDS NO.:

HSNG.MF/HTS.01.

SYSTEM NAME:

Integrated Real Estate Management System (iREMS)–F24.

SYSTEM LOCATION:

The system is hosted at the HUD data center in Charleston, West Virginia. Users have on-line access to the system at the Department of Housing and Urban Development Headquarters, 451 Seventh Street SW., Washington, DC 20410, HUD Field and Regional Offices,[1] or at the locations of the service providers under contract with HUD.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The categories of individuals covered by the system include external business

[1] *http://portal.hud.gov/hudportal/documents/huddoc?id=append2.pdf.*

partners approved to do Multifamily business with HUD (*e.g.,* property owners, management agents, contract administrators, and owner/agent contacts).

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records in the system include:

(1) Contact Information: Name, home/business address, and home/business telephone number, fax, and email address.

(2) Identification information: Social Security number (SSN) and tax identification number (TIN).

(3) Loan Servicing information: Section 8 subsidy contract renewals, property management reviews, physical condition of multifamily properties and ownership data, workload tracking of HUD staff, Departmental Enforcement Center tracking for corrective actions/referrals, and participant/partner information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Housing Act of 1937 as amended, 42 U.S.C. 1437 *et seq.;* CFR 24 Part 5.216 (c), and 5.216 (e); Housing and Community Development Act, 42 U.S.C § 3543, Section 165.

PURPOSE(S):

iREMS is HUD's multifamily property management tool for the Office of Multifamily Housing (MFH), the Departmental Enforcement Center (DEC), and the Real Estate Assessment Center (REAC). The goal of iREMS is to improve fiscal and regulatory control over HUD's Multifamily housing portfolio, and ensure compliance with HUD program requirements and business agreements. iREMS is the repository of HUD's data that define the portfolio of insured, subsidized, HUD-held, HUD-owned, co-insured, elderly and disabled properties, and provides portfolio management for Section 8 contracts to establish property ownership and management for physical property inspection follow-up, and financial assessment reviews. The data are used for tracking property status, loan status and characteristics, Section 8 contract renewals, and financial status of property owners. iREMS provides REAC with the ability to validate financial statement submissions and mortgagee inspections. iREMS provides DEC and the Office of Affordable Housing Preservation the ability to track corrective action referrals initiated against owners and/or properties not fully complying with HUD requirements (Owners not in full compliance may be subject to enforcement action, including civil money penalties, suspension and/or debarment, and referral to the Department of Justice). When criminal activity is suspected, cases are referred to HUD's Office of the Inspector General for investigation.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside HUD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons to the extent such disclosures are compatible with the purpose for which the records in this system were collected, as set forth by Appendix I [2]—HUD's Routine Uses Inventory Notice published in the **Federal Register**.

2. To appropriate agencies, entities, and persons when:

(a) HUD suspects or has confirmed that the security or confidentiality of information in a system of records has been compromised;

(b) HUD has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of systems or programs (whether maintained by HUD or another agency or entity) that rely upon the compromised information;

(c) HUD has determined that the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HUD's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm for purposes of facilitating responses and remediation efforts in the event of a data breach.

3. To the National Archives and Records Administration (NARA) or to the General Services Administration for records management inspections conducted under 44 U.S.C. § 2904 and 2906.

4. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

5. To the Department of Justice for possible enforcement action against owners or properties not complying with HUD requirements.

6. To HUD business partners (Public Housing Authorities and Community Development Corporations serving as Performance Based Contract Administrators (PBCA)) in order to fulfill their business agreements with HUD (*e.g.,* manage their assigned Section 8 contracts).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored securely electronically or on paper in secure facilities in a locked drawer behind a locked door.

RETRIEVABILITY:

Records are retrieved mainly based on the property identification number or contract ID. However, for participant/partner information and security system access it is possible to locate data via their names and/or taxpayer identification number (TIN).

SAFEGUARDS:

Access to electronic systems is by password and code identification card access and limited to authorized users. Retrievals are only accessible via entry of a valid HUD user id and password. LDAP (light-weight directory access protocol) is used to verify external users—each must be properly registered with HUD and have an LDAP user id/password. When first gaining access to iREMS and on an annual basis, all users must agree to the systems ''Rules of Behavior'' which specify handling of personal information and any physical records.

RETENTION AND DISPOSAL:

Paper records are destroyed by shredding or burning. Backup and Recovery digital media will be destroyed or otherwise rendered irrecoverable per NIST SP 800–88 Revision 1 ''Guidelines for Media Sanitization'' (December 2014). Records and data are retained and disposed of in accordance with the HUD Records Disposition Schedules Handbook (2225.6 Rev-1), as described in Records Disposition Schedule 68, Items 2 and 3.[3]

SYSTEM MANAGER(S) AND ADDRESS:

Director, Program Systems Management Office, Office of Multifamily Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410.

[2] *http://portal.hud.gov/hudportal/documents/huddoc?id=routine_use_inventory.pdf.*

[3] *http://portal.hud.gov/hudportal/documents/huddoc?id=22256x68ADMH.pdf*)

NOTIFICATION AND RECORD ACCESS PROCEDURES:

For information, assistance, or inquiries about the existence of records contact Helen Goff Foster, Chief Privacy Officer/Senior Agency Official for Privacy, 451 Seventh Street SW., Room 10139, Washington, DC 20410, telephone number 202–402–6836. When seeking records about yourself from this system of records or any other HUD system of records, your request must conform with the Privacy Act regulations set forth in 24 CFR part 16. You must first verify your identity by providing your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. In addition, your request should:

(1) Explain why you believe HUD would have information on you.

(2) Identify which HUD office you believe has the records about you.

(3) Specify when you believe the records would have been created.

(4) Provide any other information that will help the Freedom of Information Act (FOIA) staff determine which HUD office may have responsive records.

If you are seeking records pertaining to another living individual, you must obtain a statement from that individual certifying their agreement for you to access their records. Without the above information, the HUD FOIA Office may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

The Department's rules for contesting contents of records and appealing initial denials appear in 24 CFR part 16, Procedures for Inquiries. Additional assistance may be obtained by contacting Helen Goff Foster, Chief Privacy Officer/Senior Agency Official for Privacy, 451 Seventh Street SW., Room 10139, Washington, DC 20410, or the HUD Departmental Privacy Appeals Officers, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10110 Washington, DC 20410.

RECORD SOURCE CATEGORIES:

Sources of data are contractual agreements between HUD and property owners (*e.g.* Regulatory Agreement, Section 8 Housing Assistance Payments (HAP) contract) and memorandums to HUD from the business partners and from other HUD source systems that transmit data to iREMS. The HUD source systems provide information to iREMS to allow Multifamily Housing the ability to track property status, loan status and characteristics, Section 8 contract renewals, and financial data concerning property owners. The source systems and their HUD functions are listed below:

(1) Development Application Processing (DAP): DAP is a comprehensive, automated underwriting system that supports processing and tracking of HUD Multifamily Housing applications from pre-application through final closing. Once the underwriting process has been completed, the information is passed along to iREMS.

(2) FHA Subsidy Ledger (FHASL): This system contains financing instrument, primary address, holding mortgagee and servicing mortgagee information.

(3) Multifamily Accounting Report and Servicing System (MARS): This system contains FHA information for Multifamily properties.

(4) Financial Assessment Subsystem (FASS): This system provides financial statements/data for all HUD owned properties.

(5) Physical Assessment Subsystem (PASS): This system holds the physical inspection data for HUD owned properties.

(6) Geo-coding Services (GSC): This system contains geo data and also provides standardized addresses for HUD owned properties.

(7) Tenant Rental Assistant Certification System (TRACS): TRACS contains Multifamily property attribute information. It also collects certified tenant data for processing from owners and management agents of Multifamily housing projects, and from local housing authorities and state housing agencies acting as subsidy contract administrators for HUD.

(8) Automatic Renewal and Amendment Management Sub-system (ARAMS): ARAMS processes and confirms Multifamily funding reservation requests for renewal and amendment subsidy contracts.

(9) Online Property Integrated Information Suite (OPIIS): OPIIS provides Risk management scores and ratings for HUD's Multifamily insured and assisted portfolio.

(10) Line of Credit Control System (LOCCS): LOCCS is a HUD grant disbursement system.

(11) Program Accounting System (PAS): PAS is an integrated subsidiary ledger for the Department's grant, subsidy, and loan programs.

(12) Northridge Loan System/Loan Accounting System (NLS/LAS): The NLS system contains loan information on HUD's properties.

(13) Active Partners Performance System (APPS): APPS is an online system that allows for submission and review of the Housing and Urban Development (HUD) Previous Participation Certification Process (Form 2530). This information is needed for the renewal process.

(14) Multifamily Insurance System MFIS: MFIS maintains the inventory of Multifamily insurance-in-force cases, as well as all pertinent and historical data, and produces premium bills and new account receivables monthly.

(15) Lender Electronic Assessment Portal (LEAP): Maintains the official record of institutions (Title I and Title II lenders) approved by HUD/Federal Housing Administration (FHA) to originate, service, or invest in FHA-insured mortgages or loans.

SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

SYSTEM OF RECORDS NO.:

HSNG/MF.HTS.02.

SYSTEM NAME:

Tenant Rental Assistance Certification System (TRACS)—F87.

SYSTEM LOCATION:

The system is hosted at the HUD data center in Charleston, West Virginia. Users have on-line access to the system at the Department of Housing and Urban Development Headquarters, 451 Seventh Street SW., Washington, DC 20410, HUD Field and Regional Offices,[4] or at the locations of the service providers under contract with HUD.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

TRACS categories of records include, records reported to HUD for each individual receiving housing assistance from HUD under the following programs: Section 8, Section 236 (including Section 236 RAP), Rent Supplement, Section 221(d)3 BMIR, Section 811, and Section 202 (*e.g.,* all participants of certain HUD Rental Housing Assistance Programs); records for each Public Housing Authorities (PHA), PHA-owner or management agents who receives payments for these assisted housing programs (*e.g.,* sole proprietors who administer these programs).

[4] *http://portal.hud.gov/hudportal/documents/huddoc?id=append2.pdf.*

CATEGORIES OF RECORDS IN THE SYSTEM:

The system of records contains manual and automated records consisting of tenant information supplied to HUD from PHAs or PHA-owner or management agents; data supplied by the tenant, or through a third party verification process. The full extent of the data fields collected is detailed in the 202D MAT GUIDE.

The categories of records include, but are not limited to Tenant:

(1) Identification Information: Name; Social Security number (SSN); alien registration information; address and tenant unit number, date of birth, phone number, driver's license, email, DUNS number.

(2) Characteristics Information: Information about the family that would qualify them for certain adjustments or for admission to a project limited to a special population (*e.g.,* elderly, handicapped or disabled), relationships of members of the household to the Head of household (*e.g.,* spouse, child), sex and ethnicity of Head of household and their family members.

(3) Preference(s) Applicable to Family Admission: Income status at admission, adjustments to income, contract rent amount, tenant rent, unit characteristics such as number of bedrooms, tenant to determine eligibility or level of assistance.

(4) Verification Information: State wage information pertaining to collection agency on wages and claim information, information obtained through computer matching by HUD or a PHA with Federal and State agencies, information on the results of the follow-up phase of owner verifications or a computer match of tenant income (*i.e.,* dollar amount of overpaid assistance, amount repaid, prosecution, termination of assistance, and termination of tenancy), and related correspondence.

(5) Geographic Information: Street address, zip code.

TRACS also include information reported to HUD by PHA or PHA-management or owner agents or contract administrators, as follows:

(1) PHA, PHA-owner or management agent's/contractor administrator's information: Manual and automated records on all their contractual agreements, and financial information (*i.e.,* names, addresses, Taxpayer Identification Numbers (TINs) or SSNs, obligations, payments, and contract terms) for public housing agencies, and/or owners/management agents or contract administrators.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

United States Housing Act of 1937, as amended, 42 U.S.C. 1437 *et seq.,* The Housing and Community Development Act, 42 U.S.C § 3543, Section 165. The Housing and Community Development Amendments of 1981, Public Law 97–35, 95 Stat. 408. Housing and Community Development Act of 1987, Public Law 100–242, title I, § 165, Feb. 5, 1988, 101 Stat. 1864. Stewart B. McKinney Homeless Assistance Amendments Act of 1988 Section 904 as amended by the Housing and Community Development Act of 1992 Section 903, and the Omnibus Budget Reconciliation Act of 1993 Section 3003, 42 U.S.C. 3544.

PURPOSE(S):

TRACS accepts tenant and voucher request data to facilitate rental assistance for very low/low income households. It facilitates the payment to authorized owners/agents/housing authorities and/or contract administrators. TRACS has edit checks and functionality to verify data quality, and interfaces with other HUD systems exist to validate tenant income, verify contract funding, obligate and commit contract funds, provide information to other HUD divisions, and submit voucher requests for payment in order to try to minimize improper payments and fraud. TRACS provides data needed to: (1) Determine the amount of housing assistance tenants may receive, (2) Calculate payments due to PHAs, PHA-owners/management agents, or contract administrators, (3) Make budgets forecasts, (4) Control funds, (5) Collect and maintain accurate rental assistance data, (6) Automate and improve management of assisted housing programs, (7) Reduce manual processes and paperwork, and (8) Detect subsidy fraud, waste, and abuse in multifamily housing rental housing assistance programs. The assisted housing programs within TRACS' scope include:

- Section 236 Interest Reduction and Rental Assistance Payments.
- Section 8 New Construction/Substantial Rehabilitation Housing Assistance Payments.
- Section 8 Loan Management/Property Disposition Set-Aside Housing Assistance Payments.
- Section 221(d) (3) Below Market Interest Rate (BMIR) mortgage insurance.
- Rent Supplement Payments.
- Certain Section 202 programs.
- Section 202/811 Project Rental Assistance Payments.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. Section 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside HUD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons to the extent such disclosures are compatible with the purpose for which the records in this system were collected, as set forth by Appendix I [5]—HUD's Library of Routine Uses last published in the **Federal Register**.

2. To appropriate agencies, entities, and persons when:

(a) HUD suspects or has confirmed that the security or confidentiality of information in a system of records has been compromised;

(b) HUD has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of systems or programs (whether maintained by HUD or another agency or entity) that rely upon the compromised information;

(c) HUD determines that the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HUD's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm for purposes of facilitating responses and remediation efforts in the event of a data breach.

7. To the National Archives and Records Administration (NARA) or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906.

8. To individuals under contract, cooperative agreement or grant, to HUD or under contract, cooperative agreement or grant to another agency with funds provided by HUD for the performance of research and statistical activities directly related to the management of HUD's rental assistance programs, to support quality control for tenant eligibility efforts requiring a random sampling of tenant files to determine the extent of administrative errors in making rent calculations, eligibility determinations, etc., for processing certifications/recertifications, and for other research and statistical purposes not otherwise prohibited by law or regulation.

9. To Housing Authorities, (HAs) to verify the accuracy and completeness of tenant data used in determining

[5] *http://portal.hud.gov/hudportal/documents/huddoc?id=routine_use_inventory.pdf.*

eligibility and continued eligibility and the amount of housing assistance received.

10. To Private Owners of assisted housing to verify the accuracy and completeness of applicant and tenant data used in determining eligibility and continued eligibility and the amount of assistance received.

11. To HAs, owners, management agents and contract administrators to identify and resolve discrepancies in tenant data.

12. To the Internal Revenue Service to report income using IRS Form 1099.

13. To Social Security Administration and Immigration and Naturalization Service to verify alien status and continued eligibility in HUD's rental assistance programs via EIV.

14. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically or on paper in secure facilities. The records may be stored on magnetic disc, tape, and digital media. Tenant data is stored at the National Archives and Records Administration (NARA) facility.

RETRIEVABILITY:

Name, address, SSN, or other identification number (contract or project numbers)

SAFEGUARDS:

Access to TRACS is by password and user ID and limited to authorized users. Paper records are maintained and locked drawer or in file cabinets. Role-based access levels or assignment roles are restricted to those who have a need-to-know. When first gaining access to TRACS and on an annual basis, all users must agree to the systems ''Rules of Behavior'' which specify handling of personal information and any physical records. Authorized users can download reports—the SSN is masked in both the system and reports during the download process.

RETENTION AND DISPOSAL:

Data is sent to NARA on a yearly basis. Paper records are destroyed by shredding or burning. Backup and Recovery digital media will be destroyed or otherwise rendered irrecoverable per NIST SP 800–88 Revision 1 ''Guidelines for Media Sanitization'' (December 2014). All records and data are retained and disposed of in accordance with guidance from the Records Disposition Management (2228.1) and the HUD Records Disposition Schedules Handbook (2225.6 Rev–1),[6] as described in Records Disposition Schedule 10, Item 14.

SYSTEM MANAGER(S) AND ADDRESS:

For inquiries relating to TRACS, contact:

- Office of the Assistant Secretary for Housing, Director, Housing Information and Statistics Division, Office of Management; Office of Multifamily Housing Management, Director, Planning and Procedures Division; Deputy Assistant Secretary for Multifamily Housing Programs, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410, for Section 8, Section 236 (including Section 236 Rental Assistance Payments (RAP) projects), Rent Supplement, Section 221(d)3 BMIR, Section 811, and Section 202 activities.
- *Office of Assistant Secretary for Public and Indian Housing:* Office of Public Housing, Chief, Occupancy Branch, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410 for Public and Indian Housing and Section 8 existing and Moderate Rehabilitation (Mod Rehab) Program activities.
- *Office of Public and Indian Housing, Director:* Computer Matching Activities Division, Office of Public and Indian Housing, Comptroller, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410 for TRACS Computer Matching Activities.

NOTIFICATION AND RECORD ACCESS PROCEDURES:

For Information, assistance, or inquiries about the existence of records contact Helen Goff Foster, Chief Privacy Officer/Senior Agency Official for Privacy, 451 Seventh Street SW., Room 10139, Washington, DC 20410, telephone number (202) 402–6836. When seeking records about yourself from this system of records or any other HUD system of records, your request must conform with the Privacy Act regulations set forth in 24 CFR part 16. You must first verify your identity, meaning that you must provide your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. In addition, your request should:

a. Explain why you believe HUD would have information on you.

b. Identify which Office of HUD you believe has the records about you.

c. Specify when you believe the records would have been created.

d. Provide any other information that will help the FOIA staff determine which HUD office may have responsive records.

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying their agreement for you to access their records. Without the above information, the HUD FOIA Office may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

The Department's rules for contesting contents of records and appealing initial denials appear in 24 CFR part 16, Procedures for Inquiries. Additional assistance may be obtained by contacting Helen Goff Foster, Chief Privacy Officer/Senior Agency Official for Privacy, 451 Seventh Street SW., Room 10139, Washington, DC 20410, or the HUD Departmental Privacy Appeals Officers, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10110, Washington, DC 20410.

RECORD SOURCE CATEGORIES:

Records in the system are obtained from PHAs, PHA-owners, and management agents/Housing Authorities and/or Contract administrators on behalf of the assisted tenants. The basis for these electronic submissions to TRACS is the form HUD–50059, Owner's Certification of Compliance with HUD's Tenant Eligibility and Rent Procedures, and the form HUD–52670.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

SYSTEM OF RECORDS NO.:

HSNG.MFH/HTHE.01.

SYSTEM NAME:

Development Application Processing System (DAP)—F24A.

SYSTEM LOCATION:

The system is hosted at the HUD data center in Charleston, West Virginia. Users have on-line access to the system

[6] *http://portal.hud.gov/hudportal/documents/huddoc?id=22256x10ADMH.pdf.*

at the Department of Housing and Urban Development Headquarters, 451 Seventh Street SW., Washington, DC 20410, HUD Field and Regional Offices,[7] or at the locations of the service providers under contract with HUD.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The categories of individuals covered by DAP include both the Mortgagees and Mortgagors.

CATEGORIES OF RECORDS IN THE SYSTEM:

(1) Mortgagees Contact/Identification Information: Name, address, telephone, Social Security number (SSN).

(2) Application Data/Status: Financing (Federal Housing Administration, Risk Sharing, 202/811) application information and status.

(3) Mortgagors Contact/Identification Information: Name, personal/business address, telephone, tax identification number (TIN), SSN, employer identification number (EIN).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sec. 113 of the Budget and Accounting Act of 1950, The National Housing Act (12 U.S.C. 1713 *et seq.,* Pub. L. 81–784. The Housing and Community Development Act, 42 U.S.C. 3543, Section 165. National Housing Act (12 U.S.C. 1713 *et seq.*)

PURPOSE(S):

The DAP system supports processing and tracking of FHA applications, Healthcare, and the tracking and scoring of 202/811s (applications for financing the elderly and disabled.) The system provides comprehensive tracking and processing controls from the pre-application stage through the final endorsement/closing stage and monitors inspections for select Multifamily Housing Development programs. Detail business rules are automated to reduce errors, new project numbers are generated, lender/participant information collected, and data interfaced to other critical MFH systems. Additionally, the Form HUD–290 report is automatically generated at initial and final endorsement and triggers insurance in force activities in the FHA Subsidiary Ledger (FHASL).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. Section 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside HUD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons to the extent such disclosures are compatible with the purpose for which the records in this system were collected, as set forth by Appendix I[8]—HUD's Routine Uses Inventory Notice last published in the **Federal Register**.

2. To appropriate agencies, entities, and persons when:

(a) HUD suspects or has confirmed that the security or confidentiality of information in a system of records has been compromised;

(b) HUD has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of systems or programs (whether maintained by HUD or another agency or entity) that rely upon the compromised information;

(c) HUD determines that the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HUD's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm for purposes of facilitating responses and remediation efforts in the event of a data breach.

4. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

5. To the U.S. Treasury for disbursements and adjustments.

6. To the Internal Revenue Service for reporting payments for mortgage interest, for reporting of discharge indebtedness and real estate taxes.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital media.

RETRIEVABILITY:

Electronic records may be retrieved by the project number, project name, office or hub, and Section of the Act (ACT) category. Search results can further be limited by phase/status and project characteristics. The participant's TAX ID/SSN/Name can be used to search for participants.

SAFEGUARDS:

Access to electronic systems is by password and code identification card access and limited to authorized users. Paper records are maintained and locked in file cabinets. Background screening, limited authorization and access with access limited to authorized personnel and technical restraints employed with regard to accessing the records; access to automated systems by authorized users by passwords.

RETENTION AND DISPOSAL:

This is in accordance with HUD's records schedule of retention and disposal. Manual files/records are sent to storage upon project receiving final endorsement to the storage facility in Tulsa, OK. Backup and Recovery digital media will be destroyed or otherwise rendered irrecoverable per NIST SP 800–88 Revision 1 ''Guidelines for Media Sanitization'' (December 2014). F24A DAP—Use HUD Record Schedule 56 as applicable. Disposition of the DAP records varies on the type of documents. Obsolete records are destroyed after 3 years. Disposition of Application Loan and Loan Agreement Files: Destroy 3 years after final settlement or paid in full. Disposition of Construction Contracts and related documents: Destroy 6 years after final payment. Disposition of Mortgage Transcript Documents Project and Asset Management Records: Destroy 3 years after repayment.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Multifamily Production, Office of Multifamily Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410.

NOTIFICATION AND RECORD ACCESS PROCEDURES:

For Information, assistance, or inquiries about the existence of records contact Helen Goff Foster, Chief Privacy Officer/Senior Agency Official for Privacy, 451 Seventh Street SW., Room 10139, Washington, DC 20410, telephone number 202–402–6836. When seeking records about yourself from this system of records or any other HUD system of records, your request must conform with the Privacy Act regulations set forth in 24 CFR part 16. You must first verify your identity by providing your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law

[7] *http://portal.hud.gov/hudportal/documents/huddoc?id=append2.pdf.*

[8] *http://portal.hud.gov/hudportal/documents/huddoc?id=routine_use_inventory.pdf.*

that permits statements to be made under penalty of perjury as a substitute for notarization. In addition, your request should:

(1) Explain why you believe HUD would have information on you.

(2) Identify which HUD office you believe has the records about you.

(3) Specify when you believe the records would have been created.

(4) Provide any other information that will help the Freedom of Information Act (FOIA) staff determine which HUD office may have responsive records.

If you are seeking records pertaining to another living individual, you must obtain a statement from that individual certifying their agreement for you to access their records. Without the above information, the HUD FOIA Office may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

The Department's rules for contesting contents of records and appealing initial denials appear in 24 CFR part 16, Procedures for Inquiries. Additional assistance may be obtained by contacting Helen Goff Foster, Chief Privacy Officer/Senior Agency Official for Privacy, 451 Seventh Street SW., Room 10139, Washington, DC 20410, telephone number (202) 402–6836, or the HUD Departmental Privacy Appeals Officers, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410

RECORD SOURCE CATEGORIES:

Records in the system are obtained from the applications for Multifamily Housing Projects; (HUD 9213) and other required HUD forms, drawings and narratives (lender's submission package) submitted to the HUD office.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 2016–20005 Filed 8–19–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–LE–2016—N250; FF09L00200–FX–LE18110900000]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; Captive Wildlife Safety Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service, Service) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This information collection is scheduled to expire on August 31, 2016. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before September 21, 2016.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_Submission@omb.eop.gov* (email). Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or *hope_grey@fws.gov* (email). Please include ''1018–0129'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Hope Grey at *hope_grey@fws.gov* (email) or 703–358–2482 (telephone). You may review the ICR online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1018–0129.

Title: Captive Wildlife Safety Act, 50 CFR 14.250–14.255.

Service Form Number: None.

Type of Request: Extension of a currently approved collection.

Description of Respondents: Accredited wildlife sanctuaries.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Ongoing.

Estimated Number of Respondents: 750.

Estimated Number of Responses: 750.

Completion Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 750.

Estimated Annual Nonhour Burden Cost: $300.

Abstract: The Captive Wildlife Safety Act (CWSA) amends the Lacey Act by making it illegal to import, export, buy, sell, transport, receive, or acquire, in interstate or foreign commerce, live lions, tigers, leopards, snow leopards, clouded leopards, cheetahs, jaguars, or cougars, or any hybrid combination of any of these species, unless certain exceptions are met. There are several exemptions to the prohibitions of the CWSA, including accredited wildlife sanctuaries.

There is no requirement for wildlife sanctuaries to submit applications to qualify for the accredited wildlife sanctuary exemption. Wildlife sanctuaries themselves will determine if they qualify. To qualify, they must meet all of the following criteria:

- Obtain approval by the United States Internal Revenue Service (IRS) as a corporation that is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986, which is described in sections 501(c)(3) and 170(b)(1)(A)(vi) of that code.
- Do not engage in commercial trade in the prohibited wildlife species, including offspring, parts, and products.
- Do not propagate the prohibited wildlife species.
- Have no direct contact between the public and the prohibited wildlife species.

The basis for this information collection is the recordkeeping requirement that we place on accredited wildlife sanctuaries. We require accredited wildlife sanctuaries to maintain complete and accurate records of any possession, transportation, acquisition, disposition, importation, or exportation of the prohibited wildlife species as defined in the CWSA (50 CFR 14, subpart K). Records must be up to date and include: (1) Names and addresses of persons to or from whom any prohibited wildlife species has been acquired, imported, exported, purchased, sold, or otherwise transferred; and (2) dates of these transactions. Accredited wildlife sanctuaries must:

- Maintain these records for 5 years.
- Make these records accessible to Service officials for inspection at reasonable hours.
- Copy these records for Service officials, if requested.

Comments Received and Our Responses

On April 6, 2016, we published in the **Federal Register** (81 FR 19990) a notice of our intent to request that OMB renew approval for this information collection. In that notice, we solicited comments for 60 days, ending on June 6, 2016. We received the following comments in response to that notice.

Comment: One comment suggested that the recordkeeping requirement

should be expanded to other exempted entities under the CWSA, including Animal and Plant Health Inspection Service (APHIS) licensed facilities and State-licensed wildlife rehabilitators.

Response: The Service does not have the authority to establish a recordkeeping requirement on the other entities exempted under the CWSA. The accredited wildlife sanctuary was the only exemption that was specifically defined in the CWSA, and as such, was the only exemption that lent itself to a recordkeeping requirement.

Comment: One comment suggested that appropriate records should be made available to the Service on an annual basis.

Response: The Service feels that the submission of records only on an as needed basis is adequate to substantiate that a particular wildlife sanctuary qualifies as accredited under the CWSA. The submission of records on an annual basis would require an application or other mechanism to receive and evaluate those records. In the development of the regulations to implement the CWSA, we considered options for developing some type of formal accreditation mechanism for wildlife sanctuaries, but concluded that because of a lack of available staff and resources to manage the submission of records on an annual basis, such a step was not practical.

Comment: One comment suggested that records should be made available to the public through an on-line database or through Freedom of Information Act requests.

Response: The Service feels that the requirements in the final rule to implement the CWSA by requiring wildlife sanctuaries to submit records on an as needed basis is adequate to substantiate that a particular wildlife sanctuary qualifies as accredited under the CWSA. We considered options for developing some type of formal electronic on-line database for wildlife sanctuaries, but concluded that because of a lack of available resources and staff to adequately implement such a mechanism, such a step was not practical. Any records the Service possesses could be made available to the public subject to the provisions of the Privacy Act.

Comment: One comment suggested that the Service incorporate an electronic recordkeeping system for wildlife sanctuaries that could be accessed and used by other Federal, State, or local agencies, and in particular, APHIS, to among other things, reconcile the information obtained under the CWSA with that maintained by APHIS under the Animal Welfare Act to ensure compliance.

Response: We considered options for developing some type of formal electronic accreditation mechanism for wildlife sanctuaries that could be accessed by other agencies, but concluded that, because of a lack of available resources and staff to adequately implement such a mechanism, such a step was not practical.

Comment: One comment suggested that records maintained by an accredited wildlife sanctuary must identify specific prohibited species and include the date of birth, age, and date of death of the specimen, and that specimens ''otherwise transferred,'' as stated in the requirements, should include specific information on the disposition of the specimen remains.

Response: The Service feels that the requirements, as written, are sufficient to confirm the acquisition or disposition of specimens.

Comment: One comment suggested that an electronic recordkeeping system for wildlife sanctuaries could alleviate the time required to maintain records.

Response: We considered options for developing some type of formal electronic accreditation mechanism for wildlife sanctuaries, but concluded that, because of a lack of available resources and staff to adequately implement such a mechanism, such a step was not practical.

Comment: One comment suggested that maintaining records by an accredited wildlife sanctuary should not be considered a ''burden.''

Response: We used the term ''burden'' in our **Federal Register** notice simply because ''burden'' is the term typically used to measure the impact of an information collection.

Comment: One comment suggested that records maintained by an accredited wildlife sanctuary must be updated within 30 days.

Response: The Service feels that the submission of records only on an as needed basis is adequate to substantiate that a particular wildlife sanctuary qualifies as accredited under the CWSA. Updating records within 30 days would require an application or other mechanism to receive and evaluate those records. In the development of the regulations to implement the CWSA, we considered options for developing some type of formal accreditation mechanism for wildlife sanctuaries, but concluded that because of a lack of available staff and resources to manage the submission of records on an annual basis, such a step was not practical

Comment: One comment suggested that records maintained by an accredited wildlife sanctuary should be maintained for 7 years.

Response: Under 50 CFR 14.254, we require that accredited wildlife sanctuaries maintain complete and accurate records of any possession, transportation, acquisition, disposition, importation, or exportation of the prohibited wildlife species for 5 years. This time period is consistent with the records requirements contained in our general permit procedures in 50 CFR 13.46. Since wildlife sanctuaries may have applied for and been issued permits under the general permit procedures, we believe it would be in the public interest that the records maintenance requirements of this information collection be consistent with those in the general permit procedures.

Request for Public Comments

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: August 16, 2016.

Tina A. Campbell,

Chief, Division of Policy, Performance, and Management Programs, U.S. Fish and Wildlife Service.

[FR Doc. 2016–19920 Filed 8–19–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–IA–2016–N118; FXIA167109ADV16–156–FF09A00000]

Request for Nominees for the Advisory Council on Wildlife Trafficking

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Request for nominees.

SUMMARY: The Secretary of the Interior (Secretary), after consultation with the Co-Chairs of the Presidential Task Force on Wildlife Trafficking (Task Force), is seeking nominations for individuals to serve on the Advisory Council on Wildlife Trafficking (Council).

DATES: Nominations must be received by September 21, 2016.

ADDRESSES: Send nominations, preferably by email, to Mr. Cade London, Special Assistant to the Assistant Director for International Affairs, at *Cade_London@fws.gov.* You may also send nominations via U.S. mail to U.S. Fish and Wildlife Service; Attention: Mr. Cade London; 5275 Leesburg Pike, MS: IA; Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Mr. Cade London, Special Assistant to the Assistant Director for International Affairs, U.S. Fish and Wildlife Service via email at *Cade_London@fws.gov,* via phone at (703) 358–2584, or via fax at (703) 358–2115.

SUPPLEMENTARY INFORMATION:

Council's Role

The Council conducts its operations in accordance with the provisions of the Federal Advisory Committee Act (FACA; 5 U.S.C. Appendix). It reports to the Presidential Task Force on Wildlife Trafficking through the Secretary of the Interior or his/her designee and functions solely as an advisory body. It advises and makes recommendations on issues relating to combating wildlife trafficking, including, but not limited to:

(1) Effective support for anti-poaching activities,

(2) Coordinating regional law enforcement efforts,

(3) Developing and supporting effective legal enforcement mechanisms, and

(4) Developing strategies to reduce illicit trade and consumer demand for illegally traded wildlife, including protected species.

The Council meets approximately four times annually, or as often as is necessary to complete its work.

Nominating Potential Council Members

The Department of the Interior (Department) is seeking nominations for individuals to be considered as Council members. Nominations should include a resume providing contact information and a description of the nominee's qualifications that is adequate enough to enable the Department to make an informed decision regarding meeting the membership requirements of the Council.

Requirements for Council Membership

Members must not be employees of the Federal Government. Membership includes knowledgeable individuals from the private sector, former governmental officials, nongovernmental organizations, and others who are in a position to provide expertise and support to the Task Force. Individuals who are federally registered lobbyists are ineligible to serve on all FACA and non-FACA boards, committees, or councils in an individual capacity. The term ''individual capacity'' refers to individuals who are appointed to exercise their own individual best judgment on behalf of the government, such as when they are designated Special Government Employees, rather than being appointed to represent a particular interest.

Council members serve at the pleasure of the Secretary of the Interior. Appointments will be for 3-year terms.

Dated: August 11, 2016.

Bryan Arroyo,

Assistant Director for International Affairs, U.S. Fish and Wildlife Service.

[FR Doc. 2016–19934 Filed 8–19–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2016–N116; FXES11130900000C2–167–FF09E32000]

Endangered and Threatened Wildlife and Plants; 5-Year Status Reviews of 14 Caribbean Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are initiating 5-year status reviews of 14 Caribbean species under the Endangered Species Act of 1973, as amended (Act). A 5-year review is an assessment of the best scientific and commercial data available at the time of the review. We are requesting submission of information that has become available since the last review of each of these species.

DATES: To allow us adequate time to conduct these reviews, we must receive your comments or information on or before October 21, 2016. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: For instructions on how to submit information and review information we receive on these species, see ''Request for New Information.''

FOR FURTHER INFORMATION CONTACT: For species-specific information, see ''Request for New Information.''

SUPPLEMENTARY INFORMATION:

Why do we conduct a 5-year review?

Under the Act (16 U.S.C. 1531 *et seq.*), we maintain lists of endangered and threatened wildlife and plant species in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for wildlife) and 17.12 (for plants). Section 4(c)(2)(A) of the Act requires us to review each listed species' status at least once every 5 years. Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species under active review. For additional information about 5-year reviews, go to *http://www.fws.gov/endangered/what-we-do/recovery-overview.html,* scroll down to ''Learn More about 5-Year Reviews,'' and click on our factsheet.

Species Under Review

Endangered

This notice announces our active review of 12 species that are currently listed as endangered:

Fish and Wildlife

Yellow-shouldered blackbird (*Agelaius xanthomus*)
Puerto Rican plain pigeon (*Patagioenas inornata wetmorei*)
Puerto Rican boa (*Epicrates inornatus*)
Virgin Islands boa (*Epicrates monensis granti*)

Plants

Auerodendron pauciflorum (no common name)
Catesbea melanocarpa (no common name)
Elaphoglossum serpens (no common name)
Mitracarpus maxwelliae (no common name)
Mitracarpus polycladus (no common name)
Polystichum calderonense (no common name)
Tectaria estremerana (no common name)

Trichilia triacantha (bariaco)

Threatened

This notice also announces our active review of two species that are currently listed as threatened:

Fish and Wildlife

Guajon (*Elaphoglossum serpens*)

Plants

Harrisia portoricensis (Higo chumbo)

What information do we consider in our review?

A 5-year review considers the best scientific and commercial data that have become available since the current listing determination or most recent status review of each species, such as:

A. Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics;

B. Habitat conditions, including but not limited to amount, distribution, and suitability;

C. Conservation measures that have been implemented to benefit the species;

D. Threat status and trends (see five factors under heading ''How do we determine whether a species is endangered or threatened?''); and

E. Other new information, data, or corrections, including but not limited to taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

New information will be considered in the 5-year review and ongoing recovery programs for the species.

Definitions

A. *Species* means any species or subspecies of fish, wildlife, or plant, and any distinct population segment of any species of vertebrate which interbreeds when mature.

B. *Endangered* means any species that is in danger of extinction throughout all or a significant portion of its range.

C. *Threatened* means any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.

How do we determine whether a species is endangered or threatened?

Section 4(a)(1) of the Act establishes that we determine whether a species is endangered or threatened based on one or more of the following five factors:

A. The present or threatened destruction, modification, or curtailment of its habitat or range;

B. Overutilization for commercial, recreational, scientific, or educational purposes;

C. Disease or predation;

D. The inadequacy of existing regulatory mechanisms; or

E. Other natural or manmade factors affecting its continued existence.

Request for New Information

To do any of the following, contact the Service's Caribbean Ecological Services Field Office, Road 301, Km. 5.1, P.O. Box 491, Boquerón, PR 00622; fax 787–851–7440, or the specific person at that office associated with the species you are interested in below:

A. To get more information on a species;

B. To submit information on a species; or

C. To review information we receive, which will be available for public inspection by appointment, during normal business hours at the Caribbean Ecological Services Field Office at the address above.

Birds

• Yellow-shouldered blackbird (*Agelaius xanthomus*), and Puerto Rican plain pigeon (*Patagioenas inornata wetmorei*): For information on these species, contact José Cruz-Burgos, by phone at 787–851–7297, ext. 218, or by email at *josé_cruz-burgos@fws.gov.*

Reptiles

• Puerto Rican boa (*Epicrates inornatus*): For information on this species, contact Jan P. Zegarra, by phone at 787–851–7297, ext. 220, or by email at *jan_zegarra@fws.gov.*

• Virgin Islands boa (*Epicrates monensis granti*): For information on this species, contact Carlos Pacheco, by phone at 787–851–7297, ext. 221, or by email at *carlos_pacheco@fws.gov.*

Amphibians

• Guajón (*Eleutherodacytlus cooki*): For information on this species, contact Jan Zegarra (see contact information above).

Plants

• *Auerodendron pauciflorum* and Bariaco: For information on these species, contact José Martínez, by phone at 787–851–7297, ext. 219, or by email at *jose_martinez@fws.gov.*

• *Catesbea melanocarpa:* For information on this species, contact Maritza Vargas by phone at 787–851–7297 ext. 215 or by email at *maritza_vargas@fws.gov.*

• *Mitracarpus maxwelliae* and *M. polycladus:* For information on these species, contact Carlos Pacheco (see contact information above).

• *Elaphoglossum serpens, Polystichum calderonense, Tectaria estremerana, and Harrisia portoricensis* (higo chumbo): For information on these species, contact Xiomara Labiosa, by phone at 787–851–7297, ext. 213, or by email at *Xiomara_labiosa@fws.gov.*

We request any new information concerning the status of any of these 14 species. See ''What information do we consider in our review?'' heading for specific criteria. Information submitted should be supported by documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that the entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We publish this document under the authority of the Endangered Species Act (16 U.S.C. 1531 *et seq.*).

Dated: August 15, 2016.

Mike Oetker,

Acting Regional Director, Southeast Region.

[FR Doc. 2016–19940 Filed 8–19–16; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167 A2100DD/AAKC001030/A0A501010.999900]

Indian Gaming; Approval of Amendment to Tribal-State Class III Gaming Compact in the State of Wyoming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Eastern Shoshone Tribe of the Wind River Reservation and State of Wyoming entered into a compact replacing and superseding an existing Tribal-State compact governing Class III gaming. This notice announces approval of the new compact.

DATES: Effective August 22, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian

Gaming, Office of the Assistant Secretary—Indian Affairs, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Section 11 of the Indian Gaming Regulatory Act (IGRA) requires the Secretary of the Interior to publish in the **Federal Register** notice of approved Tribal-State compacts that are for the purpose of engaging in Class III gaming activities on Indian lands. *See* Public Law 100–497, 25 U.S.C. 2701 *et seq.* All Tribal-State Class III compacts, including amendments, are subject to review and approval by the Secretary under 25 CFR 293.4. In addition to various miscellaneous changes, the term of the compact runs until April 19, 2046. The compact is approved. *See* 25 U.S.C. 2710(d)(8)(A).

Dated: August 12, 2016.

Lawrence S. Roberts,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2016–19877 Filed 8–19–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[16X LLUTW000000 L14400000.FR0000 UTU–089791 24 1A]

Notice of Realty Action: Rosebud Parcel-Recreation and Public Purposes Act Classification for Conveyance of Public Lands in Box Elder County, UT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) has examined and found suitable for classification under Section 7 of the Taylor Grazing Act, and conveyance under the provisions of the Recreation and Public Purposes (R&PP) Act, as amended, 0.36 acres of public land in Box Elder County, Utah. The Utah Division of Wildlife Resources proposes to assume ownership of a 70 ft. wide by 221.56 ft.-long parcel of land with an existing building that has been used as field quarters for personnel and cooperators working in northwestern Box Elder County, Utah.

DATES: Comments regarding the proposed classification for conveyance of public land must be submitted to the Field Manager, Salt Lake Field Office, at the address below on or before October 6, 2016.

ADDRESSES: Written comments should be addressed to the Bureau of Land Management, Field Manager, Salt Lake Field Office, 2370 South Decker Lake Blvd., West Valley City, UT 84119. Comments may also be submitted by email at *blm_ut_sl_comments@blm.gov* or fax (801)977–4397. Please reference ''Rosebud Parcel-Conveyance of Public Land to the State of Utah, Division of Wildlife Resources'' on all correspondence.

FOR FURTHER INFORMATION CONTACT: Mary Higgins, Realty Specialist, Salt Lake Field Office, by phone (801) 977–4327, or by email at: *mhiggins@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. Replies are provided during normal business hours.

SUPPLEMENTARY INFORMATION: The following described public land has been examined and found suitable for classification for conveyance under the provisions of Section 7 of the Taylor Grazing Act 43 U.S.C., Sec. 315f, and the provisions of the R&PP Act as amended:

Salt Lake Meridian, Utah

T. 10 N., R. 15 W.,

Sec. 6, Lot 10.

The area described contains 0.36 acres.

The land is not needed for any Federal purpose and is not of national significance. Conveyance is consistent with the BLM Box Elder Resource Management Plan–May 1986, and would be in the public interest. The BLM conducted a Phase I Environmental Site Assessment in May 2014, and no hazardous substances, petroleum products, or recognized environmental conditions were identified on the parcel. The BLM posted the Environmental Assessment (EA) DOI–BLM–UT–W010–2014–0018–EA and an unsigned Finding of No Significant Impact on January 29, 2016, for a 30-day comment period. Comments will be considered before a final decision on the action is made. The conveyance document, if issued, would convey the surface estate of the United States, subject to the provisions of the R&PP Act and applicable regulations of the Secretary of the Interior and would contain the following reservations, terms and conditions:

1. A right-of-way thereon for ditches or canals constructed by authority of the United States pursuant to the Act of August 30, 1890, 43 U.S.C. 945.

2. An appropriate indemnification clause protecting the United States from claims arising out of the patentee's use, occupancy, or occupations on the patented lands.

3. The land conveyed shall revert to the United States upon a finding, after notice and opportunity for a hearing, that, without the approval of the Secretary of the Interior or his delegate, the patentee or its successor attempts to transfer title to or control over the lands to another, the lands have been devoted to a use other than that for which the lands were conveyed, the lands have not been used for the purpose for which the lands were conveyed for a 5-year period, or the patentee has failed to follow the approved development plan or management plan.

4. Any other terms or conditions that the Authorized Officer determines appropriate to ensure public access and proper management of the Federal land and interests therein. Detailed information concerning this proposed project, including, but not limited to documentation relating to compliance with applicable environmental and cultural resource laws, is available for review at the BLM-Utah Salt Lake Field Office at the address above.

The surface estate of the land described above was acquired by the United States in 1973 in an exchange pursuant to the Taylor Grazing Act, and the land has not been opened to appropriation under the public land laws. Publication of this notice serves to open the lands to disposition under the R&PP Act only.

Classification Comments: Interested parties may submit comments involving the suitability of the land for the proposed use. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use (or uses) of the land, whether the use is consistent with local planning and zoning, or whether the use is consistent with State and Federal programs.

Application Comments: Interested parties may submit comments regarding the specific use proposed in the application and management plan, and whether the BLM followed proper administrative procedures in reaching the decision to convey under the R&PP Act. The BLM-Utah State Director will review any adverse comments and may sustain, vacate or modify this realty action. In the absence of any adverse comments, the classification will become effective on October 21, 2016. The land will not be available for conveyance until after the decision becomes effective.

Before including your address, phone number, email address, or other

personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 CFR 2741.5.

Jenna Whitlock,

Acting State Director.

[FR Doc. 2016–19972 Filed 8–19–16; 8:45 am]

BILLING CODE 4310–DQ–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–385 (Fourth Review)]

Granular Polytetrafluoroethylene Resin From Italy Termination of Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission instituted the subject five-year review in June 2016 to determine whether revocation of the antidumping duty order on granular polytetrafluoroethylene resin from Italy would be likely to lead to continuation or recurrence of material injury. On August 11, 2016, the Department of Commerce published notice that it was revoking the order effective July 18, 2016, because ''the domestic interested parties did not participate in this sunset review.'' (81 FR 53119). Accordingly, the subject review is terminated.

DATES: *Effective Date:* August 16, 2016

FOR FURTHER INFORMATION CONTACT: Fred Ruggles (202–205–3187, *fred.ruggles@usitc.gov*), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*).

Authority: This review is being terminated under authority of title VII of the Tariff Act of 1930 and pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)). This notice is published pursuant to section 207.69 of the Commission's rules (19 CFR 207.69).

By order of the Commission.

Issued: August 16, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–19918 Filed 8–19–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–856 (Third Review)]

Ammonium Nitrate From Russia; Termination of Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission instituted the subject five-year review in June 2016 to determine whether revocation of the antidumping duty order on ammonium nitrate from Russia would be likely to lead to continuation or recurrence of material injury. On August 11, 2016, the Department of Commerce published notice that it was revoking the order effective August 20, 2016, because ''the domestic interested parties did not participate in this sunset review; the Department is revoking this antidumping duty order.'' (81 FR 53433). Accordingly, the subject review is terminated.

DATES: *Effective Date:* August 16, 2016

FOR FURTHER INFORMATION CONTACT: Fred Ruggles (202–205–3187, *fred.ruggles@usitc.gov*), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*).

Authority: This review is being terminated under authority of title VII of the Tariff Act of 1930 and pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)). This notice is published pursuant to section 207.69 of the Commission's rules (19 CFR 207.69).

By order of the Commission.

Issued: August 16, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–19913 Filed 8–19–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Personal Transporters, Components Thereof, and Packaging and Manuals Therefor, DN 3168;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under § 210.8(b) of the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to 19 CFR 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Segway Inc.; DEKA Products Limited Partnership and Ninebot (Tianjin) Technology Co., Ltd. on August 16, 2016. The complaint alleges violations of section 337 of the Tariff Act of 1930

(19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain personal transporters, components thereof, and packaging and manuals therefor. The complaint names as respondents Powerboard LLC of Scottsdale, AZ; Metem Teknoloji Sistemleri San of Turkey; Changzhou Airwheel Technology Co., Ltd. of China; Airwheel of the Netherlands; Airwheel of Hoboken, NJ; Fastwheel of China; Shenzhen Chenduoxing Electronic Technology Ltd. China, a.k.a C-Star of China; Hangzhou Chic Intelligent Technology Co., Ltd. of China; Hovershop of Placentia, CA; Shenzhen Jomo Technology Co. Ltd., a.k.a. Koowheel of China; Guanghzou Kebye Electronic Technology Co., Ltd., a.k.a. Gotway of China; and Inventist, Inc. of Camas, WA. The complainant requests that the Commission issue general exclusion order, a limited exclusion order, cease and desist orders and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3168'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures).[1] Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: August 16, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–19912 Filed 8–19–16; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0005]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application and Permit for Importation of Firearms, Ammunition and Defense Articles, ATF F 6 (5330.3A) Part I

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection which was previously known as Application and Permit for Importation of Firearms, Ammunition and Implements of War, ATF F 6 (5330.3A) Part I, was published in the **Federal Register** at 81 FR 36583, on June 7, 2016, allowing for a 60-day comment period. All previous references to ''Implements of War'' were changed to ''Defense Articles,'' since ''Implements of War'' was not defined in the regulations and Defense Articles is the legal description, defined in 27 CFR part 447.

DATES: Comments are encouraged and will be accepted for an additional 30 days until September 21, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Desiree M. Dickinson, IOI/Industry Liaison, Firearms and Explosives Imports Branch, 244 Needy Road, Martinsburg, WV 25405, at email: *desiree.dickinson@atf.gov.* Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of information collection:* Revision of a currently approved collection.

2. *The title of the form/collection:* Application and Permit for Importation of Firearms, Ammunition and Defense Articles.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF F 6 (5330.3A) Part I.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Individuals or households, Federal Government, State, Local or Tribal Government.

Abstract: The application and subsequent permit are used to bring firearms, ammunition and defense articles into the United States.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 10,000 respondents will take 30 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 6,500 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: August 17, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–19987 Filed 8–19–16; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Caledonia Investments plc; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America* v. *Caledonia Investments plc,* Civil Action No. 1:16–cv–01620 (CRC). On August 10, 2016, the United States filed a Complaint alleging that Caledonia Investments plc violated the premerger notification and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. § 18a, with respect to its acquisition of voting securities of Bristow Group, Inc. The proposed Final Judgment, filed at the same time as the Complaint, requires Caledonia Investments plc to pay a civil penalty of $480,000.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be directed to Daniel P. Ducore, Special Attorney, c/o Federal Trade Commission, 600 Pennsylvania Avenue NW., CC–8416, Washington, DC 20580 (telephone: 202–326–2526; e-mail: *dducore@ftc.gov*).

Patricia A. Brink,

Director of Civil Enforcement.

In the United States District Court for the District of Columbia

United States of America, c/o Department of Justice, Washington, DC 20530, Plaintiff, v. *Caledonia Investments PLC, Cayzer House, 30 Buckingham Gate, London, UK SW1E6NN,* Defendant.

Case No.: 1:16–cv–01620
Judge: Christopher R. Cooper
Filed: 08/10/2016

COMPLAINT FOR CIVIL PENALTIES FOR FAILURE TO COMPLY WITH THE PREMERGER REPORTING AND WAITING REQUIREMENTS OF THE HART-SCOTT RODINO ACT

The United States of America, Plaintiff, by its attorneys, acting under the direction of the Attorney General of the United States and at the request of the Federal Trade Commission, brings this civil antitrust action to obtain monetary relief in the form of civil penalties against Defendant Caledonia Investments plc (''Caledonia''). Plaintiff alleges as follows:

NATURE OF THE ACTION

1. Caledonia violated the notice and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. § 18a (''HSR Act'' or ''Act''), with respect to the acquisition of voting securities of Bristow Group, Inc. (''Bristow'') in February 2014.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to

Section 7A(g) of the Clayton Act, 15 U.S.C. § 18a(g), and pursuant to 28 U.S.C. §§ 1331, 1337(a), 1345, and 1355 and over the Defendant by virtue of Defendant's consent, in the Stipulation relating hereto, to the maintenance of this action and entry of the Final Judgment in this District.

3. Venue is properly based in this District by virtue of Defendant's consent, in the Stipulation relating hereto, to the maintenance of this action and entry of the Final Judgment in this District.

THE DEFENDANT

4. Defendant Caledonia is a public limited company organized under the laws of the United Kingdom with its principal office and place of business at Cayzer House, 30 Buckingham Gate, London, UK SW1E6NN. Caledonia is engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. § 12, and Section 7A(a)(1) of the Clayton Act, 15 U.S.C. § 18a(a)(1). At all times relevant to this complaint, Caledonia had sales or assets in excess of $141.8 million.

OTHER ENTITIES

5. Bristow is a corporation organized under the laws of Delaware with its principal place of business at 2103 City West Boulevard, Houston, TX 77042. Bristow is engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. § 12, and Section 7A(a)(1) of the Clayton Act, 15 U.S.C. § 18a(a)(1). At all times relevant to this complaint, Bristow had sales or assets in excess of $14.2 million. Bristow was formerly named Offshore Logistics, Inc. (''Offshore Logistics'').

THE HART-SCOTT-RODINO ACT AND RULES

6. The HSR Act requires certain acquiring persons and certain persons whose voting securities or assets are acquired to file notifications with the federal antitrust agencies and to observe a waiting period before consummating certain acquisitions of voting securities or assets. 15 U.S.C. § 18a(a) and (b). These notification and waiting period requirements apply to acquisitions that meet the HSR Act's thresholds, which are adjusted annually. During the period of 2014 pertinent to this complaint, the HSR Act's reporting and waiting period requirements applied to most transactions that would result in the acquiring person holding more than $50 million, as adjusted (at the time $70.9 million), if certain sales and asset thresholds were met, and all transactions (regardless of the size of the acquiring or acquired persons) where the acquiring person would hold more than $200 million, as adjusted (at the time $283.6 million), of the acquired person's voting securities and/or assets, except for certain exempted transactions.

7. The HSR Act's notification and waiting period are intended to give the federal antitrust agencies prior notice of, and information about, proposed transactions. The waiting period is also intended to provide the federal antitrust agencies with an opportunity to investigate a proposed transaction and to obtain effective preliminary relief to prevent the consummation of a transaction that may violate the antitrust laws.

8. Pursuant to Section (d)(2) of the HSR Act, 15 U.S.C. § 18a(d)(2), rules were promulgated to carry out the purposes of the HSR Act. 16 C.F.R. §§ 801–803 (''HSR Rules''). The HSR Rules, among other things, define terms contained in the HSR Act.

9. Pursuant to section 801.13(a)(1) of the HSR Rules, 16 C.F.R. § 801.13(a)(1), ''all voting securities of [an] issuer which will be held by the acquiring person after the consummation of an acquisition''—including any held before the acquisition—are deemed held ''as a result of'' the acquisition at issue.

10. Pursuant to sections 801.13(a)(2) and 801.10(c)(1) of the HSR Rules, 16 C.F.R. § 801.13(a)(2) and. § 801.10(c)(1), the value of publicly traded voting securities already held is the market price, defined to be the lowest closing price within 45 days prior to the subsequent acquisition.

11. Section 802.9 of the HSR Rules, 16 C.F.R. § 802.9, provides that acquisitions solely for the purpose of investment are exempt from the notification and waiting period requirements if the acquirer will hold ten percent or less of the issuer's voting securities.

12. Section 801.1(i)(1) of the HSR Rules, 16 C.F.R. § 801.1(i)(1), defines the term ''solely for the purpose of investment'' as follows:

> Voting securities are held or acquired ''solely for the purpose of investment'' if the person holding or acquiring such voting securities has no intention of participating in the formulation, determination, or direction of the basic business decisions of the issuer.

13. Section 802.21(a) of the HSR Rules, 16 C.F.R. § 802.21(a), provides generally that a person who files and observes the waiting period before crossing a filing threshold may, within five years of the expiration of the waiting period, acquire additional voting securities of the issuer that do not cross a higher threshold, so long as the person does not acquire control of the issuer. For example, a person who files and observes the waiting period before crossing the $50 million threshold, as adjusted, may, assuming the person does not acquire control, acquire additional voting securities of the issuer up to the next threshold, which is $100 million, as adjusted. The acquiring person must file again, however, before it can cross the next higher threshold, $500 million, as adjusted, or before the person acquires control of the issuer.

14. Section 7A(g)(1) of the Clayton Act, 15 U.S.C. § 18a(g)(1), provides that any person, or any officer, director, or partner thereof, who fails to comply with any provision of the HSR Act is liable to the United States for a maximum civil penalty of $10,000 for each day during which such person is in violation. Pursuant to the Debt Collection Improvement Act of 1996, Pub. L. 104–134, § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note), and Federal Trade Commission Rule 1.98, 16 C.F.R. § 1.98, 74 Fed. Reg. 857 (Jan. 9, 2009), the maximum amount of civil penalty was increased to $16,000 per day. Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Pub. L. 114–74, § 701 (further amending the Federal Civil Penalties Inflation Adjustment Act of 1990), and Federal Trade Commission Rule 1.98, 16 C.F.R. § 1.98, 81 Fed. Reg. 42,476 (June 30, 2016), the maximum amount of civil penalty was increased to $40,000 per day.

DEFENDANT'S PRIOR VIOLATION OF THE HSR ACT

15. On December 19, 1996, Caledonia acquired 1,300,000 shares of voting securities of Offshore Logistics in a transaction negotiated with Offshore Logistics. As a result of that transaction, Caledonia held approximately six percent of the voting securities of Offshore Logistics, valued at approximately $19.8 million. The transaction gave Caledonia the right to appoint two people to the board of Offshore Logistics. Shortly after December 19, 1996, Caledonia named two of its employees to the board of Offshore Logistics.

16. At the time of the December 19, 1996, transaction, the relevant size of the transaction was $15 million.

17. Caledonia could not rely on the exemption for acquisitions solely for the purpose of investment because it intended to, and did, exercise its rights

to appoint two members to Offshore Logistics' board of directors.

18. Although it was required to do so, Caledonia did not file under the HSR Act prior to acquiring Offshore Logistics voting securities on December 19, 1996.

19. On June 3, 1997, Caledonia made a corrective filing under the HSR Act for the December 19, 1996, acquisition of Offshore Logistics voting securities. In a letter accompanying the corrective filing, Caledonia acknowledged that the transaction was reportable under the HSR Act, but asserted that the failure to file and observe the waiting period was inadvertent. The United States and the Federal Trade Commission did not initiate an enforcement action against Caledonia for this violation of the Act.

VIOLATION

20. On June 5, 2008, Caledonia filed to acquire voting securities of Bristow valued in excess of $50 million, as adjusted. The waiting period on this filing expired on June 13, 2008.

21. Pursuant to Section 802.21(a) of the HSR Rules, 16 C.F.R. § 802.21(a), Caledonia could acquire additional voting securities of Bristow without filing under HSR for a period of five years, as long as its holdings did not exceed the $100 million threshold, as adjusted ($141.8 million as of February 3, 2014). That five-year period ended on June 13, 2013.

22. On February 3, 2014, Caledonia acquired 3,650 shares of Bristow voting securities as the result of vesting of restricted stock units. Because this acquisition occurred later than five years after the expiration of the waiting period of the previous filing, the HSR Rules required Caledonia to again file a notice prior to crossing the $50 million threshold, as adjusted ($70.9 million as of February 3, 2014). The voting securities that Caledonia held as a result of this acquisition from Bristow were valued at approximately $111 million.

23. Although it was required to do so, Caledonia did not file under the HSR Act prior to acquiring Bristow voting securities on February 3, 2014.

24. More than a year later, on February 4, 2015, Caledonia made a corrective filing under the HSR Act for the Bristow voting securities it had acquired on February 3, 2014. The HSR waiting period expired on March 6, 2015.

25. Caledonia was in continuous violation of the HSR Act from February 3, 2014, when it acquired the Bristow voting securities that resulted in it holding Bristow voting securities valued in excess of the HSR Act's $50 million size-of-transaction threshold, as adjusted, through March 6, 2015, when the waiting period expired.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff requests:

a. That the Court adjudge and decree that Defendant Caledonia's acquisition of Bristow voting securities on February 3, 2014, was a violation of the HSR Act, 15 U.S.C. § 18a; and that Defendant Caledonia was in violation of the HSR Act each day from February 3, 2014, through March 6, 2015.

b. That the Court order Defendant Caledonia to pay to the United States an appropriate civil penalty as provided by the HSR Act. 15 U.S.C. § 18a(g)(1), the Debt Collection Improvement Act of 1996, Pub. L. 104–134, § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note), and Federal Trade Commission Rule 1.98, 16 C.F.R. § 1.98, 74 Fed. Reg. 857 (Jan. 9, 2009), and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Pub. L. 114–74, § 701 (further amending the Federal Civil Penalties Inflation Adjustment Act of 1990), and Federal Trade Commission Rule 1.98, 16 C.F.R. 1.98, 81 Fed. Reg. 42,476 (June 30, 2016).

c. That the Court order such other and further relief as the Court may deem just and proper.

d. That the Court award the Plaintiff its costs of this suit.

Dated: 08/10/2016

FOR THE PLAINTIFF UNITED STATES OF AMERICA:

/s/

Renata B. Hesse,
D.C. Bar No. 466107,
Acting Assistant Attorney General, Department of Justice, Antitrust Division, Washington, DC 20530.

/s/

Daniel P. Ducore,
D.C. Bar No. 933721,
Special Attorney.

/s/

Roberta S. Baruch,
D.C. Bar No. 269266,
Special Attorney.

/s/

Kenneth A. Libby,
Special Attorney.

/s/

Jennifer Lee,
Special Attorney.
Federal Trade Commission,
Washington, DC 20580,
(202) 326–2694.

United States District Court for the District of Columbia

United States of America, Plaintiff, v. *Caledonia Investments PLC*, Defendant.
Case No.: 1:16–cv–01620
Judge: Christopher R. Cooper
Filed: 08/10/2016

COMPETITIVE IMPACT STATEMENT

The United States, pursuant to the Antitrust Procedures and Penalties Act (''APPA''), 15 U.S.C. § 16(b)–(h), files this Competitive Impact Statement to set forth the information necessary to enable the Court and the public to evaluate the proposed Final Judgment that would terminate this civil antitrust proceeding.

I. NATURE AND PURPOSE OF THIS PROCEEDING

On August 10, 2016, the United States filed a Complaint against Defendant Caledonia Investments PLC (''Caledonia''), related to Caledonia's acquisition of voting securities of Bristow Group, Inc. (''Bristow'') in February 2014. The Complaint alleges that Caledonia violated Section 7A of the Clayton Act, 15 U.S.C. § 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the ''HSR Act''). The HSR Act provides that ''no person shall acquire, directly or indirectly, any voting securities of any person'' exceeding certain thresholds until that person has filed pre-acquisition notification and report forms with the Department of Justice and the Federal Trade Commission (collectively, the ''federal antitrust agencies'' or ''agencies'') and the post-filing waiting period has expired. 15 U.S.C. § 18a(a). A key purpose of the notification and waiting period is to protect consumers and competition from potentially anticompetitive transactions by providing the agencies an opportunity to conduct an antitrust review of proposed transactions before they are consummated.

The Complaint alleges that Caledonia acquired voting securities of Bristow in excess of the statutory threshold ($70.9 million at the time of acquisition) without making the required pre-acquisition HSR filings with the agencies and without observing the waiting period, and that Caledonia and Bristow each met the statutory size of person threshold (Caledonia and Bristow had sales or assets in excess of $141.8 million and $14.2 million, respectively, at the time of the acquisition).

At the same time the Complaint was filed in the present action, the United States also filed a Stipulation and proposed Final Judgment that eliminates the need for a trial in this case. The proposed Final Judgment is designed to deter Caledonia from engaging in future HSR Act violations.

Under the proposed Final Judgment, Caledonia must pay a civil penalty to the United States in the amount of $480,000.

The United States and the Defendant have stipulated that the proposed Final Judgment may be entered after compliance with the APPA, unless the United States first withdraws its consent. Entry of the proposed Final Judgment would terminate this case, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and punish violations thereof.

II. DESCRIPTION OF THE EVENTS GIVING RISE TO THE ALLEGED VIOLATION OF THE ANTITRUST LAWS

A. Caledonia and the 2008 and 2014 Acquisitions of Bristow Voting Securities

Caledonia is a public limited company organized under the laws of the United Kingdom and headquartered in London. Caledonia has sales or assets in excess of $141.8 million.

Bristow is a Delaware corporation headquartered in Houston, Texas. Bristow provides helicopter services to the offshore energy industry and has sales or assets in excess of $14.2 million.

On June 5, 2008, Caledonia filed an HSR notification in connection with its acquisition of Bristow voting securities valued in excess of $50 million, as adjusted. The waiting period on this HSR filing expired on June 13, 2008. Pursuant to Section 802.21(a) of the HSR Rules, 16 C.F.R. § 802.21(a), Caledonia could acquire additional voting securities of Bristow without making another HSR filing for five years, or until June 13, 2013, as long as its holdings of Bristow securities did not exceed the $100 million HSR Act threshold, as adjusted.

B. Caledonia's Violation of the HSR Act

As alleged in the Complaint, on February 3, 2014, after the five-year window had elapsed, Caledonia acquired 3,650 additional shares of Bristow voting securities as the result of the vesting of restricted stock units. Following the vesting of these restricted stock units, Caledonia's voting securities of Bristow were valued at approximately $111 million, an amount in excess of the then-effective HSR Act $70.9 million size-of-transaction threshold. Accordingly, Caledonia was required to make an HSR filing and wait until the expiration of the waiting period before consummating the acquisition. Caledonia did not do so, however, incorrectly believing that its 2008 HSR filing enabled it to acquire additional shares of Bristow without making a new HSR filing. Caledonia's failure to comply with the HSR Act denied the agencies the opportunity to review Caledonia's acquisition of Bristow securities before it was consummated and thereby undermined the statutory scheme and the purpose of the HSR Act.

Caledonia made a corrective filing on February 4, 2015, shortly after learning of its obligation to file. Caledonia's February 4, 2015, corrective filing included a letter acknowledging that the acquisitions were reportable under the HSR Act. The waiting period expired on March 6, 2015.

The Complaint further alleges that Caledonia previously violated the HSR Act's notification requirements when it acquired shares in Offshore Logistics, Inc. (''OLOG'') in 1996, as Bristow was then named. On December 19, 1996, Caledonia acquired 1.3 million shares of OLOG voting securities through a transaction in which Caledonia also gained the right to name two persons to the OLOG board. Caledonia named two of its employees to the board of OLOG, and therefore could not rely on the HSR Act exemption for acquisitions made solely for the purpose of investment. *See* 15 U.S.C. § 18a(c)(9); 16 C.F.R. § 801.1(i)(1). Pursuant to the HSR Act, Caledonia was required to make a pre-acquisition notification filing prior to its acquisition of OLOG voting securities, but it failed to do so. On June 3, 1997, Caledonia made a corrective filing for this acquisition. In a letter accompanying the corrective filing, Caledonia acknowledged that the acquisition of OLOG voting securities was reportable under the HSR Act, but asserted that the failure to file and observe the waiting period was inadvertent. Caledonia also asserted that it ''will do its utmost to ensure that it submits all required filings under the Act in the future.'' The United States did not file suit against Caledonia in connection with this earlier violation of the HSR Act.

III. EXPLANATION OF THE PROPOSED FINAL JUDGMENT

The proposed Final Judgment imposes a $480,000 civil penalty designed to deter the Defendant and others from violating the HSR Act. The United States adjusted the civil penalty downward from the maximum permitted under the HSR Act because the violation was inadvertent, the Defendant promptly self-reported the violation after discovery, and the Defendant is willing to resolve the matter by consent decree and avoid prolonged investigation and litigation. The decision to seek a penalty also reflects Defendant's previous violation of the HSR Act. The relief will have a beneficial effect on competition because it will help ensure that the agencies will be properly notified of future acquisitions, in accordance with the law. At the same time, the penalty will not have any adverse effect on competition.

IV. REMEDIES AVAILABLE TO POTENTIAL PRIVATE LITIGANTS

There is no private antitrust action for HSR Act violations; therefore, entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust action.

V. PROCEDURES AVAILABLE FOR MODIFICATION OF THE PROPOSED FINAL JUDGMENT

The United States and the Defendant have stipulated that the proposed Final Judgment may be entered by this Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry of the decree upon this Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to entry. The comments and the response of the United States will be filed with this Court. In addition, comments will be posted on the U.S. Department of Justice, Antitrust Division's internet website and, under certain circumstances, published in the **Federal Register**. Written comments should be submitted to:

Daniel P. Ducore
Special Attorney, United States
c/o Federal Trade Commission
600 Pennsylvania Avenue, NW
CC–8416
Washington, DC 20580

Email: *dducore@ftc.gov*

The proposed Final Judgment provides that this Court retains jurisdiction over this action, and the parties may apply to this Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. ALTERNATIVES TO THE PROPOSED FINAL JUDGMENT

As an alternative to the proposed Final Judgment, the United States considered pursuing a full trial on the merits against the Defendant. The United States is satisfied, however, that the proposed relief is an appropriate remedy in this matter. Given the facts of this case, including the Defendant's immediate self-reporting of the violation and willingness to promptly settle this matter, the United States is satisfied that the proposed civil penalty is sufficient to address the violation alleged in the Complaint and to deter violations by similarly situated entities in the future, without the time, expense, and uncertainty of a full trial on the merits.

VII. STANDARD OF REVIEW UNDER THE APPA FOR THE PROPOSED FINAL JUDGMENT

The APPA requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty (60) day comment period, after which the court shall determine whether entry of the proposed Final Judgment is ''in the public interest.'' 15 U.S.C. § 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

> (A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

Id. § 16(e)(1)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one, as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *see generally United States* v. *SBC Commc'ns, Inc.,* 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing public interest standard under the Tunney Act); *United States v, U.S. Airways Group, Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (noting the court has broad discretion of the adequacy of the relief at issue); *United States* v. *InBev N.V./S.A.,* No. 08–1965 (JR), 2009–2 Trade Cas. (CCH) ¶ 76,736, 2009 U.S. Dist. LEXIS 84787, at *3, (D.D.C. Aug. 11, 2009) (noting that the court's review of a consent judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable'').[1]

As the United States Court of Appeals for the District of Columbia Circuit has held, a court conducting an inquiry under the APPA may consider, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States* v. *BNS, Inc.,* 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Courts have held that:

> [t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is ''*within the reaches of the public interest.''* More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[2] In determining whether a proposed settlement is in the public interest, a district court ''must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that a court should not reject the proposed remedies because it believes others are preferable); *Microsoft,* 56 F.3d at 1461 (noting the need for courts to be ''deferential to the government's predictions as to the effect of the proposed remedies''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case).

Courts have greater flexibility in approving proposed consent decrees than in crafting their own decrees following a finding of liability in a litigated matter. ''[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.' '' *United States* v. *Am. Tel. & Tel. Co.,* 552 F. Supp. 131, 151 (D.D.C. 1982) (citations omitted) (quoting *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975)), *aff'd sub nom., Maryland* v. *United States,* 460 U.S. 1001 (1983); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (noting that room must be made for the government to grant concessions in the negotiation process for settlements (citing *Microsoft,* 56 F.3d at 1461)); *United States* v. *Alcan Aluminum Ltd.,* 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy). To meet this standard, the United States ''need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17.

[1] The 2004 amendments substituted ''shall'' for ''may'' in directing relevant factors for court to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. § 16(e) (2004), *with* 15 U.S.C. § 16(e)(1) (2006); *see also SBC Commc'ns,* 489 F. Supp. 2d at 11 (concluding that the 2004 amendments ''effected minimal changes'' to Tunney Act review).

[2] *Cf. BNS,* 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass''). *See generally Microsoft,* 56 F.3d at 1461 (discussing whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest' '').

Moreover, the court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint, and does not authorize the court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (concluding that ''the 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged''). Because the ''court's authority to review the decree depends entirely on the government exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60. As this Court confirmed in *SBC Communications,* courts ''cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power.'' 489 F. Supp. 2d at 15.

In its 2004 amendments, Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. § 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language codified what Congress intended when it enacted the Tunney Act in 1974, as the author of this legislation, Senator Tunney, explained: ''The court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns,* 489 F. Supp. 2d at 11.[3] A court can make its public interest determination based on the competitive impact statement and response to public comments alone. *U.S. Airways,* 38 F. Supp. 3d at 76.

VIII. DETERMINATIVE DOCUMENTS

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Date: August 10, 2016 Respectfully Submitted,
/s/
Kenneth A. Libby
Special Attorney.

In The United States District Court for the District of Columbia

United States of America, Plaintiff, v. *Caledonia Investments PLC,* Defendant.
Case No.: 1:16–cv–01620
Judge: Christopher R. Cooper
Filed: 08/10/2016

FINAL JUDGMENT

Plaintiff, the United States of America, having commenced this action by filing its Complaint herein for violation of Section 7A of the Clayton Act, 15 U.S.C. § 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976, and Plaintiff and Defendant Caledonia Investments plc, by their respective attorneys, having consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law herein, and without this Final Judgment constituting any evidence against or an admission by the Defendant with respect to any such issue:

Now, therefore, before the taking of any testimony and without trial or adjudication of any issue of fact or law herein, and upon the consent of the parties hereto, it is hereby

Ordered, Adjudged, and Decreed as follows:

I.

The Court has jurisdiction of the subject matter of this action and of the Plaintiff and the Defendant. The Complaint states a claim upon which relief can be granted against the Defendant under Section 7A of the Clayton Act, 15 U.S.C. § 18a.

II.

Judgment is hereby entered in this matter in favor of Plaintiff United States of America and against Defendant, and, pursuant to Section 7A(g)(1) of the Clayton Act, 15 U.S.C. § 18a(g)(1), the Debt Collection Improvement Act of 1996, Pub. L. 104-134 § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461), and Federal Trade Commission Rule 1.98, 16 C.F.R. § 1.98, 61 Fed. Reg. 54549 (Oct. 21, 1996), and 74 Fed. Reg. 857 (Jan. 9, 2009), and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Pub. L. 114–74, § 701 (further amending the Federal Civil Penalties Inflation Adjustment Act of 1990), and Federal Trade Commission Rule 1.98, 16 C.F.R. 1.98, 81 Fed. Reg. 42,476 (June 30, 2016), Defendant Caledonia Investments plc is hereby ordered to pay a civil penalty in the amount of four hundred eighty thousand dollars ($480,000). Payment of the civil penalty ordered hereby shall be made by wire transfer of funds or cashier's check. If the payment is made by wire transfer, Defendant shall contact Janie Ingalls of the Antitrust Division's Antitrust Documents Group at (202) 514–2481 for instructions before making the transfer. If the payment is made by cashier's check, the check shall be made payable to the United States Department of Justice and delivered to:

Janie Ingalls
United States Department of Justice
Antitrust Division, Antitrust Documents Group
450 5th Street, NW
Suite 1024
Washington, DC 20530

Defendant shall pay the full amount of the civil penalty within thirty (30) days of entry of this Final Judgment. In the event of a default or delay in payment, interest at the rate of eighteen (18) percent per annum shall accrue thereon from the date of the default or delay to the date of payment.

III.

Each party shall bear its own costs of this action.

[3] *See also United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); *United States* v. *Mid-Am. Dairymen, Inc.,* No. 73–CV–681–W–1, 1977–1 Trade Cas. (CCH) ¶ 61,508, at 71,980, *22 (W.D. Mo. 1977) (''Absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should . . . carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.''); S. Rep. No. 93–298, at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

IV.

Entry of this Final Judgment is in the public interest.

Dated: _____

_____

United States District Judge

[FR Doc. 2016–19988 Filed 8–19–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0013]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Application for Permit to Import Controlled Substances for Domestic and/or Scientific Purposes Pursuant to 21 U.S.C 952; DEA Form 357

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until October 21, 2016.

FOR FURTHER INFORMATION CONTACT: If you have comments on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Application for Permit to Import Controlled Substances for Domestic and/or Scientific Purposes pursuant to 21 U.S.C. 952.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* DEA Form: 357. The applicable component within the Department of Justice is the Drug Enforcement Administration, Office of Diversion Control.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public (Primary): Business or other for-profit.

Affected public (Other): None.

Abstract: Section 1002 of the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 952) and Title 21, Code of Federal Regulations (21 CFR), Sections 1312.11, 1312.12 and 1312.13 requires any person who desires to import controlled substances listed in schedules I or II, any narcotic substance listed in schedules III or IV, or any non-narcotic substance in schedule III which the Administrator has specifically designated by regulation in § 1312.30, or any nonnarcotic substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substances, must have an import permit. To obtain the permit to import controlled substances for domestic and or scientific purposes, an application for the permit must be made to the DEA on DEA Form 357.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates that 151 registrants participate in this information collection, taking an estimated 0.25 hours per registrant annually.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates the total public burden (in hours) associated with this collection: 333 annual burden hours.

If additional information is required please contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Suite 3E.405B, Washington, DC 20530.

Dated: August 16, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–19916 Filed 8–19–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Survey of Occupational Injuries and Illnesses

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Bureau of Labor Statistics (BLS) sponsored information collection request (ICR) revision titled, ''Survey of Occupational Injuries and Illnesses,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 21, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201606–1220–001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–BLS, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–

395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks approval under the PRA for revisions to the Survey of Occupational Injuries and Illnesses (SOII) information collection, which is a primary indicator of the Nation's progress in providing every working man and woman safe and healthful working conditions. The survey measures the overall rate of work injuries and illnesses by industry. Survey data are also used to evaluate the effectiveness of Federal and State programs and to prioritize scarce resources. Respondents include employers who maintain records in accordance with the Occupational Safety and Health Act (OSH Act) and employers who are normally exempt from OSH Act recordkeeping. Each year a sample of exempt employers is required to keep records and participate in the SOII. This information collection has been classified as a revision, because the SOII Recontact Survey is being discontinued and the number of normally exempt employers who would otherwise participate in the SOII is being reduced. OSH Act section 24(a) authorizes this information collection. *See* 29 U.S.C. 673.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1220–0045. The current approval is scheduled to expire on September 30, 2016; however, the DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 19, 2016 (81 FR 31666).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1220–0045. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–BLS.

Title of Collection: Survey of Occupational Injuries and Illnesses.

OMB Control Number: 1220–0045.

Affected Public: State, Local, and Tribal Governments; Private Sector—businesses or other for-profits, farms, and not-for-profit institutions.

Total Estimated Number of Respondents: 240,000.

Total Estimated Number of Responses: 240,000.

Total Estimated Annual Time Burden: 310,500 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: August 16, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–19979 Filed 8–19–16; 8:45 am]

BILLING CODE 4510–24–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 52–027; NRC–2008–0441]

South Carolina Electric & Gas Company and South Carolina Public Service Authority; Virgil C. Summer Nuclear Station, Unit 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Grant of exemption; approval of alternative.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is granting an exemption from the requirements of the Commission's regulations that require a portion of the operating test, which is part of the operator licensing examination, to be administered in a plant walk-through. The NRC is also approving alternative examination criteria in response to a July 28, 2016, request from South Carolina Electric & Gas Company (SCE&G or facility licensee).

DATES: This exemption and approval is effective as of August 22, 2016.

ADDRESSES: Please refer to Docket ID NRC–2008–0441 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0441. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):*

You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select *''Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that a document is referenced. The facility licensee's exemption request was submitted to the NRC by letter dated July 28, 2016 (ADAMS Accession No. ML16210A442).

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Paul Kallan, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2809; email: *Paul.Kallan@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

South Carolina Electric & Gas Company (SCE&G) and South Carolina Public Service Authority (Santee Cooper) (together, the ''VCSNS Owners'') are the holders of Combined License Nos. NPF–93 and NPF–94, which authorize the construction and operation of Virgil C. Summer Nuclear Station (VCSNS) Units 2 and 3, respectively.[1] VCSNS Units 2 and 3 are Westinghouse AP1000 pressurized-water reactors under construction in Jenkinsville, South Carolina. They are co-located with VCSNS Unit 1, which is an operating Westinghouse three-loop pressurized-water reactor.

VCSNS Unit 2 is under construction, and most of the plant systems have not been built. The facility licensee requests an exemption from the portion of section 55.45(b) of title 10 of the *Code of Federal Regulations* (10 CFR), requiring that the ''the [operator and senior operator] operating test will be administered in a plant walkthrough.'' Pursuant to 10 CFR 55.11, the ''Commission may, upon application by an interested person, or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property and are otherwise in the public interest.''

As an alternative to the in-plant methods of testing described in NUREG–1021, ''Operator Licensing Examination Standards for Power Reactors,'' the facility licensee proposes that applicants for operator and senior operator licenses at VCSNS Unit 2 be tested using discussion and performance methods in combination with plant layout diagrams, maps, equipment diagrams, pictures, and mock-ups. Approval of proposed alternatives is addressed in NUREG–1021, ES–201, ''Initial Operator Licensing Examination Process,'' Section B, ''Background.'' As stated therein,

> Facility licensees may propose alternatives to the examination criteria contained here and evaluate how the proposed alternatives provide an acceptable method of complying with the Commission's regulations. The NRC staff will review any proposed alternatives and make a decision regarding their acceptability. The NRC will not approve any alternative that would compromise the agency's statutory responsibility to prescribe uniform conditions for the operator licensing examinations.

Requirements for Operator Licensing Examinations

The Commission's regulations in 10 CFR part 55, ''Operators' Licenses,'' in part establish procedures and criteria for the issuance of licenses to operators and senior operators of utilization facilities licensed under the Atomic Energy Act of 1954, as amended, and 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' Pursuant to 10 CFR 55.51, ''Issuance of Licenses,'' ''If the Commission determines that an applicant for an operator license or a senior operator license meets the requirements of the Act and its regulations, it will issue a license in the form and containing any conditions and limitations it considers appropriate and necessary.'' Section 55.33(a) states in part that the Commission will approve an initial application for a license if it finds that (1) the applicant's health is sufficient and (2) the applicant has passed the requisite written examination and operating test in accordance with 10 CFR 55.41, ''Written Examination: Operators,'' or 10 CFR 55.43, ''Written Examination: Senior Operators,'' and 10 CFR 55.45, ''Operating Tests.'' These examinations and tests determine whether the applicant for an operator license has learned to operate a facility competently and safely, and additionally, in the case of a senior operator, whether the applicant has learned to direct the licensed activities of licensed operators competently and safely.

The regulations in 10 CFR 55.40(a) require the Commission to use the criteria in NUREG–1021, ''Operator Licensing Examination Standards for Power Reactors,'' in effect 6 months before the examination date to prepare the written examinations required by 10 CFR 55.41 and 55.43 and the operating tests required by 10 CFR 55.45; 10 CFR 55.40(a) also requires the Commission to use the criteria in NUREG–1021 to evaluate the written examinations and operating tests prepared by power reactor facility licensees pursuant to 10 CFR 55.40(b).

As stated in 10 CFR 55.40(b), power reactor facility licensees may prepare, proctor, and grade the written examinations required by 10 CFR 55.41 and 55.43 and may prepare the operating tests required by 10 CFR 55.45, subject to the following conditions: (1) They shall prepare the required examinations and tests in accordance with the criteria in NUREG–1021 as described in 10 CFR 55.40(a); (2) pursuant to 10 CFR 55.49, they shall establish, implement, and maintain procedures to control examination security and integrity; (3) an authorized representative of the facility licensee shall approve the required examinations and tests before they are submitted to the Commission for review and approval; and (4) they must receive Commission approval of their proposed written examinations and operating tests.

In accordance with 10 CFR 55.45(a), ''[t]he operating test, to the extent applicable, requires the applicant to demonstrate an understanding of and the ability to perform the actions necessary to accomplish a representative sample from among . . . 13 [listed] items.'' In accordance with 10 CFR 55.45(b):

Implementation—Administration. The operating test will be administered in a plant walkthrough and in either—

(1) A simulation facility that the Commission has approved for use after application has been made by the facility licensee under § 55.46(b);

(2) A plant-referenced simulator (§ 55.46(c)); or

(3) The plant, if approved for use in the administration of the operating test by the Commission under § 55.46(b).

The ''in a plant walkthrough'' portion of 10 CFR 55.45(b) is the subject of the exemption request.

NUREG–1021, Revision 10 (December 2014) (ADAMS Accession No. ML14352A297) establishes the policies, procedures, and practices for examining applicants for operator and senior operator licenses and licensees pursuant to 10 CFR part 55; it contains the examination standards that ensure the equitable and consistent administration of operator licensing examinations. NUREG–1021 is organized by topic into chapters designated with ''ES,'' which stands for ''examination standard.'' As relevant here, Chapter 2 (ES–2xx) addresses initial pre-examination activities and Chapter 3 (ES–3xx) addresses initial operating tests. Chapter 3 includes ES–301, ''Preparing Initial Operating Tests,'' and ES–302,

[1] SCE&G is authorized by the VCSNS Owners to exercise responsibility and control over the physical construction, operation, and maintenance of the facility and is the ''facility licensee'' as defined in 10 CFR 55.4 for purposes of this evaluation.

''Administering Operating Tests to Initial License Applicants.''

The NRC examiners and facility licensees use NUREG–1021 together with the applicable NRC knowledge and abilities (K/A) catalog. NUREG–2103, ''Knowledge and Abilities Catalog for Nuclear Power Plant Operators: Westinghouse AP1000 Pressurized-Water Reactors,'' was developed specifically to address the passive nature of the Westinghouse AP1000 design. The NRC K/A catalogs provide the basis for the development of content-valid operator licensing examinations. NUREG–1021, Appendix A, ''Overview of Generic Examination Concepts,'' Section C.1, ''Content Validity,'' describes that a content-valid examination establishes a link between the examination and the duties that the applicants will perform on the job. Also, this section states,

> Test items selected for inclusion in an NRC examination should be based on K/As contained in the appropriate K/A catalog. Testing outside the documented K/As can jeopardize the content validity of the examination. Content validity can also be reduced if important K/As are omitted from the examination.

The NRC K/A catalogs contain K/A statements that have been rated for their importance with respect to the safe operation of the plant. An importance rating less than 2.5 represents a K/A statement of limited importance for the safe operation of a plant. Such statements are generally considered as inappropriate content for NRC licensing examinations.

Operator licensing examinations developed using the applicable NRC K/A catalog along with the guidance in NUREG–1021 will sample the 13 items listed in 10 CFR 55.45(a) and also ensure that exam topics are associated with K/A statements of significant importance for the safe operation of the plant. Thus, the examinations will be content-valid.

The Operating Test

NUREG–1021, Revision 10, ES–301, ''Preparing Initial Operating Tests,'' Section B, ''Background,'' describes that the requirements in 10 CFR 55.45 for the operating test are met by administering a simulator test and a walk-through.

The simulator test is typically administered in a team format with up to three applicants in the main control room simulator. It implements Items 1–8 and 11–13 of 10 CFR 55.45(a) and is the most performance-based aspect of the operating test. The NRC examiners use the simulator test to evaluate each applicant's ability to safely operate the plant systems under dynamic, integrated conditions.

In contrast, the NRC examiners administer the walk-through to applicants one-on-one. The walk-through consists of two parts: Administrative topics and control room/in-plant systems. The administrative topics part of the walk-through implements Items 9–12 of 10 CFR 55.45(a) and covers K/As associated with administrative control of the plant. The control room/in-plant systems part of the walk-through implements the requirements of Items 3, 4, 7, 8, and 9 of 10 CFR 55.45(a) and encompasses several types of systems, including primary coolant, emergency coolant, decay heat removal, auxiliary, radiation monitoring, and instrumentation and control. ES–301 describes that the control room/in-plant systems part of the walk-through is used to determine whether the applicant has an adequate knowledge of plant system design and is able to safely operate those systems. This part of the walk-through focuses primarily on those systems with which licensed operators are most involved (*i.e.,* those having controls and indications in the main control room). To a lesser extent, it also ensures that the applicant is familiar with the design and operation of systems located outside the main control room.

To evaluate an applicant's knowledge and abilities relative to control room/in-plant systems and competence in the administrative topics, the NRC examiners administer job performance measures (JPMs) and, when necessary, ask specific follow-up questions based on the applicant's performance of the JPM. NUREG–1021 defines a JPM as ''[a]n evaluation tool that requires the applicant to perform (or simulate) a task that is applicable to the license level of the examination.''

Tasks are selected for evaluation in accordance with ES–301, Section D.4, ''Specific Instructions for the 'Control Room/In-Plant Systems' Walk-Through.'' This section directs the NRC examiners and facility licensees to select plant systems from the nine safety functions listed in the applicable NRC K/A Catalog. Table 1, ''Plant Systems by Safety Function,'' in NUREG–2103 contains a list of the AP1000 plant systems that are important to each of the nine major safety functions. ES–301, Section D.4.a, directs exam writers to (1) select plant systems from among the nine safety functions and then (2) for each plant system selected, select from either the NRC K/A catalog or the facility licensee's site-specific task list a task for which a JPM exists or can be developed. NUREG–1021, Appendix C, ''Job Performance Measure Guidelines,'' contains Form ES–C–2, ''Job Performance Measure Quality Checklist,'' (*i.e.,* the JPM Checklist), which states that every JPM should, among other things, (1) be supported by the facility's job task analysis (*i.e.,* the JPM must require applicants to perform tasks that are included in the facility licensee's site-specific task list, which is the product of its job task analysis) and (2) be ''operationally important.'' To be ''operationally important,'' the JPM Checklist states that a JPM must meet the threshold criterion of 2.5 in NUREG–2103 (*i.e.,* the K/A statement associated with the JPM must have an importance rating of 2.5 of higher), or as determined by the facility and agreed to by the NRC.

Additionally, ES–301, Section E.2.a, ''NRC Examiner Review,'' directs examiners to independently review each operating test for content, wording, operational validity (*i.e.,* test items address an actual or conceivable mental or psychomotor activity performed on the job), and level of difficulty using Form ES–301–3, ''Operating Test Quality Checklist.'' The JPMs must satisfy the criteria on Form ES–301–3 and the JPM Checklist to be administered as part of an operating test.

Per 10 CFR 55.45(b), the operating test will be administered in part in a plant walk-through. Further requirements for the plant walk-through (*i.e.,* the in-plant portion of the operating test) are given in ES–301, Section D.3, ''Specific Instructions for the 'Administrative Topics' Walk-through,'' and Section D.4, ''Specific Instructions for the 'Control Room/In-Plant Systems' Walk-Through.'' Concerning in-plant testing (*i.e.,* ''plant walk-through''), ES–301, Section D.4.a. states that from the nine safety function groupings identified in the K/A catalog, the appropriate number of systems to be evaluated based on the applicant's license level is given by the Table 1, ''Systems JPMs,'' below: [2]

[2] In the column labeled ''License Level,'' ''RO'' means ''reactor operator'' or ''operator; ''SRO–I'' means ''senior reactor operator—instant'' or ''senior operator;'' and ''SRO–U'' means ''senior reactor operator—upgrade,'' and refers to an operator applying to upgrade to a senior operator license.

TABLE 1—SYSTEMS JPMS

License level	Control room	In-plant	Total
RO	8	3	11
SRO–I	7	3	10
SRO–U	2 or 3	3 or 2	5

In addition, ES–301, Section D.4.a states: ''Each of the control room systems and evolutions (and separately each of the in-plant systems and evolutions) selected for RO and SRO–I applicants should evaluate a different safety function, and the same system or evolution should not be used to evaluate more than one safety function in each location.''

Also, ES–301, Section D.4.b states, ''at least one of the tasks conducted in the plant shall evaluate the applicant's ability to implement actions required during an emergency or abnormal condition, and another shall require the applicant to enter the RCA [radiologically controlled area].''

Taken together, the statements in ES–301, Sections D.4.a and D.4.b show that, for purposes of testing, the control room is separate from the plant. Control room system JPMs are typically performed in the control room simulator. Because plant equipment is not controlled from the simulator, applicants can demonstrate knowledge and abilities by using the simulator to perform the actions necessary to accomplish the task during the JPM. The simulator provides feedback to the applicant about the actions that he or she takes during performance of the task. For example, if the applicant operates a switch to start a pump, the simulator provides indications to the applicant that will allow him or her to determine whether the pump has started.

Administration of In-Plant JPMs

Typically, each JPM begins with the NRC examiner providing the applicant with a cue sheet, which contains the cue for the applicant to begin to perform the task. The cue sheet also provides the applicant with any initial conditions that he or she should assume have been established. After receiving the cue sheet, the applicant leads the NRC examiner to the location in the plant where the task will be performed. Once the applicant arrives at the correct location in the plant, he or she uses the appropriate plant procedure and the plant equipment in that location as a prop to describe to the NRC examiner exactly how he or she would perform the task. In contrast to a control room system JPM, where the applicant performs the task on the control room simulator, the applicant does not actually perform the task during an in-plant system JPM because applicants are not permitted to operate plant equipment while performing a JPM; only licensed control room operators can direct the operation of plant equipment (*i.e.,* an NRC examiner cannot direct the operation of plant equipment). Therefore, as stated in NUREG–1021, ES–301, Attachment 2, Page 21, to successfully complete a JPM in the plant, the applicant must ''describe exactly what it takes to perform an action.'' As described in NUREG–1021, Appendix C, ''Job Performance Measure Guidelines,'' Section B.4, ''Develop Examiner Cues,'' the NRC examiners develop scripted cues to provide the applicant with specific feedback on the equipment's response(s) to actions the applicant describes that he or she would take. These cues are necessary during JPMs performed in the plant because the applicant is not actually operating any equipment in the plant, and therefore the applicant will not have available the normal indications that would be observed during actual task performance.

Consider the following example. An NRC examiner provides the applicant with a cue sheet that directs him or her to start a standby diesel generator from its local control panel, which is located in the plant (*i.e.,* outside of the main control room), for a monthly equipment performance test. The applicant first must demonstrate to the NRC examiner that he or she can locate that particular local control panel in the plant by walking the NRC examiner to it. Once at the local control panel, the applicant must then verbally describe exactly how he or she would operate the control panel to perform the task of starting the standby diesel generator. The applicant will use the local control panel as a prop during this discussion (*e.g.,* the applicant could point to a control switch on the control panel to show the NRC examiner that he or she knows which one must be operated during actual task performance to raise the speed of the diesel generator). The applicant would also need to describe how he or she would expect the standby diesel generator to respond to his or her actions and the indications that he or she would use to monitor whether the standby diesel generator responded as expected. Because the equipment is not actually being operated during an in-plant JPM, the NRC examiner provides specific feedback regarding the equipment's reactions to the actions the applicant says that he or she would take.

If the applicant correctly locates the equipment in the plant and describes what it takes to perform the task, then the applicant will successfully complete the JPM. If the applicant demonstrates a lack of understanding of the equipment and procedures, then the NRC examiner will ask follow-up questions, as necessary, to confirm whether the applicant is familiar with the design and operation of that plant system.

Additionally, at least one JPM must be performed in the RCA. This provides an opportunity for the applicant to demonstrate knowledge of significant radiation hazards located in radiation and/or contamination areas inside the RCA and the ability to perform procedures to reduce excessive levels of radiation and to guard against personnel exposure.

Cold Licensing Process

NUREG–1021, ES–202, Section D.4, ''Cold License Eligibility,'' states, ''[c]old licensing is the process used prior to fuel load that provides a consistent method for operations personnel to acquire the knowledge and experience required for licensed operator duties following fuel load.'' The cold licensing process is described in Appendix A, ''Cold License Training Plan,'' of NEI 06–13A, ''Template for an Industry Training Program Description,'' Revision 2 (ADAMS Accession No. ML090910554). ''Final Safety Evaluation for Topical Report NEI 06–13A, 'Template for an Industry Training Program Description,' '' Revision 1, dated December 5, 2008 (ADAMS Accession No. ML082950140), documents the NRC staff's approval of NEI 06–13A for use in combined license applications. The facility licensee incorporated NEI 06–13A, Revision 2, by reference into the VCSNS Units 2 and 3 Updated Final Safety Analysis Report (UFSAR), Chapter 13, ''Conduct of Operation'' (ADAMS Accession No. ML15196A320). Section 13.2A.3,

''Conduct of On-the-Job Training (OJT),'' of the VCSNS Units 2 and 3 UFSAR states, ''[u]ntil plant construction is completed, acceptable methods for the conduct of on-the-job training include discussion, simulation, and use of mockup equipment and virtual reality technology.'' Section 13.2A.6, ''Cold Licensing Process Applicability and Termination,'' provides additional guidance on the conduct of OJT:

> As plant systems, components, and structures are completed, and as integrated plant operations begin, the systematic approach to training process will be used to adjust cold license class training methods and settings . . . The purpose is to optimize student learning using actual in-plant training and experience opportunities as they become available.

Additionally, Section 13.2A.7, ''Initial Licensed Operator Examination Schedule,'' states, ''[a]dministration of [initial] licensed operator examinations begins approximately 18 months prior to fuel load.''

II. Request/Action

By letter number NND–16–0266 from April R. Rice, Manager, Nuclear Licensing, New Nuclear Deployment; to the NRC dated July 28, 2016; titled, ''Request for an Exemption: Operator Licensing'' (ADAMS Accession No. ML16210A442); the facility licensee stated that it seeks to begin operator licensing examinations in September 2016. The facility licensee (1) applied for an exemption from the requirement in 10 CFR part 55 that requires using a plant walk-through as part of the operating test (*i.e.,* in-plant testing); and (2) proposed alternative examination criteria and methods. SCE&G's request is similar to the request submitted by letter number ND–16–0747 from Ms. Karen Fili, Site Vice President, Vogtle Electric Generating Plant (VEGP) Units 3 and 4; to the NRC dated May 27, 2016; titled, ''Southern Nuclear Operating Company Vogtle Electric Generating Plant (VEGP) Units 3 and 4 Revised Request for Exemption and RAI Response: Operator Licensing'' (ADAMS Accession No. ML16148A484). Southern Nuclear Company (SNC) is also constructing two Westinghouse AP1000 reactors at VEGP Units 3 and 4 in Burke County, Georgia. On June 24, 2016, the NRC staff granted SNC an exemption from the requirement in 10 CFR part 55 that requires using a plant walk-through as part of the operating test and approved SNC's alternative examination criteria and methods (ADAMS Accession No. ML16174A447).

Application for Exemption

Because VCSNS Unit 2 is under construction and most of the plant systems have not yet been built, the facility licensee requests an exemption from the requirement in 10 CFR 55.45(b) to administer a portion of the operating test ''in a plant walkthrough.''

Proposed Alternative

The facility licensee proposes an alternative to administering in-plant system JPMs in the plant: it proposes to use ''cold license training plan evaluation methods'' to administer in-plant system JPMs. Specifically, in Enclosure 1, ''Plant Walkthrough Exemption,'' Section 3.1, ''Administration of In-Plant JPMs Using Cold License Training Plan Methods,'' and Section 3.2, ''RCA Mockup Alternative to RCA Entry,'' of letter NND–16–0266, the facility licensee proposes using the following ''cold license training plan evaluation methods'' in lieu of the plant and plant equipment to administer in-plant system JPMs on an operating test:

- Plant layout diagrams,[3] equipment diagrams and plant maps—these documents will be used as necessary and/or as appropriate to allow an applicant to demonstrate knowledge of plant and equipment locations. Applicants will use these tools to describe how they would get to the location of the equipment that is the subject of the JPM instead of walking to the location. Applicants will identify the building, elevation, and room number in the plant where the equipment will be located when construction is complete.
- Maintenance Flow Loop—contains generic plant equipment, such as pumps, valves, and instruments for demonstrating the fundamental knowledge of operation and monitoring of plant equipment.
- Remote Shutdown Workstation—The VCSNS Unit 2 simulation facility includes a Remote Shutdown Workstation that simulates the controls located in the Remote Shutdown Room.
- Radiologically Controlled Area (RCA) mock-up—A training environment that allows applicants to demonstrate knowledge of radiation control subjects. Standards for entry into the mock-up RCA are identical to the actual RCA. The mock-up is used to train outage workers and licensed operators at VCSNS Unit 1. It contains simulated radiation areas and contaminated areas.
- Breaker Lab—the facility licensee expects to add a breaker lab to its training facilities before the end of 2016. It will not be available for the NRC exam planned for September 2016. When it is available, applicants will be able to use the breaker lab to demonstrate knowledge and abilities associated with operating breakers installed in the plant.
- Discuss method—using the procedure and props such as plant layout drawings, mock-ups, maps and pictures of equipment, the applicant will describe the actions he or she would take to operate equipment and explain how the equipment should respond to these actions. Discussion can cover required personal protective equipment, actions, system response and location. Location information can include specifics such as building, elevation, and room.
- Perform method—if the JPM is administered in the breaker lab, the flow loop trainer, or the part of the VCSNS simulation facility modeling the Remote Shutdown Workstation, applicants can perform actions during the JPM.

Additionally, the facility licensee stated that plant location drawings and pictures of plant components not directly related to the task that is the subject of the JPM will also be made available to maintain discriminatory value. Therefore, applicants that perform in-plant system JPMs in the plant as well as applicants that perform them using the proposed method must correctly identify the equipment that is the subject of the JPM to pass the JPM.

Expiration of Exemptions and Alternative

The facility licensee requested that the exemption expire after the Commission makes its finding in accordance with 10 CFR 52.103(g) (''The licensee shall not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met, except for those acceptance criteria that the Commission found were met under § 52.97(a)(2)'') for VCSNS Unit 2. The facility licensee requested that approval to use the alternative method terminate after the Commission makes its finding in accordance with 10 CFR 52.103(g) for VCSNS Unit 2. Additionally, the facility licensee stated that tasks that are selected to be part of an operating task in accordance with NUREG–1021, ES–301, Section D.4.a and Section D.4.b, where it is possible to both perform OJT for the task in the plant and administer a JPM developed from the task in a plant walk-through, then those JPMs will be administered in the plant.

[3] A plant layout diagram typically includes building names, building elevations, and room numbers.

III. Discussion

Granting of Exemption

Pursuant to 10 CFR 55.11, the Commission may, upon application by an interested person, or upon its own initiative, grant exemptions from the requirements of 10 CFR part 55 as it determines are (1) authorized by law and (2) will not endanger life or property and (3) are otherwise in the public interest.

1. The Exemption Is Authorized by Law

Exemptions are authorized by law where they are not expressly prohibited by statute or regulation. A proposed exemption is implicitly ''authorized by law'' if all of the conditions listed therein are met (*i.e.,* will not endanger life or property and is otherwise in the public interest), and no other provision prohibits, or otherwise restricts, its application. No provisions in law restrict or prohibit an exemption to the requirements concerning the plant walk-through portion of the operating test; the ''endanger'' and ''public interest'' factors are addressed later in this evaluation.

The regulations in 10 CFR part 55 implement Section 107 of the Atomic Energy Act of 1954, as amended (AEA), which sets requirements upon the Commission concerning operators' licenses and states, in part, that the Commission shall ''prescribe uniform conditions for licensing individuals as operators of any of the various classes of . . . utilization facilities licensed'' by the NRC. These requirements in the AEA do not expressly prohibit exemptions to the portion of 10 CFR 55.45(b) addressing in-plant JPMs and plant walk-throughs.

Preparing and evaluating operator examinations using the criteria in NUREG–1021 is a means of ensuring the equitable and consistent administration of operator licensing examinations for all applicants and thus helps to ensure uniform conditions exist for the operator licensing examinations administered as part of the licensing process. If the exemption is granted, there will be no changes to the preparation and grading of the written examinations, including the generic fundamentals examinations. There will be no changes to the preparation and evaluation of the simulator portions of the operating test. There will be no changes to the administrative portion of the operating tests. Although under the exemption part of the in-plant test will not be administered in the plant, the preparation and grading of the in-plant portion will be unchanged.

Upon balancing the overall effect on uniformity and consistency under the exemption, the NRC staff concludes that the uniform conditions will be maintained; the differences in the testing under the exemption will not prevent equitable administration of the operator licensing examinations or challenge the basis for the NRC examiners' licensing decisions. Accordingly, the testing will continue to comply with Section 107 of the AEA. Accordingly, the NRC staff has determined that granting of the facility licensee's proposed exemption will not result in a violation of the AEA, or the Commission's regulations. Therefore, the exemption is authorized by law.

2. The Exemption Will Not Endanger Life or Property

The exemption will not change the fundamental findings needed to issue an operator's or senior operator's license to an applicant. As stated in 10 CFR 55.33 ''Disposition of an initial application,''

(a) *Requirements for the approval of an initial application.* The Commission will approve an initial application for a license pursuant to the regulations in this part, if it finds that—

. . .

(2) *Written examination and operating test.* The applicant has passed the requisite written examination and operating test in accordance with §§ 55.41 and 55.45 or 55.43 and 55.45. These examinations and tests determine whether the applicant for an operator's license has learned to operate a facility competently and safely, and additionally, in the case of a senior operator, whether the applicant has learned to direct the licensed activities of licensed operators competently and safely.

Competent and safe operators protect against endangerment of life or property. Accordingly, where the tests adequately determine who is competent, those tests are protective of and do not endanger life or property.

The exemption from the requirement in 10 CFR 55.45(b) that the operating test be administered partially ''in a plant walkthrough'' will not endanger life or property mainly because 10 CFR 55.45(a) will still require the applicant to demonstrate an understanding of and the ability to perform the actions necessary to accomplish a representative sample of tasks. As required by 10 CFR 55.45(a), the content of the operating test will continue to be identified, in part, from learning objectives derived from a systematic analysis of licensed operator or senior operator duties performed by each facility licensee and contained in its training program and from information in the Final Safety Analysis Report, system description manuals and operating procedures, facility license and license amendments, Licensee Event Reports, and other materials requested from the facility licensee by the Commission. Although applicants will not be tested while physically located in front of installed in-plant equipment until the Commission makes its finding in accordance with 52.103(g), the knowledge and abilities applicants must demonstrate to pass the operating test will not change.

Accordingly, there is no endangerment of life or property as a result of the exemption.

3. The Exemption Is Otherwise in the Public Interest

The Commission's values guide the NRC in maintaining certain principles as it carries out regulatory activities. These principles focus the NRC on ensuring safety and security while appropriately balancing the interests of the NRC's stakeholders, including the public and licensees. These principles include Independence, Openness, Efficiency, Clarity, and Reliability. Whether granting of an exemption to the requirement to perform in-plant system JPMs in the plant would be in the public interest depends on consideration and balancing of the foregoing factors.

Efficiency

The public and licensees are all entitled to the best possible management and administration of regulatory activities. Regulatory activities should be consistent with the degree of risk reduction they achieve. Where several effective alternatives are available, the option that minimizes the use of resources should be adopted.

The NRC staff considered two options to determine whether one would minimize the use of resources and/or minimize risk: (1) Grant the exemption to the plant walk-through requirement and administer operator licensing examinations prior to completion of VCSNS Unit 2, or (2) deny the exemption and wait until the completion of construction to administer the operator licensing examinations. For either option, the same number of NRC examiners will be required to administer the operator licensing examinations at VCSNS Unit 2 prior to fuel load. Thus, the use of resources is not minimized by administering exams before the plant is built. Accordingly, the exemption is neutral with respect to the public's interest in efficiency.

Clarity

Regulations should be coherent, logical, and practical. There should be

a clear nexus between regulations and agency goals and objectives whether explicitly or implicitly stated. Here, the goal of the agency is to determine whether applicants for a license have learned to operate a facility competently and safely. Because the applicants must still demonstrate familiarity with the design and operation of systems located outside the main control room using the method proposed by the facility licensee, it is not necessary to perform the in-plant system JPMs within the completed VCSNS Unit 2 to achieve this goal. Accordingly, this factor shows that the exemption maintains the public interest in clarity.

Reliability

Regulations should be based on the best available knowledge from research and operational experience. Systems interactions, technological uncertainties, and the diversity of licensees and regulatory activities must all be taken into account so that risks are maintained at an acceptably low level. Once established, regulation should be perceived to be reliable and not unjustifiably in a state of transition. Regulatory actions should always be fully consistent with written regulations and should be promptly, fairly, and decisively administered so as to lend stability to the nuclear operational and planning processes.

If a sufficient number of applicants do not pass the exams, then the facility licensee may not have a sufficient number of personnel available for fuel load due to the mandatory time periods of 2 months to 2 years from the time of denial before an applicant may re-apply. Specifically per 10 CFR 55.35(a), an applicant whose application for a license has been denied because of failure to pass the written exam or the operating test, or both, may file a new application 2 months after the date of denial. The new application must include a statement signed by an authorized representative of the facility licensee that states in detail the extent of the applicant's additional training since the denial and certifies that the applicant is ready for re-examination. If the candidate fails a second time, then the applicant may file a third application 6 months after the date of denial, and may file further successive applications 2 years after the date of denial of each prior application. In Enclosure 1, ''Plant Walkthrough Exemption,'' Section 6.3, ''Otherwise in the Public Interest,'' of letter NND–16–0266, the facility licensee stated, ''[t]he current estimated forecast date of plant construction completion . . . is expected not earlier than June 2018.'' Fuel load is scheduled for Quarter 4 of 2018; however, the facility licensee also stated that this is subject to change due to ''developments during construction.'' If exams commence in June 2018, and fuel load occurs in late 2018, then there will only be at most 6 months between the time when licensing decisions will be made and fuel load. If a sufficient number of applicants do not pass the operating test, then the facility licensee must follow the re-application process in 10 CFR 55.35(a) or start training new candidates. As stated in Enclosure 1, Section 6.3, ''Otherwise in the Public Interest,'' of letter NND–16–0266, initial license training lasts approximately 24 months. Starting the exam process in 2016 will provide a sufficient amount of time for retraining applicants or training new candidates. Thus, granting the exemption will lend stability to the nuclear operational and planning process in that the individual operator licensing decisions will be made much sooner than otherwise would be possible, allowing the facility licensee to follow 10 CFR 55.35 in an orderly manner.

With respect to risk reduction, granting of the exemption will not require the NRC examiners or the applicants to enter the actual RCA, and therefore, the risk of radiation exposure for applicants and NRC examiners will be reduced to zero. Although NRC examiners and applicants typically do not receive any significant exposure to radiation or contamination during the conduct of operating tests administered inside the RCA, the NRC staff concludes that reducing the risk of exposure to zero aligns with the agency's goal of maintaining exposure to ionizing radiation as low as is reasonable achievable (ALARA). Accordingly, this factor shows that the exemption favors the public's interest in reliability.

Independence

Nothing but the highest possible standards of ethical performance and professionalism should influence regulation. However, independence does not imply isolation. All available facts and opinions must be sought openly from licensees and other interested members of the public. The many and possibly conflicting public interests involved must be considered. Final decisions must be based on objective, unbiased assessments of all information, and must be documented with reasons explicitly stated.

With the granting of this exemption, the NRC staff will still continue to independently assess whether the applicants at VCSNS Unit 2 have the skills, knowledge, and abilities necessary to operate the plant safely and competently. The operator licensing decisions will continue to be based on the NRC examiners' objective, unbiased assessments of each applicant's performance, which will be documented in accordance with NUREG–1021, ES–303, ''Documenting and Grading Initial Operating Tests.'' Accordingly, this factor shows that the exemption maintains the public interest in independence.

Openness

Nuclear regulation is the public's business, and it must be transacted publicly and candidly. The public must be informed about and have the opportunity to participate in the regulatory processes as required by law. Open channels of communication must be maintained with Congress, other government agencies, licensees, and the public, as well as with the international nuclear community.

Granting the exemption allows the portion of the operating test that would otherwise be performed in the plant to be administered in a location other than the plant. The operator licensing examination process described in NUREG–1021 will still be followed using the alternate method proposed by the facility licensee. Therefore, this factor shows that the exemption maintains the public's interest in openness.

Balancing of Factors

Accordingly, the balancing of these factors shows that the exemption is otherwise in the public interest.

Conclusion

The Commission concludes that the exemption is (1) authorized by law and (2) will not endanger life or property and (3) is otherwise in the public interest. Therefore, the Commission grants SCE&G an exemption from the requirement of 10 CFR 55.45(b) to administer a portion of the operating test ''in a plant walkthrough.''

Approval of Alternative

NUREG–1021, ES–201, Section B, ''Background,'' states,

> Facility licensees may propose alternatives to the examination criteria contained here and evaluate how the proposed alternatives provide an acceptable method of complying with the Commission's regulations. The NRC staff will review any proposed alternatives and make a decision regarding their acceptability. The NRC will not approve any alternative that would compromise the agency's statutory responsibility to prescribe uniform conditions for the operator licensing examinations.

As discussed below, the facility licensee's proposed alternatives provide an acceptable method of complying with the Commission's regulations and will not compromise the agency's statutory responsibility to prescribe uniform conditions for the operator licensing examinations.

NUREG–1021, Appendix A, ''Overview of Generic Examination Concepts,'' Section B, ''Background,'' discusses internal and external attributes of an examination and their relationship to uniform conditions. The internal attributes of an examination include its level of knowledge (LOK), level of difficulty (LOD), and the use of exam question banks. The external attributes of an examination include the number and types of items, the length of the examination, security procedures, and proctoring instructions. Appendix A states,

> If the internal and external attributes of examinations are allowed to vary significantly, the uniform conditions that are required by Section 107 of the Atomic Energy Act of 1954, as amended, and the basis upon which the NRC's licensing decisions rest are challenged. The NRC must reasonably control and structure the examination processes to ensure the integrity of the licenses it issues.

In order to determine whether uniform conditions for licensing individuals as operators and senior operators at VCSNS Unit 2 will be maintained using the method proposed by the facility licensee, the NRC staff performed two actions. First, the NRC staff identified the differences between performing in-plant system JPMs in the plant and the facility licensee's proposed method of performing in-plant system JPMs. These are listed in the table below.

TABLE 2—SUMMARY OF DIFFERENCES

Performing in-plant system JPMs in the plant	Facility licensee's proposed method of performing in-plant system JPMs
1. Applicants demonstrate knowledge of equipment locations by walking the NRC examiner to the location of the equipment that is the subject of the JPM in the plant.	In lieu of walking the NRC examiner to the equipment that is the subject of the JPM, applicants demonstrate knowledge of equipment locations by using plant layout diagrams, equipment diagrams, and maps to describe to the NRC examiner how they would get to the location of the plant equipment that is the subject of the JPM. Applicants identify the building, elevation, and room number associated with the plant equipment that is the subject of the JPM.
2. Applicants use the plant equipment as a prop while they describe and how to operate the equipment to perform the task.	In lieu of using plant equipment as a prop, applicants use pictures of equipment or a mock-up of the equipment as a prop while they describe and simulate how to operate the equipment to perform the task.
3. Applicants must enter the RCA for at least one JPM	In lieu of entering the RCA in the plant, applicants enter a mock-up RCA for at least one JPM.

Second, the NRC staff evaluated whether the differences could cause the internal and external attributes of the in-plant system JPMs administered to applicants at VCSNS Unit 2 prior to the completion of plant construction to vary significantly from those administered to applicants at VCSNS Unit 2 after the completion of construction. The evaluation is documented below.

Evaluation of Internal Attributes

Level of Knowledge: As stated in NUREG–1021, Appendix A, Section C.3.c, ''Level of Knowledge Versus Level of Difficulty,'' LOK represents the range of mental demands required to answer a question or perform a task. It is a continuum of mental rigor that ranges from retrieving fundamental knowledge, which requires demonstrating a relatively low LOK, to retrieving that knowledge and also understanding, analyzing, and synthesizing that knowledge with other knowledge, which requires demonstrating a relatively high LOK. Test items that require an applicant to demonstrate a high LOK require multiple mental processing steps, which are usually the recall and integration of two or more pieces of data.

In-plant system JPMs performed in the plant are high LOK test items because they require applicants to recall knowledge such as the location of plant equipment, which was acquired during the initial training program, and also to demonstrate, by walking the NRC examiner to the correct equipment in the plant and by describing the actions that they would take to operate the equipment, an understanding of and familiarity with the design and operation of that equipment. Applicants must also respond to the cues provided by the NRC examiner during the JPM. To successfully complete the JPM, the applicant must be able to analyze the information provided by these cues, apply knowledge of the design and operation of the equipment to determine the appropriate action(s), and then describe the action(s) to the NRC examiner.

The NRC staff determined that the three differences listed in Table 2 do not cause the LOK that an applicant at VCSNS Unit 2 must demonstrate during in-plant system JPMs administered prior to the completion of plant construction to vary significantly from the LOK that an applicant must demonstrate during in-plant system JPMs performed after the completion of construction at VCSNS Unit 2 for the following reasons.

- As shown in Difference #1 in Table 2, the facility licensee proposes that applicants at VCSNS Unit 2 demonstrate knowledge of equipment locations by using plant layout diagrams, equipment diagrams, and/or maps to show the NRC examiner how they would get to the location in the plant where the task would be performed. The facility licensee stated in Enclosure 1, ''Plant Walkthrough Exemption,'' Section 5.5, ''Conclusion,'' of letter NND–16–0266 that the proposed method of performing in-plant system JPMs ''does not impact the ability to maintain equitable and consistent testing under uniform conditions because license applicants will be evaluated using the same methods employed during their training.'' Therefore, the NRC staff concludes that this method will require applicants at VCSNS Unit 2 to recall and demonstrate knowledge of plant equipment location(s), which were addressed in the training program, to successfully complete the JPM even though the JPM will not be performed in the plant.
- As shown in Difference #2 in Table 2, the facility licensee proposes that applicants at VCSNS Unit 2 describe how they will operate the equipment and explain how they expect the

equipment and systems to respond to their actions using props such as pictures of the equipment or a mock-up equipment in lieu of the actual equipment in the plant. Just as during a JPM in the plant, NRC examiners will need to provide scripted cues to the applicants in response to the actions the applicants say that they would take. The applicants will have to analyze the information provided by these cues, apply knowledge of the design and operation of the equipment to determine the appropriate action(s), and then describe the action(s) to the NRC examiner. Therefore, the NRC staff concludes that this method will require applicants at VCSNS Unit 2 to describe the actions that they would take to operate the equipment and analyze information provided by cues to successfully complete the JPM even though the JPM will not be performed in the plant.

• As shown in Difference #3 in Table 2, applicants at VCSNS Unit 2 will be required to demonstrate how to enter the RCA. The facility licensee has established a mock-up of the RCA that contains simulated radiation areas and contaminated areas, and ''standards for entry into the mockup RCA are identical to an actual RCA.'' Therefore, the NRC staff concludes that this method will require applicants at VCSNS Unit 2 to demonstrate knowledge of significant radiation hazards located in radiation and/or contamination areas inside the RCA and the ability to perform procedures to reduce excessive levels of radiation and to guard against personnel exposure even though the JPM will not be performed in the plant.

Accordingly, the NRC staff concludes that the facility licensee's proposed method of performing in-plant system JPMs will not cause the LOK of the in-plant system JPMs administered to applicants at VCSNS Unit 2 prior to the completion of plant construction to vary significantly from those administered to applicants at VCSNS Unit 2 after the completion of construction.

Level of Difficulty: As stated in NUREG–1021, Appendix A, Section C.3.c, ''Level of Knowledge Versus Level of Difficulty,'' the NRC examiners evaluate a test item's LOD ''to ensure that the item can help discriminate between safe and unsafe operators.'' ''Safe operators'' are the applicants who pass all portions of the operator licensing examination in accordance with the grading criteria identified in NUREG–1021, ES–303, ''Documenting and Grading Initial Operating Tests.'' To pass the walk-through portion of the operating test, applicants must earn a score of 80% or higher. Thus, NUREG–1021 recommends that the difficulty for individual test items range between 70% and 90% (*i.e.,* 70–90% of applicants could successfully perform the test item). To achieve this, NUREG–1021 states that the NRC examiners must integrate the following concepts: the LOK of the test item, the operational validity of the test item (*i.e.,* the test item requires applicants to perform mental or psychomotor activities that they will have to perform on the job), the ability of distractors to distract the examinees, and the examinees' past performance on items of similar difficulty. Appendix A acknowledges that ''assigning a level of difficulty rating to an individual test item is a somewhat subjective process.''

The NRC staff determined that the three differences listed in Table 2 do not cause the LOD that an applicant at VCSNS Unit 2 must demonstrate during in-plant system JPMs administered prior to the completion of plant construction to vary significantly from the LOD that an applicant must demonstrate during in-plant system JPMs performed after the completion of construction at VCSNS Unit 2 for the following reasons.

• As shown in Difference #1 in Table 2, the facility licensee proposes that applicants at VCSNS Unit 2 demonstrate knowledge of equipment locations by using plant layout diagrams, equipment diagrams, and/or maps to (1) to describe to the NRC examiner how they would get to the location of the plant equipment that is the subject of the JPM and to (2) correctly identify the building, elevation of the building, and room number where the equipment will be located in VCSNS Unit 2. Additionally, the facility licensee proposes that ''plant layout diagrams and/or pictures of components not directly related to the task will also be made available to the applicant to maintain discriminatory value . . .''

When an in-plant system JPM is performed in the plant, applicants must physically walk the NRC examiner to the correct location in the plant where the task will be performed. Applicants must choose the correct location from among all of the other accessible plant locations. Similarly, applicants at VCSNS Unit 2 must choose the correct plant layout diagram(s), equipment diagrams and/or map(s) from a set of diagrams and/or maps in order to show the NRC examiner how they would locate the equipment in the plant.

If an applicant at an operating reactor has spent a sufficient amount of time in the plant becoming familiar with its layout and the location of plant equipment, then walking the NRC examiner to the correct location during a JPM in the plant should be a relatively easy task. Otherwise, this will be a relatively difficult task, and the applicant may not be able to perform the JPM if he or she cannot find the equipment that is the subject of the JPM. Similarly, if an applicant at VCSNS Unit 2 has spent a sufficient amount of time becoming familiar with the plant layout diagrams and maps, then using these tools to show the NRC examiner how he or she would access the equipment should be a relatively easy task. Otherwise, this will be a relatively difficult task, and the applicant may not be able to continue with the JPM because he or she will not successfully demonstrate the ability to access the equipment. In both cases, the applicants will either be able to demonstrate knowledge to the NRC examiner, or they will not be able to demonstrate knowledge. The NRC staff concludes that both methods require applicants to select the correct location of plant equipment from among other choices, and therefore the NRC examiners will still be able to discriminate between operators that have this knowledge and those that do not. Therefore, the LOD of the two methods is comparable.

Also, the NRC staff considered the implications for the testing process of physically walking in the plant to a specific location as compared to using plant layout diagrams and/or maps to show and describe the route that would be taken to find the correct location impacted LOD. Both methods require an applicant to recall and show knowledge of plant locations to the NRC examiner. However, applicants at plants that have been constructed will have spent time becoming familiar with the routes through the plant that they must take to access equipment during the conduct of OJT in the plant. During an in-plant system JPM in the plant, they will likely be able to recall the route(s) they have previously traveled by relying on unique visual clues available in the plant such as signage and various access control points that they must pass through to navigate their path to the equipment that is the subject of the JPM. They may also possibly rely on muscle memory to some extent to locate the equipment that is the subject of the JPM. Additionally, NUREG–1021, Appendix E, ''Policies and Guidelines for Taking NRC Examinations,'' contains directions that NRC examiners provide to applicants and licensed operators prior to every NRC examination. Appendix E, Section C.3, states,

> The operating test is considered ''open reference.'' The reference materials that are normally available to operators in the facility

and control room (including calibration curves, previous log entries, piping and instrumentation diagrams, calculation sheets, and procedures) are also available to you during the operating test.

Plant layout diagrams and site maps are normally available to operators. Thus, applicants at plants that have been constructed may use plant layout diagrams and site maps to help them to locate the equipment that is the subject of the JPM if they cannot recall the location of the equipment from memory.

Unlike applicants at plants that have been constructed, the applicants at VCSNS Unit 2 that take operator licensing examinations prior to the completion of plant construction will only use plant layout diagrams and maps to describe the route they would take to access the plant equipment. This method requires applicants to stand in front of a document and trace or identify the route that would be taken. This method is different from actually walking to a location in the plant because (1) visual clues that would be available to applicants in the plant will not be available, and (2) this method requires applicants to use fewer motor skills, and thus it is not likely that applicants will be able to use any muscle memory. This may increase the LOD. However, the facility licensee stated in Enclosure 1, ''Plant Walkthrough Exemption,'' Section 5.5, ''Conclusion,'' of the letter NND–16–0266 that the proposed method of performing in-plant system JPMs will ''not impact the ability to maintain equitable and consistent testing under uniform conditions because license applicants will be evaluated using the same methods employed during their training.'' The NRC staff concludes that any increase in LOD as a result of only using plant layout diagrams and maps to demonstrate knowledge of locations will be offset by the fact that the applicants will have been specifically trained on the locations of plant equipment with these tools.

• As shown in Difference #2 in Table 2, applicants will use pictures of equipment or a mock-up of the equipment as a prop while they describe and simulate how to operate the equipment to perform the task. Instead of pointing to a piece of equipment in the plant and verbally describing how to operate it, the applicant will either point to a diagram or picture of the equipment as a prop while describing how to operate it or use a piece of mock-up equipment to actually perform the task required by the JPM. The facility licensee proposes that diagrams and pictures of components not directly related to the task will also be made available to the applicant so that the applicant must make a choice. The NRC staff determined that the facility licensee's proposed method of performing in-plant system JPMs will require an applicant to select the correct piece of equipment from among other options, which is similar to having to make that selection in the plant. Therefore, the NRC examiners will still be able to discriminate between operators that have this knowledge and those that do not, and thus the LOD of the two methods is comparable.

The NRC staff also considered the difference in the quality of the props that the facility licensee proposes to use compared to the quality of the plant equipment as a prop. Enclosure 2, ''Information Related to the Vogtle Electric Generating Plant (VEGP) Units 3 and 4 NRC Requests for Additional Information (RAIs) on VEGP Plant Walkthrough Exemption,'' contains Table E–2, which lists tasks from the VCSNS Unit 2 site-specific task list for which an in-plant system JPM exists or could be developed. The NRC staff reviewed Table E–2 and determined that the maintenance flow loop trainer, the RCA mock-up, the Remote Shutdown Workstation, and the breaker lab (when it is available) can be used as props during some JPMs developed from the tasks listed in Table E–2. These props are realistic representations of certain pieces of plant equipment and are therefore equivalent to the actual plant equipment.

However, these props will not be able to be used for every in-plant system JPM because the in-plant tasks listed in Table E–2 include tasks unrelated to breaker operation, remote plant shutdown, the RCA, or plant components modeled in the flow loop trainer. For these tasks, which include tasks related to breaker operation that are developed into JPMs on operating tests administered before the breaker lab is available, the facility licensee proposes to use equipment diagrams or pictures of plant equipment as props. Pictures may not be the same size as the actual plant equipment, or they might not provide the same visual detail to an applicant that would be provided by the actual plant equipment. This could make these props more difficult to use compared to the actual plant equipment. However, because the facility licensee proposes to use the same methods during the administration of in-plant system JPMs that have been used in the training program, the NRC staff concludes that any increase in LOD as a result of using pictures or equipment diagrams to demonstrate knowledge will be offset by the fact that the applicants have used these props during their training.

• As shown in Difference #3 in Table 2, applicants will have to enter a mock-up of the RCA for at least one in-plant JPM. As stated in the facility licensee's submittal, the ''standards for entry into the mockup RCA are identical to an actual RCA.'' Therefore, the NRC staff concludes that this difference has no impact on the LOD of the in-plant system JPMs because there is no difference between demonstrating the ability to enter the actual RCA and demonstrating the ability to enter a mock-up of the RCA.

Accordingly, the NRC staff concludes that the facility licensee's proposed method of performing in-plant system JPMs will not cause the LOD of the in-plant system JPMs administered to applicants at VCSNS Unit 2 prior to the completion of plant construction to vary significantly from those administered to applicants at VCSNS Unit 2 after the completion of construction.

Use of Exam Banks: NUREG–1021, Form ES–301–2, ''Control Room/In-Plant Systems Outline,'' contains criteria for the use of JPMs in the facility licensee's exam bank that may be used on operator licensing examinations. In Enclosure 1, ''Plant Walkthrough Exemption,'' Section 5.3, ''Discrimination Validity,'' the facility licensee stated, ''[a]ny questions, discussions, or other cold licensing methods used for task evaluation will have no impact on how the examination bank is used.'' The NRC staff also concludes that the facility licensee's proposed method of performing in-plant system JPMs does not impact the use of exam banks because the facility licensee's proposed method of administering JPMs has nothing to do with the selection of JPMs from its exam bank.

In summary, the NRC staff concludes that the facility licensee's proposed method of performing in-plant system JPMs does not significantly impact the internal attributes of the in-plant system JPMs that will be administered to applicants at VCSNS Unit 2 prior to the completion of plant construction as compared to the in-plant system JPMs administered to applicants to applicants at VCSNS Unit 2 after the completion of construction.

Evaluation of External Attributes

The external attributes of an examination include the number and types of items (*e.g.,* in-plant system JPMs), the length of the examination, security procedures, and proctoring instructions. The facility licensee is not proposing to alter the number or types

of items, the length of the examination, security procedures, or proctoring instructions for any part of the operator licensing examination. Therefore, the NRC staff concludes that the external attributes of the in-plant system JPMs that will be administered to applicants at VCSNS Unit 2 prior to the completion of plant construction will be the same as those administered to applicants at VCSNS Unit 2 after the completion of construction.

Summary of Evaluation of Internal and External Attributes

In summary, the NRC staff concludes that the facility licensee's proposed method of performing in-plant system JPMs does not cause the internal and external attributes of the in-plant system JPMs administered to applicants at VCSNS Unit 2 prior to the completion of plant construction to vary significantly from those administered to applicants at VCSNS Unit 2 after the completion of construction. Because in-plant system JPMs are a portion of the operator licensing examination, the NRC staff also concludes that the facility licensee's proposed method does not cause the internal or external attributes of the operator licensing examinations that will be administered to applicants at VCSNS Unit 2 prior to the completion of plant construction to vary significantly from those administered to applicants at VCSNS Unit 2 after the completion of construction. Accordingly, the NRC staff finds that because the applicant's proposed method of performing in-plant system JPMs does not cause the internal and external attributes of the operator licensing examination to vary significantly, uniform conditions are sufficiently maintained, and the alternative method is acceptable.

Impact of Plant Construction on Developing Content-Valid Exams

Using NUREG–2103 in conjunction with NUREG–1021 ensures that exams are consistently content-valid. Table 1, ''Plant Systems by Safety Function,'' in NUREG–2103, lists each of the AP1000 plant systems associated with the nine safety functions. NUREG–1021, ES–301, Section D.4.a states that each of the three in-plant systems selected for an operating test should (1) be different and (2) be associated with a different safety function as listed in Table 1 of NUREG–2103. Administering a set of three in-plant system JPMs that are each associated with different plant systems and different safety functions maximizes the variety and scope of in-plant system K/As that NRC examiners sample during the operating test. If the variety and scope of in-plant system K/As that NRC examiners could sample were limited for some reason, then the content validity of the operating test could be reduced.

In Enclosure 2, ''Information Related to the Vogtle Electric Generating Plant (VEGP) Units 3 and 4 NRC Requests for Additional Information (RAIs) on VEGP Plant Walkthrough Exemption'' of letter NND–16–0266, the facility licensee provided Table E–2, ''In-Plant Task List.'' Table E–2 lists 91 tasks from the site-specific task list that can be used to develop an in-plant JPM at this time. These tasks have an importance rating of 2.5 or higher, can be performed using the proposed alternative method, and have procedures available. Because not all plant systems have been constructed, some procedures are not available at this time for some of the tasks on the site-specific task list. A JPM cannot be performed without a procedure. Consequently, there are in-plant tasks on the site-specific task list that have an importance rating of 2.5 or higher and cannot be used to develop a JPM at this time. To determine whether this would significantly reduce the content validity of the exam, the NRC staff performed the following actions.

First, the NRC staff reviewed the 91 tasks in Table E–2 and counted the number of tasks associated with each plant system listed in the table. Then, the staff counted how many of these plant systems were associated with each of the safety functions listed in Table 1 of NUREG–2103. The NRC staff found that an in-plant system JPM can be developed for at least one plant system associated with each of the nine safety functions except for Safety Function 3, ''Reactor Pressure Control.'' NUREG–2103 lists two plant systems associated with Safety Function 3: The Automatic Depressurization System (ADS) and the Pressurizer Pressure Control System (PPCS). The ADS and PPCS are primarily operated from the main control room, and therefore the control room system JPMs can be used to test the applicants' knowledge of and ability to operate the two systems related to Safety Function 3. Thus, the NRC staff concludes that a set of three in-plant system JPMs that are associated with three different plant systems as well as with three different safety functions can be developed, and therefore, the sample of in-plant tasks that exists at this time is sufficient to ensure that the examinations administered to applicants at VCSNS Unit 2 before the completion of construction and the examinations administered to applicants at VCSNS Unit 2 when construction is complete are content-valid exams.

Impact of Alternative Method on Knowledge Retention and Learning New Knowledge

The NRC staff has assurance that all applicants who become licensed at VCSNS Unit 2 will be trained and tested on new procedures and tasks as they become available. This is because all licensed operators are subject to the requalification requirements of 10 CFR 55.59. These requirements include additional operating tests as follows:

(a) *Requalification requirements.* Each licensee shall—

(1) Successfully complete a requalification program developed by the facility licensee that has been approved by the Commission. This program shall be conducted for a continuous period not to exceed 24 months in duration.

(2) Pass a comprehensive requalification written examination and an annual operating test.

(i) The written examination will sample the items specified in §§ 55.41 and 55.43 of this part, to the extent applicable to the facility, the licensee, and any limitation of the license under § 55.53(c) of this part.

(ii) The operating test will require the operator or senior operator to demonstrate an understanding of and the ability to perform the actions necessary to accomplish a comprehensive sample of items specified in § 55.45(a) (2) through (13) inclusive to the extent applicable to the facility.

In other words, the applicants who receive a license will be required to take additional operating tests to maintain the license as part of the licensed operator requalification program. Therefore, the requalification program gives the NRC staff additional confidence that, as the plant is completed, operators will be continually trained and tested on operationally-important in-plant systems and tasks directed by procedures that have not been developed yet.

NUREG–1021 provides guidance for applicants transitioning from the initial license program to the requalification program: ES–605, Section C.1.b, states, ''Newly licensed operators must enter the requalification training and examination program promptly upon receiving their licenses.'' Also, ES–204 states that the region may administer a license examination to an applicant who has not satisfied the applicable training or experience requirements at the time of the examination, but is expected to complete them shortly thereafter. These requirements in NUREG–1021 help to ensure that the period of time between completing all of the requirements to be licensed, which includes completing the initial license training program and

passing the operator licensing examination, and entering a requalification program that meets the requirements of 10 CFR 55.59 is minimized so that applicants (1) receive refresher training on topics learned in the initial training program, which ensures knowledge retention of operationally-important topics, and (2) receive training on new operationally-important topics as they becomes available (*e.g.,* new procedures and tasks).

In Enclosure 1, ''Plant Walkthrough Exemption,'' Section 6.3, ''Otherwise in the Public Interest,'' of letter NND–16–0266, the facility licensee stated that applicants ''cannot simultaneously participate in preoperational testing activities while in ILO [initial licensed operator] classes.'' As described in NEI 06–13A, Appendix A, applicants in the cold licensing process must complete at least 6 months of ''practical and meaningful work experience,'' which includes participation in preoperational testing, as part of the experience requirements for an operator's license. Applicants that do not complete any or a portion of the 6 months of practical and meaningful work assignments prior to enrolling in the ILO program will have to do so before the NRC issues a license. Therefore, some applicants at VCSNS Unit 2 may not complete the requirements to be licensed ''shortly'' after taking the operator licensing examination. Because these applicants would not yet be licensed, under NRC regulations they would not be required to be enrolled in a training program that meets the requirements of 10 CFR 55.59, ''Requalification.''

Although these applicants will be participating in practical and meaningful work assignments to gain experience with the AP1000 design, these assignments do not necessarily ensure that these applicants will receive refresher training on topics learned in the ILO program or receive training on new topics as they become available. In accordance with 10 CFR 55.51,

> If the Commission determines that an applicant for an operator license or a senior operator license meets the requirements of the Act and its regulations, it will issue a license in the form and containing any conditions and limitations it considers appropriate and necessary.

Therefore, the Commission may find it necessary to issue licenses with any conditions or limitations that may be necessary to ensure that the applicants have retained knowledge and learned new operationally-important topics during the time between completion of the operator licensing examination and issuance of the license.

In summary, as allowed by NUREG–1021, ES–201, Section B, ''Background,'' with its exemption request, the facility licensee proposed alternatives to the examination criteria contained in NUREG–1021 with respect to the in-plant/plant walk-through portions of the operating test. The NRC staff reviewed the proposed method of administering in-plant system JPMs described in letter NND–16–0266. For the reasons described above, the NRC staff concluded that the proposed alternatives provide an acceptable method of complying with the Commission's regulations, as exempted.

If, in the future, the facility licensee desires to implement an approach that differs from the alternative described in letter NND–16–0266, then it should seek approval from the NRC.

Limitations and Expiration

The facility licensee requested the exemption from the regulation that requires the operating test to be administered in a plant walk-through because of the incomplete construction of the plant. As construction of different sections of the facility becomes substantially complete and in-plant systems, components, and structures (SSCs) near completion, use of this exemption will become unnecessary for those areas and SSCs. Accordingly, on a case-by-case basis, for those tasks that are selected to be part of an operating task in accordance with NUREG–1021, ES–301, Section D.4.a and Section D.4.b, where it is possible to both perform OJT for an in-plant task in the plant and administer a JPM developed from that task in a plant walk-through, as determined by the NRC examiners, this exemption may not be used. Furthermore, this exemption will finally expire and may no longer be used upon the Commission's finding for VCSNS Unit 2 in accordance with 10 CFR 52.103(g) (''The licensee shall not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met, except for those acceptance criteria that the Commission found were met under § 52.97(a)(2).'').

Environmental Consideration

This exemption allows one, two, or three of the required in-plant system JPMs to be performed using discussion and performance methods in combination with plant layout diagrams, maps, equipment diagrams, pictures, and mock-ups in lieu of plant equipment. The NRC staff evaluated whether there would be significant environmental impacts associated with the issuance of the requested exemptions. The NRC staff determined the proposed action fits a category of actions that do not require an environmental assessment or environmental impact statement.

For the following reasons, this exemption meets the eligibility criteria of 10 CFR 51.22(c)(25) for a categorical exclusion. There is no significant hazards consideration related to this exemption. The NRC staff has also determined that the exemption involves no significant increase in the amounts, and no significant change in the types, of any effluents that may be released offsite; that there is no significant increase in individual or cumulative public or occupational radiation exposure; that there is no significant construction impact; and that there is no significant increase in the potential for or consequences from radiological accidents. Finally, the requirements to which the exemption applies involve qualification requirements. Accordingly, the exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(25). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the exemption.

IV. Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 55.11, issuing this exemption from the requirement in 55.45(b) to administer a portion of the operating test in a plant walk-through is authorized by law and will not endanger life or property and is otherwise in the public interest. The Commission also has approved the facility licensee's proposed alternative to the examination criteria in NUREG–1021, ES–301, Section D.4.a and Section D.4.b and therefore will allow one, two, or three of the required in-plant system JPMs to be performed using discussion and performance methods in combination with plant layout diagrams, maps, equipment diagrams, pictures, and mock-ups in lieu of plant equipment until the Commission makes a finding for VCSNS Unit 2 that acceptance criteria in the combined license are met in accordance with 10 CFR 52.103(g).

Dated at Rockville, Maryland, this 12th day of August 2016.

For the Nuclear Regulatory Commission.

Francis M. Akstulewicz,

Director, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2016–20030 Filed 8–19–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–280 and 50–281; NRC–2016–0105]

Virginia Electric Power Company; Surry Power Station, Unit Nos. 1 and 2; Use of AREVA's M5® Alloy Fuel Rod Cladding Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice that was published in the **Federal Register** (FR) on August 3, 2016, regarding an exemption issued on July 27, 2016. This action is necessary to correct a typographical error in the **SUMMARY** section from ''September 30, 2016,'' to ''September 30, 2015.''

DATES: The correction is effective August 22, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0105 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID: NRC–2016–0105. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Karen R. Cotton, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1438, email: *Karen.Cotton@nrc.gov.*

SUPPLEMENTARY INFORMATION: In the FR on August 3, 2016, in FR Doc. 2016–18357, on page 51218, the second column, first paragraph, fourth line, replace ''2016'' with ''2015.''

Dated at Rockville, Maryland, this 16th day of August, 2016.

For the Nuclear Regulatory Commission.

Karen R. Cotton,

Project Manager, Plant Licensing Branch 2–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–19982 Filed 8–19–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0001]

Sunshine Act Meeting Notice

DATES: August 22, 29, September 5, 12, 19, 26, 2016.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of August 22, 2016

There are no meetings scheduled for the week of August 22, 2016.

Week of August 29, 2016—Tentative

There are no meetings scheduled for the week of August 29, 2016.

Week of September 5, 2016—Tentative

There are no meetings scheduled for the week of September 5, 2016.

Week of September 12, 2016—Tentative

Monday, September 12, 2016

1:30 p.m. NRC All Employees Meeting (Public Meeting), Marriott Bethesda North Hotel, 5701 Marinelli Road, Rockville, MD 20852

Tuesday, September 13, 2016

2:00 p.m. Briefing on NRC International Activities (Closed—Ex. 1 & 9)

Friday, September 16, 2016

9:00 a.m. Briefing on Fee Process (Public Meeting) (Contact: Michele Kaplan: 301–415–5256)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of September 19, 2016—Tentative

Monday, September 19, 2016

9:00 a.m. Briefing on NRC Tribal Policy Statement (Public Meeting) (Contact: Michelle Ryan: 630–829–9724)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of September 26, 2016—Tentative

There are no meetings scheduled for the week of September 26, 2016.

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The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.*

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The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: August 18, 2016.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2016–20085 Filed 8–18–16; 4:15 pm]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2016–166; CP2016–261; MC2016–182 and CP2016–262; MC2016–183 and CP2016–263; MC2016–184 and CP2016–264]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing recent Postal Service filings for the

Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 24, 2016 (Comment due date applies to all Docket Nos. listed above)

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2016–166; *Filing Title:* Notice of the United States Postal Service of Filing Modification One to a Global Reseller Expedited Package Contracts 2 Negotiated Service Agreement; *Filing Acceptance Date:* August 16, 2016; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Katalin K. Clendenin; *Comments Due:* August 24, 2016.

2. *Docket No(s).:* CP2016–261; *Filing Title:* Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 6 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* August 16, 2016; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Natalie R. Ward; *Comments Due:* August 24, 2016.

3. *Docket No(s).:* MC2016–182 and CP2016–262; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 31 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* August 16, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Jennaca D. Upperman; *Comments Due:* August 24, 2016.

4. *Docket No(s).:* MC2016–183 and CP2016–263; *Filing Title:* Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contact 27 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* August 16, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Jennaca D. Upperman; *Comments Due:* August 24, 2016.

5. *Docket No(s).:* MC2016–184 and CP2016–264; *Filing Title:* Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contact 28 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* August 16, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Katalin K. Clendenin; *Comments Due:* August 24, 2016

This notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–20003 Filed 8–19–16; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78589: File No. SR–NYSE–2016–55]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change Adopting Maximum Fees Member Organizations may Charge in Connection With the Distribution of Investment Company Shareholder Reports Pursuant to Any Electronic Delivery Rules Adopted by the Securities and Exchange Commission

August 16, 2016.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 15, 2016, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'' or the ''SEC'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt maximum fees member organizations may charge in connection with the distribution of investment company shareholder reports pursuant to any electronic delivery rules adopted by the Securities and Exchange Commission. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On May 20, 2015, the SEC proposed new rules that would expand the information that registered investment companies are required to report (the ''Investment Company Proposal'').[4] In addition to the expanded reporting requirements, the Investment Company Proposal includes proposed new Rule 30(e)–3, which would permit, but not require, investment companies to satisfy their annual and semiannual shareholder report delivery obligations under the Investment Company Act by making shareholder reports available on the investment company's Web site. Investment companies relying on this provision would be required to meet conditions relating to, among other things, prior shareholder consent to electronic access rather than paper delivery of reports and notice to shareholders of the availability of shareholder reports.

Specifically, proposed Rule 30e–3 would require an investment company intending to rely on electronic access to reports to: (i) Transmit a statement to the shareholder at least 60 days prior to its reliance on proposed Rule 30e–3, notifying the shareholder of the issuer's intent to make future shareholder reports available on the issuer's Web site until the shareholder revokes consent; and (ii) send a notice within 60 days of the close of the fiscal period to shareholders who have consented to electronic transmission informing them that the report is available online. Proposed Rule 30e–3 would also require investment companies to send, at no cost to the requestor, a paper copy of any shareholder reports to any shareholder requesting such a copy.

NYSE Rule 451 requires NYSE member organizations to distribute proxy and other materials on behalf of issuers to the beneficial owners of the issuers' securities on whose behalf member organizations hold securities in ''street name'' accounts. This obligation is conditioned on the member organization's receipt from the issuer of reimbursement of all out-of-pocket expenses, including reasonable clerical expenses, incurred by such member organization in connection with such distribution. Rule 451 establishes maximum fees which member organizations may charge for handling distributions required under the rule.

Rule 451 also establishes maximum fees paid by issuers using the SEC's Notice and Access provisions pursuant to Rule 14a–16 under the proxy rules.[5] When an issuer elects to utilize Notice and Access for a proxy distribution, there is an incremental fee based on all nominee accounts through which the issuer's securities are beneficially owned as follows:

- 25 cents for each account up to 10,000 accounts;
- 20 cents for each account over 10,000 accounts, up to 100,000 accounts;
- 15 cents for each account over 100,000 accounts, up to 200,000 accounts;
- 10 cents for each account over 200,000 accounts, up to 500,000 accounts
- 5 cents for each account over 500,000 accounts.[6]

While mutual funds are not listed on the NYSE, the fees set forth in Rule 451 are applied by NYSE members in relation to distributions to ''street name'' holders of mutual fund and operating company shares. Mutual funds typically do not have to elect directors every year, and for this reason tend not to have shareholder meetings every year. However, every mutual fund is required by SEC rules to distribute each year both an annual and a semi-annual report to its shareholders, and so mutual funds pay the interim report fee set forth in Rule 451 of 15 cents per account each time they distribute materials to shareholders who hold mutual fund shares in ''street name.'' In addition, mutual funds pay a Preference Management Fee of 10 cents for every account with respect to which a member organization has eliminated the need to send paper materials. Under the current rule, the Preference Management Fee is in addition to, and not in lieu of, the interim report fee.

Under the rule as currently in effect, the Notice and Access fees in Rule 451 were intended to apply specifically to Notice and Access distributions under the SEC's proxy rules and they would not apply to electronic distributions under proposed Rule 30e–3 without a rule amendment. There have been a number of comment letters filed in relation to the Investment Company Proposal addressing the question of how the fees set forth in Rule 451 would apply to electronic distributions under proposed Rule 30e–3. The Investment Company Institute (''ICI'') submitted a comment letter on the Investment Company Proposal in which it noted that the NYSE ''appears to have little regulatory interest in fees brokers charge for delivery of fund materials'' and recommends that responsibility for the fees in relation to mutual fund distributions should be given instead to FINRA. As noted above, the Exchange has no involvement in the mutual fund industry and we therefore agree with the ICI that we may not be best positioned to take on the regulatory role in setting fees for mutual funds. To that end, we welcome the idea of considering whether FINRA should assume this role in the near future.[7] However, we also understand that the success of the electronic delivery system in proposed Rule 30e–3 is significantly dependent on the establishment of reasonable and transparent levels of reimbursement to brokers for their role in the process. Given the potential immediacy of this need, the Exchange has agreed to a request from the SEC that we adopt fees specific to electronic distributions of investment company materials.[8] We are doing so because the NYSE's historical role as the fee setter enables it to meet this need more efficiently in the short term than would be possible if that role were assumed by FINRA at this time.

The electronic delivery process under proposed Rule 30e–3 would require additional work on the part of the member organizations and their agents. As the proposed process is very similar to the existing Notice and Access process for which the Exchange has

[4] 80 FR 33590 (June 12, 2015); Investment Company Reporting Modernization, Securities Act Release No. 33–9776, Exchange Act Release No. 34–75002, Investment Company Act Release No. IC–31610 (May 20, 2015).

[5] 17 CFR 240.14a–16.

[6] To clarify, under this schedule, every issuer pays the tier one rate for the first 10,000 accounts, or portion thereof, with decreasing rates applicable only on additional accounts in the additional tiers.

[7] The Exchange believes that consideration should be given to the question of whether it would be more appropriate for FINRA to become the primary regulator of all fees charged by brokers in connection with distributions (*i.e.,* including operating company distributions and not just those of investment companies).

[8] These proposed fees would be effective only if the SEC adopts Rule 30e–3.

already adopted a fee schedule in Rule 451, the Exchange believes that it is appropriate to apply the existing Notice and Access fees to distributions under the SEC's proposed new rule. As such, the Exchange proposes to amend Section 5 of Rule 451.90 to specify that the Notice and Access fees set forth therein would also be charged with respect to the distribution of investment company shareholder reports pursuant to any ''notice and access'' rules adopted by the SEC in relation to such distributions.

In applying the Notice and Access fees to deliveries under proposed Rule 30e–3, the Exchange proposes to modify their application in one significant respect. Specifically, the Notice and Access fee will not be charged for any account with respect to which the investment company pays a Preference Management Fee. A Preference Management Fee is paid whenever a broker or its agent is able to suppress the need to send a physical mailing to an account, for example through ''householding'' of accounts (*i.e.,* the elimination of duplicative mailings to multiple accounts at the same address) or by getting account holders to agree to access materials through the broker's own enhanced broker's internet platform (or ''EBIP''). Under the current rule, an issuer utilizing Notice and Access pays Notice and Access fees with respect to all accounts, including those with respect to which it is paying a Preference Management Fee (and to which it is therefore not sending a notice). The Exchange proposes to amend Rule 451 to provide that investment companies utilizing any notice and access process established by the SEC will not be charged a Notice and Access fee for any account with respect to which they are being charged a Preference Management Fee. As such, funds will only pay Notice and Access fees with respect to accounts that actually receive Notice and Access mailings.[9]

Mutual funds often issue multiple classes of shares, so it is necessary to be clear how the pricing tiers in the Notice and Access fees would be applied to investment company shareholder report distributions. Therefore, the Exchange proposes to amend the rule to clarify that, in calculating the rates at which the issuer will be charged Notice and Access fees for investment company shareholder report distributions, all accounts holding shares of any class of share of the applicable issuer eligible to receive an identical distribution will be aggregated in determining the appropriate pricing tier.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act'') generally.[10] Section 6(b)(4) [11] requires that exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using the facilities of an exchange. Section 6(b)(5) [12] requires, among other things, that exchange rules promote just and equitable principles of trade and that they are not designed to permit unfair discrimination between issuers, brokers or dealers. Section 6(b)(8) [13] prohibits any exchange rule from imposing any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that the proposed amendment represents a reasonable allocation of fees among issuers as required by Section 6(b)(4) and is not designed to permit unfair discrimination within the meaning of Section 6(b)(5), as all issuers are subject to the same fee schedule.[14]

The Exchange believes that the proposed amendment does not impose any unnecessary burden on competition within the meaning of Section 6(b)(8). Issuers are unable to make distributions themselves to ''street name'' account holders, but must instead rely on the brokers that are record holders to make those distributions. In the Exchange's view, the proposed amendment does not create either any barriers to brokers being able to make their own distributions without an intermediary or any impediments to other intermediaries being able enter the market. For some time now a single intermediary has come to have a predominant role in the distribution of proxy material. The Exchange does not believe that the predominance of this existing single intermediary results from the level of the existing fees or that the proposed amended fees will change its competitive position or create any additional barriers to entry for potential new intermediaries. Moreover, brokers have the ultimate choice to use an intermediary of their choice, or perform the work themselves. Competitors are also free to establish relationships with brokers, and the proposed fees would not operate as a barrier to entry. For the foregoing reasons, the Exchange believes that its proposed fee schedule does not place any unnecessary burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that Rule 451 as amended by the proposed amendments does not impose any burdens on competition. Under Rule 451, a member organization is required to forward proxy and other material to beneficial owners of an issuer's securities only if the issuer reimburses it for its reasonable expenses incurred in connection with these distributions. Consequently, in amending Rule 451 to establish fees to be charged in connection with the SEC's proposed rule permitting the electronic distribution of investment company shareholder reports, the Exchange intended to establish fees which represented a reasonable level of reimbursement. As the Exchange's purpose was to establish fees that reflected a reasonable expense reimbursement level, the Exchange does not believe that the proposed amended fees will have the effect of providing a competitive advantage to any particular broker or existing intermediary or creating any barriers to entry for potential new intermediaries. For some time now a single intermediary has come to have a predominant role in the distribution of proxy material. The Exchange does not believe that the predominance of this existing single intermediary results from the level of the existing fees or that the proposed amended fees will change its competitive position or create any additional barriers to entry for potential new intermediaries. Moreover, brokers have the ultimate choice to use an intermediary of their choice, or perform the work themselves. Competitors are also free to establish relationships with brokers, and the proposed fees would not operate as a barrier to entry.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange received one written comment relevant to the proposal prior

[9] The Exchange is not proposing any modifications to the amount or application of the Preference Management Fee at this time.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78f(b)(8).

[14] The Exchange notes that the rules in this proposal do not involve dues, fees or other charges paid to the Exchange. Nonetheless, to the extent a Section 6(b)(4) analysis is appropriate, the Exchange has included one herein.

to its filing. This letter was from the ICI, in which it argued that the Exchange should interpret its existing rules as providing for the following:

• Investment companies should only have to pay interim report fees once per year rather than each time a report is delivered to shareholders;

• the Preference Management Fee should be charged only on a one-time basis in relation to any specific account;

• brokers should not be permitted to collect any fees whatsoever from investment companies in relation to fund shares held in managed accounts;

• brokers should not be allowed to receive any portion of the regulated fees collected by intermediaries conducting distributions on their behalf;

• the current rule should be interpreted as applying the Notice and Access fees to electronic deliveries under proposed Rule 30e–3; and

• the Notice and Access Fees should not be payable in relation to any account that does not actually receive a Notice and Access delivery under proposed Rule 30e–3.

The Exchange does not agree that there is any justification in the text of Rule 451 for regarding any of these positions as accurate interpretations of Rule 451 in its current form. The purpose of the current proposal is solely to amend Rule 451 to facilitate the SEC's potential finalization of proposed Rule 30e–3. Accordingly, and consistent with certain of ICI's recommendations, the Exchange is proposing changes to its rules to apply the Notice and Access fees with respect to the distribution of investment company shareholder reports pursuant to any ''notice and access'' rules adopted by the SEC in relation to such distributions. In addition, and also as recommended by the ICI in its letter, the Exchange's proposal would provide that the Notice and Access fee would only apply to accounts that actually receive Notice and Access deliveries under proposed Rule 30e–3 and not to accounts with respect to which investment companies are charged a Preference Management fee. The Exchange does not believe that the other, more substantial changes to the application of Rule 451 suggested by the ICI are necessary to implementation of Rule 30e–3 if the SEC were to finalize its proposal and, thus the Exchange believes those proposals should be given separate consideration.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2016–55 on the subject line.

Paper Comments

• Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2016–55. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2016–55 and should be submitted on or before September 12, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19897 Filed 8–19–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78586; File No. SR–NYSEMKT–2016–62]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing of Proposed Rule Change Amending Section 146 of the NYSE MKT Company Guide To Adjust the Entitlement to Services of Special Purpose Acquisition Companies

August 16, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 2, 2016, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Section 146 of the NYSE MKT Company Guide (the ''Company Guide'') to adjust the entitlement to services of special purpose acquisition companies. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of,

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 146 of the Company Guide to adjust the service entitlements of special purpose acquisition companies (''SPACs'') under that rule.

The Exchange offers complimentary products and services for a period of 24 calendar months from the date of initial listing to a category of listed companies defined as Eligible New Listings. Eligible New Listings include: (i) any U.S. company that lists common stock on the Exchange for the first time and any non-U.S. company that lists an equity security on the Exchange under Section 101 or 110 of the Company Guide for the first time, regardless of whether such U.S. or non-U.S. company conducts an offering, (ii) any U.S. or non-U.S. company that transfers its listing of common stock or equity securities, respectively, to the Exchange from another national securities exchange or (iii) any U.S. or non-U.S. company emerging from a bankruptcy, spinoff (where a company lists new shares in the absence of a public offering), and carve-out (where a company carves out a business line or division, which then conducts a separate initial public offering).

Eligible New Listings are entitled to receive Web-hosting products and services (with a commercial value of approximately $16,000 annually), web-casting services (with a commercial value of approximately $6,500 annually), whistleblower hotline services (with a commercial value of approximately $4,000 annually), news distribution products and services (with a commercial value of approximately $20,000 annually) and corporate governance tools (with a commercial value of approximately $15,000 annually) for a period of 24 calendar months from the date of initial listing on the Exchange. Notwithstanding the foregoing, however, if an Eligible New Listing begins to use a particular product or service provided for under Section 146 within 30 days of its initial listing date, the complimentary period will begin on the date of first use.

A SPAC is a special purpose company formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more operating businesses or assets. To qualify for initial listing a SPAC must meet one of the quantitative standards in Section 101 or 102 and also the SPAC-specific requirements of Section 119. At least 90% of the gross proceeds from the SPAC's initial public offering and any concurrent sale by the company of equity securities must be deposited in a trust account maintained by an independent trustee, an escrow account maintained by an ''insured depository institution'', as that term is defined in Section 3(c)(2) of the Federal Deposit Insurance Act, or in a separate bank account established by a registered broker or dealer (collectively, a ''deposit account''). Under Section 119(b), within 36 months of the effectiveness of a SPAC's initial public offering registration statement, or such shorter period that the company specifies in its registration statement, the company must complete one or more business combinations having an aggregate fair market value of at least 80% of the value of the deposit account (excluding any deferred underwriter's fees and taxes payable on the income earned on the deposit account) at the time of the agreement to enter into the initial combination (the ''Business Combination Condition'').

The Exchange now proposes to amend Section 146 to exclude newly-listed SPACs from the definition of Eligible New Listings. In lieu of receiving these services at the time of initial listing, the proposed amended rule would treat a SPAC that remains listed after meeting the Business Combination Condition as an Eligible New Listing and would provide the services to which that status would entitle it for 24 months from the date of meeting the Business Combination Condition.

The Exchange believes this approach is appropriate in light of the special characteristics of a SPAC. SPACs raise money on a one-time basis and typically trade at a price that is very close to their liquidation value. As such, SPAC managements are typically not focused on their stock price and investor relations to the same degree as operating companies are. As the services provided to Eligible New Listings are targeted in large part on those market-driven concerns of newly-listed operating companies, they are less useful to SPACs. A SPAC that has met the Business Combination Condition, on the other hand, is similarly situated to a newly-formed publicly-traded operating company and the Exchange believes that the services provided to Eligible New Listings will be as relevant and attractive to a SPAC that has met the Business Combination Condition as to the newly-listed operating companies that are generally eligible for those services.

The Exchange believes that companies will often require a period of time after meeting the Business Combination Condition to complete the contracting and training process with vendors providing the complimentary products and services. Therefore, many companies may not be able to begin using the suite of products offered to them immediately on becoming eligible. To address this issue, the Exchange proposes to specify in Section 146 that if a SPAC that has met the Business Combination Condition begins using a particular service within 30 days after the date of it met [sic] the Business Combination Condition, the complimentary period begins on such date of first use. In all other instances, the complimentary period will begin on the date the SPAC meets the Business Combination Condition.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Sections 6(b)(4)[5] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(5)[6] of the Act in that it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that it is reasonable to offer complimentary products and services to attract and retain listings and respond to competitive pressures. As SPACs are unlikely to utilize the services available to them currently at the time of initial listing but would likely find those services useful if they remain listed after they meet the Business Combination Condition, the Exchange believes it is reasonable to shift the time when SPACs are eligible for the services available to Eligible New Listings to the period

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(4).

[6] 15 U.S.C. 78f(b)(5).

immediately after meeting the Business Combination Condition.

The Exchange believes that it is not unfairly discriminatory to provide SPACs with the applicable services only if and when they meet the Business Combination Condition. The Exchange recognizes that not all SPACs will meet the Business Combination Condition and that some listed SPACs will therefore never become eligible for the services that would be provided to an otherwise similarly qualified operating company. However, given the specific characteristics of the SPAC structure, these services are generally not of any particular value to a SPAC prior to meeting the Business Combination Condition and the Exchange therefore believes that those SPACs that never qualify for the services will not suffer any meaningful detriment as a consequence.

Allowing SPACs up to 30 days after meeting the Business Combination Condition to start using the complimentary products and services is a reflection of the Exchange's experience that it can take companies a period of time to review and complete necessary contracts and training for services following their becoming eligible for those services. Allowing this modest 30 day period, if the company needs it, helps ensure that the company will have the benefit of the full period permitted under the rule to actually use the services, thus giving companies the full intended benefit.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In many cases, SPACs will consider transferring to a new listing venue at the time they meet the Business Combination Condition. The proposed rule change enables the Exchange to compete for the retention of these companies by offering them a package of complimentary products and services that assist their transition to being a publicly listed operating company for the first time. All similarly situated companies are eligible for the same package of services. Therefore, the proposed creation of Section 146 of the Company Guide will increase competition by enabling the Exchange to more effectively compete for listings.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or *up to 90 days* (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEMKT–2016–62 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–62. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–62 and should be submitted on or before September 12, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19894 Filed 8–19–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32219; 812–14632]

Davis Fundamental ETF Trust, et al.; Notice of Application

August 16, 2016.

Agency: Securities and Exchange Commission (''Commission'').

Action: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested order would permit (a) actively-managed series of certain open-end management investment companies (''Funds'') to issue shares redeemable in large aggregations only (''Creation Units''); (b) secondary market transactions in Fund shares to occur at negotiated market prices rather than at net asset value (''NAV''); (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of shares for redemption; (d) certain affiliated persons of a Fund to deposit securities

[7] 17 CFR 200.30–3(a)(12).

into, and receive securities from, the Fund in connection with the purchase and redemption of Creation Units; and (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the Funds (''Funds of Funds'') to acquire shares of the Funds.

Applicants: Davis Fundamental ETF Trust (the ''Trust''), a Delaware statutory trust, which will be registered under the Act as an open-end management investment company with multiple series, Davis Selected Advisers, L.P. (the ''Initial Adviser''), an investment adviser registered under the Investment Advisers Act of 1940, and Foreside Fund Services, LLC (the ''Distributor''), a broker-dealer registered under the Securities Exchange Act of 1934 (''Exchange Act'').

Filing Dates: The application was filed on March 24, 2016, and amended on June 14, 2016 and August 15, 2016.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on September 12, 2016, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

Addresses: Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: 2949 E. Elvira Road, Suite 101, Tucson, Arizona 85756.

For Further Information Contact: Hae-Sung Lee, Attorney-Adviser, at (202) 551–7345, or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

Supplementary Information: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. Applicants request an order that would allow Funds to operate as actively-managed exchange traded funds (''ETFs'').[1] Fund shares will be purchased and redeemed at their NAV in Creation Units only. All orders to purchase Creation Units and all redemption requests will be placed by or through an ''Authorized Participant'', which will have signed a participant agreement with the Distributor. Shares will be listed and traded individually on a national securities exchange, where share prices will be based on the current bid/offer market. Any order granting the requested relief would be subject to the terms and conditions stated in the application.

2. Each Fund will consist of a portfolio of securities and other assets and investment positions (''Portfolio Instruments''). Each Fund will disclose on its Web site the identities and quantities of the Portfolio Instruments that will form the basis for the Fund's calculation of NAV at the end of the day.

3. Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified in the application, purchasers will be required to purchase Creation Units by depositing specified instruments (''Deposit Instruments''), and shareholders redeeming their shares will receive specified instruments (''Redemption Instruments''). The Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund's portfolio (including cash positions) except as specified in the application.

4. Because shares will not be individually redeemable, applicants request an exemption from section 5(a)(1) and section 2(a)(32) of the Act that would permit the Funds to register as open-end management investment companies and issue shares that are redeemable in Creation Units only.

5. Applicants also request an exemption from section 22(d) of the Act and rule 22c–1 under the Act as secondary market trading in shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. Applicants state that (a) secondary market trading in shares does not involve a Fund as a party and will not result in dilution of an investment in shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants represent that share market prices will be disciplined by arbitrage opportunities, which should prevent shares from trading at a material discount or premium from NAV.

6. With respect to Funds that hold non-U.S. Portfolio Instruments and that effect creations and redemptions of Creation Units in kind, applicants request relief from the requirement imposed by section 22(e) in order to allow such Funds to pay redemption proceeds within fifteen calendar days following the tender of Creation Units for redemption. Applicants assert that the requested relief would not be inconsistent with the spirit and intent of section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds.

7. Applicants request an exemption to permit Funds of Funds to acquire Fund shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter for the Funds, and/or any broker or dealer registered under the Exchange Act, to sell shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act. The application's terms and conditions are designed to, among other things, help prevent any potential (i) undue influence over a Fund through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A) and (B) of the Act.

8. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act to permit persons that are Affiliated Persons, or Second Tier Affiliates, of the Funds, solely by virtue of certain ownership interests, to effectuate purchases and redemptions in-kind. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions of Creation Units will be the same for all purchases and redemptions and Deposit Instruments

[1] Applicants request that the order apply to the initial Fund, as well as to future series of the Trust and any future open-end management investment companies or series thereof (each, included in the term ''Fund''), each of which will operate as an actively-managed ETF. Any Fund will (a) be advised by the Initial Adviser or an entity controlling, controlled by, or under common control with the Initial Adviser (each, an ''Adviser'') and (b) comply with the terms and conditions of the application.

and Redemption Instruments will be valued in the same manner as those Portfolio Instruments currently held by the Funds. Applicants also seek relief from the prohibitions on affiliated transactions in section 17(a) to permit a Fund to sell its shares to and redeem its shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.[2] The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the policies of the Fund of Funds and will be based on the NAVs of the Funds.

9. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19900 Filed 8–19–16; 8:45 am]

BILLING CODE 8011–01–P

[2] The requested relief would apply to direct sales of shares in Creation Units by a Fund to a Fund of Funds and redemptions of those shares. Applicants, moreover, are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an Affiliated Person, or a Second-Tier Affiliate, of a Fund of Funds because an Adviser or an entity controlling, controlled by or under common control with an Adviser provides investment advisory services to that Fund of Funds.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78593; File No. SR–Phlx–2016–82]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing of Proposed Rule Change To Adopt a New Exception in Exchange Rule 1000(f) for Sub-MPV Split-Priced Orders

August 16, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 3, 2016, NASDAQ PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to adopt a new exception in Rule 1000(f) permitting Floor Brokers to execute certain split price orders in the trading crowd rather than electronically through the Options Floor Broker Management System, as described in detail below.

The text of the proposed rule change is set forth below. Proposed new language is underlined.

* * * * *

NASDAQ PHLX Rules

* * * * *

Options Rules

* * * * *

Rule 1000. Applicability, Definitions and References

(a)–(e) No change.

(f) All Exchange options transactions shall be executed in one of the following ways[, once the Exchange's new Options Floor Broker Management System functionality has been operating for a certain period to be established by the Exchange]:

(i) Automatically by the Exchange Trading System pursuant to Rule 1080 and other applicable options rules;

(ii) by and among members in the Exchange's options trading crowd none of whom is a Floor Broker; or

(iii) through the Options Floor Broker Management System for trades involving at least one Floor Broker. Although Floor Brokers may represent orders in the trading crowd, Floor Brokers are not permitted to execute orders in the Exchange's options trading crowd, except as follows:

(A) The Exchange may determine to permit executions otherwise than in accordance with subparagraphs (i)—(iii) above respecting an option or all options in the event of a problem with Exchange systems.

(B) In addition, Floor Brokers can execute orders in the options trading crowd pursuant to Rule 1059, Accommodation Transactions (cabinet trades), and Rule 1079, FLEX Equity, Index and Currency Options.

(C) Multi-leg orders with more than 15 legs can be executed in the trading crowd.

(D) The following split price orders that, due to FBMS system limitations, require manual calculation:

(I) simple orders not expressed in the applicable minimum increment (''sub-MPV'') and that cannot be evenly split into two whole numbers to create a price at the midpoint of the minimum increment; and

(II) complex and multi-leg orders with at least one option leg with an odd-numbered volume that must trade at a sub-MPV price or one leg that qualifies under (I) above.

Surveillance staff must approve all executions submitted under this Rule 1000(f)(iii) to validate that each abides by applicable priority and trade through rules, and that rounding of prices is used only where necessary to execute the trade at the MPV, and only to the benefit of a customer order or, where multiple customers' orders are involved, for the customer order that is earliest in time.

(g) No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposal is to provide an exception to the mandatory use of the Floor Broker Management System (''FBMS'') pursuant to Rule 1000(f) to permit Floor Brokers to execute certain split price orders in the trading crowd rather than electronically and to facilitate these transactions. Through the use of a surveillance process to verify that the conditions of the exception are met, the Exchange will ensure that the proposed exception is used only rarely.

Development of FBMS System

Until April 1, 2016, the Exchange operated two Options Floor Broker Management Systems concurrently on the options trading floor: the original Floor Broker Management System operating since 2005 (''FBMS 1'');[3] and the enhanced Floor Broker Management System (''FBMS 2''). After March 31, 2016, FBMS 1 was retired and Floor Brokers were required to use FBMS 2.

FBMS 2 was launched in March 2014 in order to prevent certain types of violations and enhance order handling protections. Currently, with FBMS 2, all options transactions on the Exchange involving at least one Floor Broker are required to be executed by FBMS 2 as opposed to being executed by the Floor Broker in the trading crowd.[4] All orders must continue to be represented in the trading crowd, but the negotiation and agreement that occurs in the trading crowd does not result in a final trade, but rather a ''meeting of the minds'' that is then submitted through FBMS 2 for execution in the matching engine.

The Exchange received approval to implement FBMS 2 as of June 1, 2013,[5] and delayed its implementation until July 2013,[6] until September 2013,[7] until December 2013,[8] and until March 2014.[9] Implementation began on March 7, 2014, with FBMS 2 operating concurrently with FBMS 1. FBMS 2 has been made available to all Floor Brokers in all options and, on March 31, 2016, FBMS 1 was retired.[10] As a result, FBMS 2 is the only system currently in use.

The Exchange has contracted with a third-party to build an alternative system (''FBMS 3'') to replace FBMS 2. The Exchange had intended to implement FBMS 3 by November 3, 2015, and then by March 2016, but, based on recent estimates from the third-party entity, it will be ready by November 30, 2016.[11] Despite the delays in launching FBMS 3, the new system is still needed to reduce the occurrence of latencies and abnormalities that have occurred with FBMS 2 that has affected multiple firms multiple times per week. The Exchange is committed to distributing a next-generation product in the form of FBMS 3.

Beginning last year, the Exchange explained the state of FBMS 3 to Commission staff in the spirit of sharing the context around the delay and the Exchange's then-current thoughts about deployment going forward. The Commission's notice of filing and immediate effectiveness of the proposed rule change extending the operation of FBMS 1 until March 31, 2016 stated that until FBMS 3 becomes available, the Exchange would continue to operate FBMS 1 and FBMS 2 concurrently and that all Floor Brokers may use either FBMS. Although that was the Exchange's intent at the time, the Exchange did not intend to tie the retirement of FBMS 1 to the deployment of FBMS 3; the availability of FBMS 1 until FBMS 3 became available was a likely assumption, but not the only possible outcome.

Despite the possibility that FBMS 2 may experience some latency or potential glitches, the Exchange determined in its regulatory discretion to retire FBMS 1 and not seek an extension of the rule permitting the concurrent operation of FBMS 1 and FBMS 2, a determination the Exchange announced on March 14, 2016.[12] Specifically, the Exchange believed that the regulatory and other benefits of exclusively using FBMS 2 across the trading floor should no longer be delayed. The electronic protections associated with the Commission's Market Access Rule[13] requirements are available on FBMS 2 (but not FBMS 1) such that the Exchange concluded this was a key reason to require the use of FBMS 2. The Floor Brokers themselves benefit from using FBMS 2 because they avoid certain violations, process complicated multi-leg orders more quickly and manage their orders, overall, better. The FBMS 3 delay and the importance of the Exchange's compliance record changed the situation such that the Exchange determined to let the permission to operate FBMS 1 expire.[14] FBMS 1 has not operated since March 31, 2016.

Proposal

The Exchange proposes to adopt a new exception to the mandatory use of FBMS to execute trades for the processing of split-price orders. Currently, Rule 1000(f) provides that all Exchange options transactions shall be executed in one of the following ways:

(i) Automatically by the Exchange Trading System pursuant to Rule 1080 and other applicable options rules;

(ii) by and among members in the Exchange's options trading crowd none of whom is a Floor Broker; or

(iii) through the Options Floor Broker Management System for trades involving at least one Floor Broker. Although Floor Brokers may represent orders in the trading crowd, Floor Brokers are not permitted to execute orders in the Exchange's options trading crowd.

[3] Under FBMS 1, orders were executed in the trading crowd by the Floor Broker and that execution was recorded in FBMS 1, which enabled the Exchange to electronically process the order in terms of trade reporting and clearing. If a trade that occurred in the trading crowd fails to give priority to an order on the book, for example, such violation is addressed by the Exchange's surveillance and enforcement programs after the fact.

[4] Securities Exchange Act Release No. 69471 (April 29, 2013), 78 FR 26096 (May 3, 2013) (SR–Phlx–2013–09).

[5] *Id.*

[6] Securities Exchange Act Release No. 69811 (June 20, 2013), 78 FR 38422 (June 26, 2013) (SR–Phlx–2013–67).

[7] Securities Exchange Act Release No. 70141 (August 8, 2013), 78 FR 49565 (August 14, 2013) (SR–Phlx–2013–83).

[8] Securities Exchange Act Release No. 70629 (October 8, 2013), 78 FR 62852 (October 22, 2013) (SR–Phlx–2013–100).

[9] Securities Exchange Act Release No. 71212 (December 31, 2013), 79 FR 888 (January 7, 2014) (SR–Phlx–2013–129).

[10] *See* Securities Exchange Act Release Nos. 72135 (May 9, 2014), 79 FR 27966 (May 15, 2014) (SR–Phlx–2014–33). Accordingly, the Exchange proposes to delete language from the first sentence of Rule 1000(f) that refers to the continued operation of FBMS 1. Nevertheless, the Exchange delayed the retirement of FBMS 1 until September 1, 2014, November 3, 2014, November 3, 2015, and, most recently, until April 1, 2016. *See also* Securities Exchange Act Release Nos. 72135 (May 9, 2014), 79 FR 27966 (May 15, 2014) (SR–Phlx–2014–33); 73246 (September 29, 2014), 79 FR 59874 (October 3, 2014) (SR–Phlx–2014–59); 73586 (November 13, 2014), 79 FR 68931 (November 19, 2014) (SR–Phlx–2014–71); and 67187 (October 19, 2015), 80 FR 64462 (October 23, 2015) (SR–Phlx–2015–80).

[11] Before FBMS 3 becomes available, the Exchange will provide notice in the form of an options circular to the Floor Broker community establishing a schedule for training and a reasonable implementation period. The Exchange does not expect that this will be a long or difficult transition from FBMS 2 to FBMS 3 because the functionality is the same and the interface to the Floor Broker is as well; the principal differences lie in the background, involving the architecture that is the backbone of the system.

[12] *http://www.nasdaqtrader.com/MicroNews.aspx?id=OTA2016-8.*

[13] 17 CFR 240.15c3–5.

[14] *See* note 10 above.

There are currently three exceptions to Rule 1000(f)(iii) that permit executions otherwise than in accordance with subparagraphs (i)–(iii) above. The first, under subparagraph (A), applies to executions respecting an option or all options in the event of a problem with Exchange systems. In addition, under subparagraph (B), Floor Brokers can execute orders in the options trading crowd pursuant to Rule 1059, Accommodation Transactions (cabinet trades), and Rule 1079, FLEX Equity, Index and Currency Options. Finally, under subparagraph (C), Multi-leg orders with more than 15 legs can be executed in the trading crowd. These three exceptions in (A)–(C) have been narrowly crafted to address specific situations, such as the complexity of a trade involving more than 15 legs. Each time a Floor Broker invokes an exception to Rule 1000(f), the Floor Broker is required by Rule 1063(e)(ii) to record the information required by Rule 1063(e)(i) on paper trade tickets, and may not represent an order for execution that has not been time stamped with the time of entry on the trading floor; such trade tickets must be time stamped upon the execution of such an order.

Creation of Split-Price Orders. The Exchange first recognized the complexity of the split-price order in 2005 when it filed to create an exception from existing priority rules for split-price orders under Rule 1014(g)(i)(B).[15] The purpose behind the split-price priority exception was ''to bring about the execution of large orders, which by virtue of their size and the need to execute them at multiple prices may be difficult to execute without a limited exception to the priority rules.'' The proposed exception allows a member effecting a trade that betters the market to have priority on the balance of that trade at the next pricing increment, even if there are orders in the book at the same price. Floor Brokers that avail themselves of the split-price priority rule are obligated to ensure compliance with Section 11(a) of the Act.[16]

Today, split-price orders are processed via either FBMS 2 or paper ticket. If the split-price order is evenly split and requires simple calculations to determine the number of contracts at two price points, the order is handled through FBMS 2. If the split-price order computation is more complicated, involving non-even integers and sub MPV price points, the surveillance staff declare an FBMS 2 system malfunction—in accordance with PHLX Rules 1000(f)(iii)(A) and 1063(e)(ii)—and allow the floor broker to utilize a paper ticket and oral execution of the split-price order in the trading crowd. The Exchange believes that the treatment of split-price orders under Rule 1000(f) should be made clearer.

Therefore, the Exchange proposes to add an additional exception to Rule 1000(f)(iii), also narrowly crafted to reflect the complexities of executing split-price orders. Specifically, pursuant to proposed Rule 1000(f)(iii)(D), the following split price orders that require, due to a system limitation, a manual calculation to determine specific volumes at different prices can be executed in the trading crowd: (I) Simple orders with a price not expressed in the applicable minimum increment (''sub-MPV'') [17] and that cannot be evenly split into two whole numbers to create a price at the midpoint of the minimum increment; and (II) complex and multi-leg orders with at least one option leg with an odd-numbered volume that must trade at a sub-MPV price or one leg that qualifies under (I) above, thereby requiring the Floor Broker to determine the specific volumes to trade at each price. Surveillance staff must approve any such executions in open outcry to validate that such execution abides by applicable priority and trade through rules.

The proposed exception is similar to the existing exceptions in that it permits additional time when there is a system problem or when needed for the entry and completion of complicated trades. Here, the additional time provided by the proposed exception is needed when a split-price trade calculation is complicated or requires contracts be rounded in favor of the customer due to the fact that it requires manual intervention. If, at the end of the manual calculation, the Floor Broker is able to input the determined split prices into FBMS 2 he may do so; otherwise he may use paper tickets. The use of a paper ticket will be necessary where, for example, the NBBO has moved and the trade no longer complies with the applicable trade through restrictions. Even if the Floor Broker is unable to use FBMS 2 to complete the entry of the split-price trade, the Floor Broker must still enter the order information into FBMS 2 for audit trail purposes.

The Surveillance staff will oversee Floor Brokers' use of the proposed exception as it does today under the current exceptions. Currently, when a Floor Broker states that there is a problem with the FBMS system, the Floor Broker will continue to input the order into FBMS (to the extend order entry functionality is accessible) and continue to announce the order in the trading crowd. Surveillance staff, knowing that the Floor Broker stated that he is experiencing a system problem or limitation will attempt to confirm the system problem with Exchange Operations staff. If Surveillance staff is able to confirm that FBMS has a performance problem, Surveillance staff will approve the use of a paper trade ticket and oral consummation of a transaction in the trading crowd that is contingent on Surveillance staff's additional confirmation that the trade complies with the time and price priority rules of the Exchange—a ''pending trade.''

If the pending trade complies with the time and price priority rules of the Exchange, the trade is approved and determined to have occurred at the time it would have occurred in the trading crowd but for the system problem or limitation. If the pending trade does not comply with the time and price priority rules of the Exchange, the Surveillance staff will inform the applicable trading crowd participants that the pending trade does not comply with Exchange rules and not permit the trade to occur. This manual process performed by the Surveillance staff parallels the electronic process performed within the Exchange matching engine when FBMS is able to process a trade. The delay attributable to this manual surveillance process does not change the time of trade execution, which is set at the time the trade would have occurred in the trading crowd.

With respect to simple orders, if a Floor Broker attempts to execute a customer order to sell 357 contracts in symbol XYZ (with a Minimum Price Variation increment of $0.05) at a price of $0.11 by way of split price execution, the floor broker must perform a manual calculation. As a result of FBMS 2 being unable to calculate the number of contracts to split to determine a net price of at least $0.11, the floor broker will manually enter 285 contracts @ $0.10 and 72 contracts @ $0.15 to arrive at an execution price as close as possible to an $0.11 ($0.110084 in this case) aggregate price for the 357 contracts ensuring that, when applicable, the customer side of the trade benefits from the difference between the $0.11 limit and the actual

[15] Securities Exchange Act Release No. 51820 (June 10, 2005), 70 FR 35759 (June 21, 2005) (SR–Phlx–2005–028) (pilot approval). *See also* Securities Exchange Act Release No. 55993 (June 29, 2007), 72 FR 37301 (July 9, 2007) (SR–Phlx–2007–044) (permanent approval).

[16] *Id.*

[17] *See* Nasdaq Rule 1034.

average price. This example would qualify for the proposed exception because it is a sub-MPV price (not in $0.05 increments) and cannot be evenly split to obtain the desired aggregate price.[18]

With respect to complex and multi-leg orders, consider the following example: A Floor Broker receives a two legged call spread in XYZ (with a Minimum Price Variation increment of $0.05) to sell 456 contracts of leg A @ $1.23 and buy 229 contracts of leg B @ $0.50. Because a Floor Broker is restricted to trading in not less than the permitted MPV increments, the Floor Broker will need to manually calculate to trade 274 contracts of leg A @ $1.25 and 182 contracts of leg A @ $1.20. This equals a net price on leg A of $1.23004. This is the closest achievable net price that is at least equal to the limit price of the Floor Broker's client without breaking the limit price. This would qualify because the Floor Broker will need to determine at which of the price points the additional contract will trade, given that the odd number of contracts cannot be split evenly across two price points.

Another example involving a simple order is if a Floor Broker has a customer order to buy 479 GOOG May 440 calls for $3.67: GOOG has a Minimum Price Variation of $0.10 in trades over $3.00 so the Floor Broker will need to determine the calculation that will amount to a price closest to $3.67; namely, 70% of 479 equals 335.3 but 335.3 is a non-round number and the customer buying the volume entered at the lower price gets a price that is rounded up while the volume at the higher price is rounded down so as to offer an advantage to the customer.[19] The result is 335 at $3.70 and 144 at $3.60. Since the customer is buying, the volume at the lower price of 3.60 gets rounded up to offer the advantage of rounding to the customer. This transaction would qualify for the exception because the simple order is for a sub-MPV price and cannot be evenly split.

Under this proposal, Surveillance staff must validate that split-price executions abide by all applicable priority and trade through rules using the time of execution recorded by the Floor Broker (and separately confirmed by Surveillance staff) on the paper order ticket. Referring back to a prior example involving a simple customer order to execute 357 contracts in symbol XYZ (with a Minimum Price Variation increment of $0.05) at $0.11 (285 contracts @ $0.10/72 contracts @ $0.15), if FBMS 2 is unable to determine the correct number of contracts to split to derive the net price of $0.11, the Floor Broker, upon confirmation and approval of the Surveillance staff, can verbally execute the order and Surveillance staff would capture the verbal execution time of the pending transaction and determine if the Floor Broker established priority over the bids and/or offers based on the documented verbal execution time. If the market was $0.05 bid and $0.15 offer, Surveillance staff would approve this transaction because the Floor Broker established priority over the $0.15 offers by trading more contracts at the better price of $0.10. However, if the market was $0.10 bid and $0.20 offer, On-Floor Surveillance staff would not approve this transaction because the Floor Broker did not establish priority over the $0.10 bids by trading the greater number of contracts at the inferior price. Finally, if the market was $0.10 bid and $0.15 offer (with no public customer orders on either side of the market), On-Floor Surveillance staff would approve this transaction because the Floor Broker would have priority over the non-customer book (bids/offers) given that customer orders always have priority pursuant to Rule 1014(g)(i)(A).

In conclusion, the Exchange believes that certain split-price orders warrant an exception from the requirement that the order be executed by FBMS. First, the exception is needed because FBMS is not currently programmed to perform the calculations associated with split prices not at the minimum price variation. Accordingly, the Floor Broker must do so manually, which can be time consuming; by the time the calculation is made, the market may have changed such that FBMS would return the order to the Floor Broker unexecuted. Second, heightened surveillance will be imposed. Under the proposal, the execution would occur on the trading floor in open outcry as a pending transaction. The transaction is completed only upon validation from Surveillance staff, based on the market prices at the time of execution. The proposal clarifies the need for a manual handling of the execution for these complicated split price trades, rather than leaving ambiguous the question of whether a split-price trade amounts to an FBMS system problem. This proposal does not change what is considered by the Exchange as a FBMS system problem, but rather clearly sets forth a defined system limitation for a split-price order with specific characteristics.

2. Statutory Basis

The Exchange believes that the proposed exception is consistent with Section 6(b) of the Act,[20] in general, and furthers the objectives of Section 6(b)(5) of the Act,[21] in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest by permitting split-price trades, which are complicated, to be executed in the trading crowd, which should, in turn, result in a greater likelihood that such orders are properly executed. FBMS 2 cannot calculate these particular prices, as described in the examples above.

The Exchange believes that the proposed exception is consistent with the Act because it is narrowly tailored to permit a small number of beneficial trades. As stated earlier, the Commission has recognized the importance of split-price trades because they permit the execution of large blocks, even permitting a limited exception to priority rules. Although FBMS was designed to enhance compliance to the greatest extent possible, FBMS does not have the capability to calculate and process certain split-price trades. If an exception was denied, Floor Brokers' ability to execute these large, split-price trades that benefit the market would be substantially impaired.

Additionally, Exchange surveillance is well-designed to protect customer when the exception is used. As set forth above, every split-price trade that invokes the proposed exception will require approval by Exchange surveillance staff in order to validate compliance with applicable priority and trade through rules. Additionally, all relevant trade data will be recorded on both paper tickets and in the FBMS system in order to ensure a proper audit trail for T+1 surveillance. Finally, to the extent the exception permits rounding of prices, rounding is required to occur in the customer's favor, a result that is itself consistent with the Act.

The proposal is not unfairly discriminatory because it applies to all Floor Brokers the same way. Nor is it unfairly discriminatory with respect to market participants other than Floor Brokers because only Floor Brokers use FBMS 2.

[18] The exemption would not apply where an order for 500 contracts could be traded at a split price of .125 by splitting it into two lots of 250 contracts at .10 and 250 contracts at .15.

[19] Under Proposed Rule 1000(f)(iii)(D), Exchange surveillance staff would be required to validate the use of price rounding to ensure that it is necessary and to the benefit of the customer.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposal should allow it to compete with other floor-based exchanges and help the Exchange's Floor Brokers compete with floor brokers on other options exchanges by accommodating another type of complicated order. Through the use of a surveillance process to verify that the conditions of the exception are met, the Exchange will ensure that the exception is used only rarely.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–Phlx–2016–82 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–Phlx–2016–82. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–Phlx–2016–82, and should be submitted on or before September 12, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19899 Filed 8–19–16; 8:45 am]

BILLING CODE 8011–01–P

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78587; File No. SR–NYSEArca–2016–87]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the First Trust Horizon Managed Volatility Domestic ETF and the First Trust Horizon Managed Volatility Developed International ETF Under NYSE Arca Equities Rule 8.600

August 16, 2016.

On June 16, 2016, NYSE Arca, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the First Trust Horizon Managed Volatility Domestic ETF and the First Trust Horizon Managed Volatility Developed International ETF. The proposed rule change was published for comment in the **Federal Register** on July 6, 2016.[3] On July 18, 2016, the Exchange submitted Amendment No. 1 to the proposed rule change.[4] The Commission received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act[5] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is August 20, 2016. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates October 4, 2016, as the date by which the Commission shall either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File Number SR–NYSEArca–2016–87), as modified by Amendment No. 1.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19895 Filed 8–19–16; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 78191 (June 29, 2016), 81 FR 44056.

[4] Amendment No. 1 replaced and superseded the original filing in its entirety. Amendment No. 1 is available at *https://www.sec.gov/comments/sr-nysearca-2016-87/nysearca201687-1.pdf.*

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78592; File No. SR–NASDAQ–2016–061]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Order Granting Approval of Proposed Rule Change To List and Trade Shares of the First Trust Equity Market Neutral ETF of the First Trust Exchange-Traded Fund VIII

August 16, 2016.

I. Introduction

On May 4, 2016, The NASDAQ Stock Market LLC (''Exchange'' or ''Nasdaq'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the First Trust Equity Market Neutral ETF (''Fund''), under Nasdaq Rule 5735. The proposed rule change was published for comment in the **Federal Register** on May 25, 2016.[3] On July 5, 2016, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] The Commission received no comments on the proposed rule change. This order grants approval of the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange proposes to list and trade Shares of the Fund, an actively-managed exchange-traded fund (''ETF''), under Nasdaq Rule 5735, which governs the listing and trading of ''Managed Fund Shares'' on the Exchange. The Shares will be offered by the First Trust Exchange-Traded Fund VIII (''Trust'').[6] First Trust Advisors L.P. will be the investment adviser (''Adviser'') to the Fund.[7] Perella Weinberg Partners Capital Management LP will serve as investment sub-adviser (''Sub-Adviser'') to the Fund and provide day-to-day portfolio management. First Trust Portfolios L.P. will be the principal underwriter and distributor of the Fund's Shares. The Bank of New York Mellon Corporation will act as the administrator, accounting agent, custodian, and transfer agent to the Fund. The Exchange has made the following representations and statements in describing the Fund and its investment strategy, including the Fund's portfolio holdings and investment restrictions.[8]

A. Exchange's Description of the Fund's Principal Investments

According to the Exchange, the investment objective of the Fund will be to seek long-term capital appreciation independent of market direction. Under normal market conditions,[9] the Fund will seek to achieve its investment objective by investing at least 80% of its net assets in ''Equity Securities'' (as defined below), which may be represented by certain derivative instruments,[10] as well as ETFs [11] that invest primarily in Equity Securities (''80% Investments'').[12] The Equity Securities in which the Fund will invest will be listed on a U.S. or a non-U.S. exchange and will consist of the following: (i) Common stocks; (ii) preferred securities; (iii) warrants to purchase common stocks or preferred securities; (iv) securities convertible into common stocks or preferred securities; (v) securities issued by real estate investment trusts (''REITs''); (vi) securities issued by master limited partnerships (''MLPs''); and (vii) American Depositary Receipts (''ADRs''), European Depositary Receipts (''EDRs''), and Global Depositary Receipts (''GDRs'' and, together with ADRs and EDRs, ''Depositary Receipts'').[13]

The Sub-Adviser will use a long/short strategy in seeking to construct a portfolio that it believes, based on its proprietary analysis, will provide the opportunity for capital preservation and appreciation across a wide variety of market conditions. A portion of the Fund's portfolio will typically be invested in Equity Securities selected by the Sub-Adviser through application of an event-driven strategy that seeks to identify and capitalize on certain corporate actions which may affect the value of Equity Securities, such as mergers and acquisitions, divestitures,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 77854 (May 19, 2016), 81 FR 33307 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 78227, 81 FR 44907 (July 11, 2016).

[6] The Trust is registered with the Commission as an investment company and has filed a registration statement on Form N–1A (''Registration Statement'') with the Commission. *See* Registration Statement on Form N–1A for the Trust filed on March 14, 2016 (File Nos. 333–210186 and 811–23147). In addition, the Exchange represents that the Trust has obtained certain exemptive relief under the Investment Company Act of 1940 (''1940 Act''). *See* Investment Company Act Release No. 28468 (October 27, 2008) (File No. 812–13477).

[7] The Exchange represents that neither the Adviser nor the Sub-Adviser is registered as a broker-dealer. The Adviser is affiliated with a broker-dealer, and the Sub-Adviser is affiliated with two broker-dealers. Each has implemented and will maintain a fire wall with respect to its respective broker-dealer affiliate(s) regarding access to information concerning the composition of and/or changes to the portfolio. In the event (a) the Adviser or Sub-Adviser becomes newly affiliated with a broker-dealer or registers as a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel and/or such broker-dealer affiliate, if applicable, regarding access to information concerning the composition of, or changes to, the portfolio and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

[8] The Commission notes that additional information regarding the Fund, the Trust, and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, calculation of net asset value (''NAV''), distributions, and taxes, among other things, can be found in the Notice and the Registration Statement, as applicable. *See* Notice and Registration Statement, *supra* notes 3 and 6, respectively.

[9] The term ''under normal market conditions'' as used herein includes, but is not limited to, the absence of adverse market, economic, political or other conditions, including extreme volatility or trading halts in the securities markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or *force majeure* type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance. On a temporary basis, including for defensive purposes, during the initial invest-up period and during periods of high cash inflows or outflows, the Fund may depart from its principal investment strategies; for example, it may hold a higher than normal proportion of its assets in cash. During such periods, the Fund may not be able to achieve its investment objective. The Fund may adopt a defensive strategy when the Adviser or the Sub-Adviser believes securities in which the Fund normally invests have elevated risks due to political or economic factors and in other extraordinary circumstances.

[10] Such derivatives are defined as ''Principal Derivatives.'' *See* ''The Fund's Use of Derivatives,'' *infra.*

[11] ETFs included in the Fund will be listed and traded in the U.S. on registered exchanges. The Fund may invest in the securities of ETFs in excess of the limits imposed under the 1940 Act pursuant to exemptive orders obtained by other ETFs and their sponsors from the Commission. In addition, the Fund may invest in the securities of certain other investment companies in excess of the limits imposed under the 1940 Act pursuant to an exemptive order that the Trust has obtained from the Commission. *See* Investment Company Act Release No. 30377 (February 5, 2013) (File No. 812–13895). The ETFs in which the Fund may invest include Index Fund Shares (as described in Nasdaq Rule 5705), Portfolio Depository Receipts (as described in Nasdaq Rule 5705), and Managed Fund Shares (as described in Nasdaq Rule 5735). While the Fund may invest in inverse ETFs, the Fund will not invest in leveraged or inverse leveraged (*e.g.,* 2X or −3X) ETFs.

[12] The 80% Investments will take into account such derivative instruments and ETFs.

[13] The Fund will not invest in any unsponsored Depositary Receipts.

tender offers, and other corporate events.[14]

The Fund's Use of Derivatives

The Fund may engage in transactions in derivative instruments, as described in this paragraph. As noted above under ''Principal Investments,'' the Fund's investments in Equity Securities may be represented by derivatives. Investments in Equity Securities that are represented by derivatives (referred to collectively as ''Principal Derivatives'') will be treated as investments in Equity Securities for purposes of the 80% Investments. Principal Derivatives will consist of the following: (i) Total return swap agreements; [15] (ii) exchange-traded options on stock indices; (iii) exchange-traded options on equity securities; and (iv) exchange-traded stock index futures contracts. In addition to purchasing exchange-traded options on stock indices and exchange-traded options on equity securities, the Fund may also sell such exchange-traded options, either outright or as part of an options strategy (such as a collar or an option spread). Additionally, the Fund may invest in non-U.S. currency swap agreements and forward foreign currency exchange contracts (collectively, ''Non-Principal Derivatives'') to the extent described below in ''Other Investments.'' The Fund may also enter into currency transactions on a spot (*i.e.,* cash) basis. The Fund will invest (in the aggregate) no more than 30% of the value of its net assets (calculated at the time of investment) in Principal Derivatives and Non-Principal Derivatives (''30% Limitation'').

The Fund will only enter into transactions in over-the-counter (''OTC'') derivatives (including non-U.S. currency swap agreements, total return swap agreements, and forward foreign currency exchange contracts) with counterparties that the Adviser and/or the Sub-Adviser reasonably believes are capable of performing under the applicable contract or agreement.

According to the Exchange, the Fund's investments in derivative instruments will be made in accordance with the 1940 Act, will be consistent with the Fund's investment objective and policies, and will not be used to seek to achieve a multiple or inverse multiple of an index. To limit the potential risk associated with the Fund's derivatives transactions, the Exchange states that the Fund will segregate or ''earmark'' assets determined to be liquid by the Adviser and/or the Sub-Adviser in accordance with procedures established by the Board of Trustees of the Trust (''Trust Board'') and in accordance with the 1940 Act (or, as permitted by applicable regulation, enter into certain offsetting positions) to cover its obligations under derivative instruments. In addition, the Exchange provides that the Fund will include appropriate risk disclosure in its offering documents, including leveraging risk.[16] The Exchange represents that because the markets for certain securities, or the securities themselves, may be unavailable or cost prohibitive as compared to derivative instruments, suitable derivative transactions may be an efficient alternative for the Fund to obtain the desired asset exposure.

The Exchange states that the Adviser believes there will be minimal, if any, impact to the arbitrage mechanism as a result of the use of derivatives. Market makers and participants should be able to value derivatives as long as the positions are disclosed with relevant information. The Exchange states that the Adviser believes that the price at which Shares trade will continue to be disciplined by arbitrage opportunities created by the ability to purchase or redeem creation units at their NAV, which should ensure that Shares will not trade at a material discount or premium in relation to their NAV.

The Exchange states that the Adviser does not believe there will be any significant impact to the settlement or operational aspects of the Fund's arbitrage mechanism due to the use of derivatives. Because derivatives generally are not eligible for in-kind transfer, they will typically be substituted with a ''cash in lieu'' amount when the Fund processes purchases or redemptions of creation units in-kind.

B. Exchange's Description of the Fund's Other Investments

With respect to up to 20% of its net assets, the Fund may invest in and/or include in its portfolio (as applicable) the following securities and instruments (in the aggregate).

The Fund may invest in non-exchange-traded equity securities (''Non-Exchange-Traded Equity Securities'') acquired in conjunction with its event-driven strategy.[17] The Fund may also invest in exchange-traded notes (''ETNs'') and in Non-Principal Derivatives.

The Fund may invest in short-term debt securities and other short-term debt instruments described below, as well as cash equivalents, or it may hold cash. The Fund may invest in the following short-term debt instruments: (1) Fixed rate and floating rate U.S. government securities, including bills, notes, and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. government agencies or instrumentalities; (2) certificates of deposit issued against funds deposited in a bank or savings and loan association; (3) bankers' acceptances; (4) repurchase agreements,[18] which involve purchases of debt securities; (5) bank time deposits; and (6) commercial paper.[19]

The Fund may invest in money market mutual funds, U.S. exchange-traded closed-end funds, and other ETFs [20] that, in each case, will be investment companies registered under the 1940 Act. In addition to ETFs and closed-end funds, the Fund may invest in certain other exchange-traded pooled investment vehicles (''ETPs'').[21]

The Fund's portfolio may include exchange-traded and OTC contingent

[14] In connection with its event-driven strategy, the Fund may also invest a portion of its assets in Non-Exchange-Traded Equity Securities (as defined *infra*). *See infra* note 17 and accompanying text under ''Other Investments.''

[15] The Fund will only invest in total return swap agreements that have (i) referenced assets that are exchange-traded securities or (ii) referenced indexes that are comprised of exchange-traded securities.

[16] The Exchange represents that to mitigate leveraging risk, the Adviser and/or the Sub-Adviser will segregate or ''earmark'' liquid assets or otherwise cover the transactions that may give rise to such risk.

[17] For example, in conjunction with its event-driven strategy, the Fund may acquire a Non-Exchange-Traded Equity Security as a result of a merger or other corporate reorganization. Certain Non-Exchange-Traded Equity Securities may be Rule 144A securities; the Fund will not invest in Rule 144A securities other than Non-Exchange-Traded Equity Securities. Additionally, Non-Exchange-Traded Equity Securities will not be represented by derivative instruments.

[18] According to the Exchange, the Fund intends to enter into repurchase agreements only with financial institutions and dealers believed by the Adviser and/or the Sub-Adviser to present minimal credit risks in accordance with criteria approved by the Trust Board. The Adviser and/or the Sub-Adviser will review and monitor the creditworthiness of such institutions. The Adviser and/or the Sub-Adviser will monitor the value of the collateral at the time the transaction is entered into and at all times during the term of the repurchase agreement.

[19] The Fund may only invest in commercial paper rated A–1 or higher by S&P Ratings, Prime–1 or higher by Moody's or F1 or higher by Fitch.

[20] Such ETFs will not invest primarily in Equity Securities (and, therefore, will not be taken into account for purposes of the 80% Investments) but may otherwise invest in assets of any type.

[21] The Fund may invest in the following ETPs: Trust certificates, commodity-based trust shares, currency trust shares, commodity index trust shares, commodity futures trust shares, partnership units, trust units, and managed trust securities (as described in Nasdaq Rule 5711); paired class shares (as described in Nasdaq Rule 5713); trust issued receipts (as described in Nasdaq Rule 5720); and exchange-traded managed fund shares (as described in Nasdaq Rule 5745).

value rights (''CVRs'') received by the Fund as consideration in connection with a corporate action related to a security held by the Fund.[22]

C. Exchange's Description of the Fund's Investment Restrictions

According to the Exchange, the Fund may not invest 25% or more of the value of its total assets in securities of issuers in any one industry. This restriction will not apply to (a) obligations issued or guaranteed by the U.S. government, its agencies, or instrumentalities or (b) securities of other investment companies.[23]

The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), including Rule 144A securities deemed illiquid by the Adviser and/or the Sub-Adviser. The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets.

III. Discussion and Commission's Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of Section 6 of the Act [24] and the rules and regulations thereunder applicable to a national securities exchange.[25] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[26] which requires, among other things, that the Exchange's rules be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission also finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act,[27] which sets forth the finding of Congress that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities. Quotation and last sale information for the Shares will be available via Nasdaq proprietary quote and trade services, as well as in accordance with the Unlisted Trading Privileges and the Consolidated Tape Association (''CTA'') plans for the Shares. In addition, an estimated value, defined in Nasdaq Rule 5735(c)(3) as the Intraday Indicative Value,[28] will be available on the NASDAQ OMX Information LLC proprietary index data service,[29] and will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Regular Market Session.[30] On each business day, before commencement of trading in Shares in the Regular Market Session on the Exchange, the Fund will disclose on its Web site the identities and quantities of the Disclosed Portfolio that will form the basis for the Fund's calculation of NAV at the end of the business day.[31]

The Fund's NAV will be determined as of the close of regular trading on the New York Stock Exchange (''NYSE'') (ordinarily 4:00 p.m., E.T.) on each day the NYSE is open for trading. Additionally, information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for the following equity securities (to the extent traded on a U.S. exchange) will be available from the exchanges on which they are traded as well as in accordance with any applicable CTA plans: Equity Securities; ETFs; closed-end funds; and ETPs. In addition, quotation and last sale information for U.S. exchange-traded options (including U.S. exchange-traded options on equity securities and U.S. exchange-traded options on stock indices) will be available via the Options Price Reporting Authority. Quotation and last sale information for U.S. exchange-traded stock index futures contracts, ETNs and CVRs will be available from the exchanges on which they are traded. Pricing information for exchange-traded equity securities (including Equity Securities; closed-end funds; ETFs; and ETPs), ETNs, exchange-traded CVRs, and exchange-traded derivatives (including options on stock indices; options on equity securities; and stock index futures contracts) will be available from the applicable listing exchange and from major market data vendors. Pricing information for Non-Exchange-Traded Equity Securities (including without limitation Rule 144A securities), short-term U.S. government securities, commercial paper, bankers' acceptances, repurchase agreements, OTC CVRs, non-U.S. currency swap agreements, total return swap agreements, forward foreign currency exchange contracts, bank time deposits, certificates of deposit, and currency spot transactions will be available from major broker-dealer firms, major market data vendors, and/or third party pricing services. Money market mutual funds are typically priced once each business day, and their prices will be available through the applicable fund's Web site or from major market data vendors. In addition, the Fund's Web site will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information.

The Commission further believes that the proposal to list and trade the Shares

[22] CVRs will not be taken into account for purposes of the 30% Limitation.

[23] *See* Form N–1A, Item 9. The Commission has taken the position that a fund is concentrated if it invests more than 25% of the value of its total assets in any one industry. *See, e.g.,* Investment Company Act Release No. 9011 (October 30, 1975), 40 FR 54241 (November 21, 1975).

[24] 15 U.S.C. 78f.

[25] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[26] 15 U.S.C. 78f(b)(5).

[27] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[28] The Intraday Indicative Value will be based upon the current value for the components of the Disclosed Portfolio, as defined in Nasdaq Rule 5735(c)(2).

[29] Currently, the NASDAQ OMX Global Index Data Service (''GIDS'') is the NASDAQ OMX global index data feed service, offering real-time updates, daily summary messages, and access to widely followed indexes and ETFs. GIDS provides investment professionals with the daily and historical information needed to track or trade NASDAQ OMX indexes, listed ETFs or third-party partner indexes and ETFs.

[30] *See* Nasdaq Rule 4120(b)(4) (describing the three trading sessions on the Exchange: (1) Pre-Market Session from 4 a.m. to 9:30 a.m. Eastern Time (''*E.T.''*); (2) Regular Market Session from 9:30 a.m. to 4 p.m. or 4:15 p.m. *E.T.;* and (3) Post-Market Session from 4 p.m. or 4:15 p.m. to 8 p.m. *E.T.*).

[31] The Fund's disclosure of derivative positions in the Disclosed Portfolio will include sufficient information for market participants to use to value these positions intraday. On a daily basis, the Fund will disclose on the Fund's Web site the following information regarding each portfolio holding, as applicable to the type of holding: Ticker symbol, CUSIP number or other identifier, if any; a description of the holding (including the type of holding, such as the type of swap); the identity of the security, commodity, index or other asset or instrument underlying the holding, if any; for options, the option strike price; quantity held (as measured by, for example, par value, notional value or number of shares, contracts or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and percentage weighting of the holding in the Fund's portfolio. The Web site information will be publicly available at no charge.

is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Commission notes that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. Trading in the Shares will also be subject to Nasdaq Rules 4120 and 4121, including the trading pause provisions under Nasdaq Rules 4120(a)(11) and (12). Trading in the Shares may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the other assets constituting the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares will also be subject to Nasdaq Rule 5735(d)(2)(D), which sets forth additional circumstances under which trading in the Shares may be halted. The Exchange states that it has a general policy prohibiting the distribution of material, non-public information by its employees. In addition, the Exchange represents that neither the Adviser nor Sub-Adviser is registered as a broker-dealer; however, the Adviser is affiliated with a broker-dealer, and the Sub-Adviser is affiliated with two broker-dealers, and each has implemented and will maintain a fire wall with respect to its respective broker-dealer affiliate(s) regarding access to information concerning the composition and/or changes to the portfolio.[32]

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by both Nasdaq and also the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[33] The Exchange also represents that FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and the exchange-traded securities and instruments held by the Fund (including Equity Securities, closed-end funds, ETFs, ETPs, ETNs, exchange-traded CVRs, options on stock indices, options on equity securities, and stock index futures contracts) with other markets and other entities that are members of the Intermarket Surveillance Group (''ISG''),[34] and FINRA may obtain trading information regarding trading in the Shares and such exchange-traded securities and instruments held by the Fund from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and the exchange-traded securities and instruments held by the Fund from markets and other entities that are members of ISG, which includes securities and futures exchanges, or with which the Exchange has in place a CSSA. Moreover, FINRA, on behalf of the Exchange, will be able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's Trade Reporting and Compliance Engine (''TRACE'').

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. In support of this proposal, the Exchange has made representations, including the following:

(1) The Shares will be subject to Rule 5735, which sets forth the initial and continued listing criteria applicable to Managed Fund Shares.[35]

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.[36] Trading in the Shares will be subject to the existing trading surveillances, administered by both Nasdaq and also FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws, and these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.[37]

(3) FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and the exchange-traded securities and instruments held by the Fund (including Equity Securities, closed-end funds, ETFs, ETPs, ETNs, exchange-traded CVRs, options on stock indices, options on equity securities, and stock index futures contracts) with other markets and other entities that are members of the ISG, and FINRA may obtain trading information regarding trading in the Shares and such exchange-traded securities and instruments held by the Fund from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and the exchange-traded securities and instruments held by the Fund from markets and other entities that are members of ISG, which includes securities and futures exchanges, or with which the Exchange has in place a CSSA. Moreover, FINRA, on behalf of the Exchange, will be able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's TRACE.[38]

(4) At least 90% of the Fund's net assets that are invested (in the aggregate) in exchange-traded derivatives and in exchange-traded CVRs will be invested in instruments that trade in markets that are members of ISG or are parties to a CSSA with the Exchange.[39]

(5) At least 90% of the Fund's net assets that are invested (in the aggregate) in ETNs and in exchange-traded equity securities will be invested in securities that trade in markets that are members of ISG or are parties to a CSSA with the Exchange.[40]

[32] *See supra* note 7. The Exchange further represents that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (''Advisers Act''). As a result, the Adviser, Sub-Adviser, and their related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act, which requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of their relationship with their clients as well as compliance with other applicable securities laws. Accordingly, investment advisers must have procedures designed to prevent the communication and misuse of non-public information, consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[33] The Exchange states that FINRA surveils trading on the Exchange pursuant to a regulatory services agreement and that the Exchange is responsible for FINRA's performance under this regulatory services agreement.

[34] For a list of the current members of ISG, *see www.isgportal.org.* The Exchange notes that not all components of the Disclosed Portfolio may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement (''CSSA'').

[35] *See* Notice, *supra* note 3, at 33313.

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] *Id.* at 33313–33314.

[40] *Id.* at 33314.

(6) The Equity Securities in which the Fund will invest will be listed on a U.S. or a non-U.S. exchange.[41]

(7) ETFs included in the Fund will be listed and traded in the U.S. on registered exchanges.[42]

(8) The Fund will not invest in any unsponsored Depositary Receipts.[43]

(9) The Fund will only invest in total return swap agreements that have (i) referenced assets that are exchange-traded securities or (ii) referenced indexes that are comprised of exchange-traded securities.[44]

(10) While the Fund may invest in inverse ETFs, the Fund will not invest in leveraged or inverse leveraged (*e.g.,* 2X or −3X) ETFs.[45]

(11) The Fund will only enter into transactions in OTC derivatives with counterparties that the Adviser and/or the Sub-Adviser reasonably believes are capable of performing under the applicable contract or agreement.[46]

(12) The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), including Rule 144A securities deemed illiquid by the Adviser and/or the Sub-Adviser.[47]

(13) The Fund will not invest in Rule 144A securities other than Non-Exchange-Traded Equity Securities. Additionally, Non-Exchange-Traded Equity Securities will not be represented by derivative instruments.[48]

(14) The Fund may not invest 25% or more of the value of its total assets in securities of issuers in any one industry. This restriction does not apply to (a) obligations issued or guaranteed by the U.S. government, its agencies or instrumentalities or (b) securities of other investment companies.[49]

(15) The Fund will invest (in the aggregate) no more than 30% of the value of its net assets (calculated at the time of investment) in Principal Derivatives and Non-Principal Derivatives.[50]

(16) Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (a) The procedures for purchases and redemptions of Shares in creation units (and that Shares are not individually redeemable); (b) Nasdaq Rule 2111A, which imposes suitability obligations on Nasdaq members with respect to recommending transactions in the Shares to customers; (c) how information regarding the Intraday Indicative Value and the Disclosed Portfolio is disseminated; (d) the risks involved in trading the Shares during the Pre-Market and Post-Market Sessions when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (e) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information. The Information Circular will also discuss any exemptive, no-action and interpretive relief granted by the Commission from any rules under the Act.[51]

(17) For initial and continued listing, the Fund must be in compliance with Rule 10A–3 under the Act.[52]

(18) The Fund's investments in derivative instruments will be made in accordance with the 1940 Act, will be consistent with the Fund's investment objective and policies, and will not be used to seek to achieve a multiple or inverse multiple of an index.[53]

(20) To limit the potential risk associated with the Fund's derivatives transactions, the Fund will segregate or ''earmark'' assets determined to be liquid by the Adviser and/or the Sub-Adviser in accordance with procedures established by the Trust Board and in accordance with the 1940 Act (or, as permitted by applicable regulation, enter into certain offsetting positions) to cover its obligations under derivative instruments. These procedures have been adopted consistent with Section 18 of the 1940 Act and related Commission guidance. In addition, the Fund will include appropriate risk disclosure in its offering documents, including leveraging risk.[54]

(21) A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange.[55]

The Exchange represents that all statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules and surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange. In addition, the issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under the Nasdaq 5800 Series.

This approval order is based on all of the Exchange's representations, including those set forth above and in the Notice, and the Exchange's description of the Fund. The Commission notes that the Fund and the Shares must comply with the initial and continued listing criteria in Nasdaq Rule 5735 for the Shares to be listed and traded on the Exchange.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act[56] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

IT IS THEREFORE ORDERED, pursuant to Section 19(b)(2) of the Act,[57] that the proposed rule change (SR–NASDAQ–2016–061), be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[58]

Robert W. Errett,

Deputy Secretary.

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[41] *Id.* at 33308.
[42] *Id.* at n.10.
[43] *Id.* at 33309, n.12.
[44] *Id.* at 33309, n.15.
[45] *Id.* at 33308, n.10.
[46] *Id.* at 33309.
[47] *Id.* at 33310.
[48] *Id.* at n.20.
[49] *Id.* at 33310.
[50] *Id.* at 33314.
[51] *Id.*
[52] *See* 17 CFR 240.10A–3.
[53] *See* Notice, *supra* note 3, at 33309.
[54] *Id.*
[55] *Id.* at 33313.
[56] 15 U.S.C. 78f(b)(5).
[57] 15 U.S.C. 78s(b)(2).
[58] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78588; File No. SR–Phlx–2016–79]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing of Proposed Rule Change To Amend Rule 1017, Openings in Options

August 16, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 4, 2016, NASDAQ PHLX LLC (''Phlx'' or

[1] 15 U.S.C. 78s(b)(1).
[2] 17 CFR 240.19b–4.

''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 1017, Openings in Options, as described in detail below.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqphlx.cchwallstreet.com/*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend its rules relating to its opening process. This rule change proposes to amend the current functionality of the Exchange's trading system (''system'') [3] regarding the opening of trading in an option series.

Definitions

First, the Exchange proposes to adopt a ''Definitions'' section as new Rule 1017(a) [4] to define several terms that are used throughout the Rule. The new section will state that the Exchange conducts an electronic opening for all option series [5] traded on Phlx using its trading system (hereinafter ''system'').[6]

The Exchange proposes to define the following terms, which are described below: ''Opening Process,'' ''Opening Price,'' ''Potential Opening Price,'' ''ABBO,'' ''Phlx Electronic Market Maker,'' ''Pre-Market BBO,'' ''Quality Opening Market,'' ''Valid Width Quote,'' and ''Zero Bid Market.''

The Exchange defines ''Opening Process'' by cross-referencing Rule 1017(d).[7] The Exchange defines ''Opening Price'' by cross-referencing Rule 1017(i) and (k).[8] The Exchange defines ''Potential Opening Price'' by cross-referencing Rule 1017(h).[9] The Exchange defines ''ABBO'' as the Away Best Bid or Offer.[10] The ABBO does not include Phlx's market. The Exchange defines ''market for the underlying security'' as either the primary listing market or the primary volume market (defined as the market with the most liquidity in that underlying security for the previous two calendar months), as determined by the Exchange by underlying and announced to the membership on the Exchange's Web site.[11] Currently, this term is defined in Rule 1017(j) as either the primary listing market or the primary volume market (defined as the market with the most liquidity in that underlying security for the previous two calendar months), or the first market to open the underlying security, as determined by the Exchange on an issue-by-issue basis and announced to the membership on the Exchange's Web site. In practice, the Exchange does not and has not considered the first market to open in determining the primary market for an underlying, and therefore the new definition will not refer to it. The existing language in Rule 1017(j) regarding the first market to open is thus being deleted.

The term ''Phlx Electronic Market Makers'' is defined as a Specialist,[12] Streaming Quote Trader or ''SQT,'' [13] and Remote Streaming Quote Trader or ''RSQT'' [14] who is required to submit continuous two-sided electronic quotations pursuant to Rule 1014(b)(ii)(D).[15] Currently, Rule 1017(a) utilizes the term ''Phlx XL Participant'' which is not as precise as the term ''Phlx Electronic Market Makers'' as it also includes non-SQT Registered Options Traders or ROTs.[16] This is incorrect because non-SQT ROTs cannot submit quotes electronically and therefore should not be subject to Rule 1017, which applies only to electronic trading. By definition, these non-SQT ROTs make markets verbally and thus provide on-floor liquidity; they have chosen not to submit quotes electronically to the Exchange. To be considered in the Opening Process, orders represented by Floor Brokers must be entered electronically.[17] The next definition is ''Pre-Market BBO'' defined as the highest bid and the lowest offer among Valid Width Quotes.[18] The rule currently refers to the highest bid and the lowest offer multiple times, so defining the term is more efficient and consistent. References to determining the highest quote bid and lowest quote offer are being replaced with the new term, ''Pre-Market BBO'' throughout. The term ''Quality Opening Market'' is defined as a bid/ask differential applicable to the best bid and offer from all Valid Width Quotes defined in a table to be determined by the Exchange and published on the Exchange's Web site.[19] This definition appears in current Rule 1017(l)(v)(B) and is being deleted. Next, a ''Valid Width Quote'' is defined as a two-sided electronic quotation submitted by a Phlx Electronic Market Maker that consists of a bid/ask differential that is compliant with Rule

[3] The Exchange is replacing references to Phlx XL II with the word ''system'' to reflect current usage.

[4] The current text of Rule 1017(a) is being deleted and replaced by proposed Rule 1017(a)(iii), as described below.

[5] Rule 1017 only applies to simple (non-Complex) orders; the opening process for Complex Orders is described in Rule 1080.07.

[6] The Exchange notes that Rule 1017 describes the Exchange's opening process for its electronic order book. Rule 1017 does not apply to trading on the Exchange's trading floor.

[7] *See* proposed Rule 1017(a)(i).

[8] *See* proposed Rule 1017(a)(ii).

[9] *See* proposed Rule 1017(a)(iii).

[10] *See* proposed Rule 1017(a)(iv). This term is also used in Phlx Rule 1082(a)(ii)(B)(3)(g).

[11] *See* proposed Rule 1017(a)(v).

[12] A Specialist is an Exchange member who is registered as an options specialist pursuant to Rule 1020(a). An options Specialist includes a Remote Specialist which is defined as an options Specialist in one or more classes that does not have a physical presence on an Exchange floor and that is approved by the Exchange pursuant to Rule 501.

[13] An SQT is defined in Exchange Rule 1014(b)(ii)(A) as an ROT who has received permission from the Exchange to generate and submit option quotations electronically in options to which such SQT is assigned.

[14] An RSQT is defined in Exchange Rule in 1014(b)(ii)(B) as an ROT that is a member affiliated with an RSQTO with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically in options to which such RSQT has been assigned.

[15] *See* proposed Rule 1017(a)(vi).

[16] A non-SQT ROT is an ROT who is neither an SQT nor an RSQT. *See* Rule 1014(b)(ii)(C).

[17] *See* current rule 1017(c).

[18] *See* proposed Rule 1017(a)(vii). Valid Width Quotes is defined at proposed Rule 1017(a)(ix).

[19] *See* proposed Rule 1017(a)(viii).

1014(c)(i)(A)(1)(a).[20] This term appears in current Rule 1017(l)(ii) and is being deleted. The term ''Zero Bid Market'' is where the best bid for an options series is zero.[21] The Exchange currently uses this concept in other rules.[22]

Reorganization of Certain Provisions

New rule text is being added to Rule 1017 and certain provisions are being relocated within the rule for better organization and understanding.

Eligible Interest

The Exchange proposes to move the language from current Rule 1017(l)(vii) to new Rule 1017(b), with minor changes. Specifically, the Exchange proposes to adopt in new paragraph (b) a provision that eligible opening interest includes: (i) Valid Width Quotes; (ii) Opening Sweeps; and (iii) orders. Specialists, SQTs, and RSQTs may submit quotes,[23] Opening Sweeps and orders, but quotes other than Valid Width Quotes will not be included in the Opening Process. Non-SQT ROTs may submit orders; provided they are submitted electronically.[24]

New Rule 1017 paragraph (b) will provide that all-or-none (''AON'') interest [25] that can be satisfied is considered for execution and in determining the Opening Price throughout the Opening Process. The rule is currently silent on the eligibility of AON interest on the opening, from which it can be inferred that they are accepted; nevertheless, the Exchange is proposing to add this specific provision to add detail to the rule. The Exchange is specifically addressing AON interest to make clear that this type of contingency market or limit order which would be executed in its entirety or not at all, will be considered for execution within the Opening, provided that this interest can be satisfied.

Opening Sweep

Proposed new Rule 1017(b)(i) provides that an Opening Sweep is a one-sided electronic quotation submitted for execution against eligible opening trading interest in the system.[26] A Phlx Electronic Market Maker assigned in a particular option may only submit an Opening Sweep if, at the time of entry of the Opening Sweep, that Phlx Electronic Market Maker has already submitted and maintained a Valid Width Quote. All Opening Sweeps in the affected series entered by a Phlx Electronic Market Maker will be cancelled immediately if that Phlx Electronic Market Maker fails to maintain a continuous quote with a Valid Width Quote in the affected series.[27]

Opening Sweeps may be entered at any price with a minimum price variation applicable to the affected series, on either side of the market, at single or multiple price level(s), and may be cancelled and re-entered. A single Phlx Electronic Market Maker may enter multiple Opening Sweeps, with each Opening Sweep at a different price level. If a Phlx Electronic Market Maker submits multiple Opening Sweeps, the system will consider only the most recent Opening Sweep at each price level submitted by such Phlx Electronic Market Maker in determining the Opening Price. Unexecuted Opening Sweeps will be cancelled once the affected series is open.[28] Except as described above, most of the language mimics current Rule 1017(l)(vii); it is being relocated because it is more logical to refer to the types of eligible opening interest in the beginning of the rule.

Proposed new Rule 1017(b)(ii) generally tracks current Rule 1017(l)(vii)(B) in stating that the system will aggregate the size of all eligible interest for a particular participant category at a particular price level for trade allocation purposes. For example, all Phlx Electronic Market Maker (a participant category) quotes, Opening Sweeps, and orders are thus aggregated in determining the pro-rata allocation. The proposed rule is broader than the existing language, which is limited to Opening Sweeps, because it includes quotes and orders. The Exchange believes it is appropriate to amend the rule to expressly state that the Exchange currently considers this interest because there is no need to exclude quotes and orders, which contribute liquidity just like Opening Sweeps.

Proposed Rule 1017(c) simplifies the current rule text to simply provide that to be considered in the Opening Process, orders represented by Floor Brokers must be entered electronically.

Proposed new Rule 1017(d) is based on existing paragraph Rule 1017(k). The Exchange seeks to organize this rule more logically by describing when the Opening Process can begin and adding more detail related to specific time-related triggers. Specifically, Phlx Electronic Market Maker Valid Width Quotes and Opening Sweeps may start at 9:25 a.m. and are included in the Opening Process. Orders may be entered at any time before an options series opens and are included in the Opening Process. This proposed language adds greater specificity to the rule regarding the submission of orders. The 9:25 a.m. trigger is intended to tie the option Opening Process to quoting in the underlying security; [29] it presumes that option quotes submitted before any indicative quotes have been disseminated for the underlying security may not be reliable or intentional. Therefore, the Exchange has chosen a reasonable timeframe at which to begin utilizing option quotes, based on the Exchange's experience when underlying quotes start becoming available.

Furthermore, the Opening Process for an option series will be conducted pursuant to paragraphs (f)–(k) on or after 9:30 a.m. if: [30] The ABBO, if any, is not crossed; [31] and if the system has received, within two minutes (or such shorter time as determined by the Exchange and disseminated to membership on the Exchange's Web site) of the opening trade or quote on the market for the underlying security in the case of equity options or, in the case of index options, within two minutes of the receipt of the Opening Price in the underlying index (or such shorter time as determined by the Exchange and disseminated to membership on the Exchange's Web site), or within two minutes of market opening in the case of U.S. dollar-settled FCO (or such shorter time as determined by the Exchange and disseminated to membership on the Exchange's Web site) either:

(A) The Specialist's Valid Width Quote;

(B) the Valid Width Quotes of at least two Phlx Electronic Market Makers other than the Specialist; or

(C) if neither the Specialist's Valid Width Quote nor the Valid Width Quotes of two Phlx Electronic Market

[20] *See* proposed Rule 1017(a)(ix).

[21] *See* proposed Rule 1017(a)(x).

[22] *See* Rule 1080(i)(A)(1) and Rule 1082(a)(ii)(B)(4)(C); a zero priced bid equates with a Zero Bid Market.

[23] Rule 1017(l)(vii) currently provides that quotes may be submitted; the Exchange is now specifying that these must be Valid Width Quotes, which will be defined in proposed Rule 1017(a)(ix).

[24] *See* note 17 above.

[25] All-or-none (''AON'') means a contingency market or limit order which is to be executed in its entirety or not at all.

[26] This rule text is currently located in current Rule 1017(l)(vii)(A). This rule text is being relocated with this rule change.

[27] *See* proposed Rule 1017(b)(i)(A).

[28] *See* proposed Rule 1017(b)(i)(B).

[29] For purposes of this rule, the underlying security can also be an index.

[30] The new reference to 9:30 a.m. adds detail; of course, the market cannot open before 9:30 a.m.

[31] The crossed ABBO is currently referred to in Rule 1017(l)(x), which provides that: ''If at any point during the Opening Process the ABBO becomes crossed (*e.g.,* 1.05 bid, 1.00 offer), the opening process will be terminated and the Exchange will not open the affected series. A new opening process for the affected series will commence at the time the ABBO is uncrossed.''

Makers have been submitted within such timeframe, one Phlx Electronic Market Maker has submitted a Valid Width Quote.

These requirements are intended to tie the option Opening Process to receipt of liquidity. These requirements are the same as those of current Rule 1017(k) and are reorganized.

In addition, the Exchange is proposing to state in proposed Rule 1017(d)(ii) that the underlying security, including indexes, must be open on the primary market for a certain time period for all options to be determined by the Exchange. The Exchange is proposing that the time period be no less than 100 milliseconds and no more than 5 seconds. The Exchange currently applies a minimal delay of 500 milliseconds. This proposal is intended to permit the price of the underlying security to settle down and not flicker back and forth among prices after its opening. The Exchange is adding this detail to Rule 1017(d)(ii). It is common for a stock to fluctuate in price immediately upon opening; such volatility reflects a natural uncertainty about the ultimate Opening Price, while the buy and sell interest is matched. The Exchange is proposing a range of no less than 100 milliseconds and no more than 5 seconds in order to ensure that it has the ability to adjust the period for which the underlying security must be open on the primary market. The Exchange may determine that in periods of high/low volatility that allowing the underlying to be open for a longer/shorter period of time may help to ensure more stability in the marketplace prior to initiating the Opening Process.

The Exchange is proposing to relocate the obligations of Phlx Electronic Market Makers to new paragraph (d) as well. They are unchanged. The Specialist assigned in a particular equity option must enter a Valid Width Quote not later than one minute following the dissemination of a quote or trade by the market for the underlying security or, in the case of index options, following the receipt of the Opening Price in the underlying index. The Specialist assigned in a particular U.S. dollar-settled FCO must enter a Valid Width Quote not later than 30 seconds after the announced market opening.[32]

Furthermore, a Phlx Electronic Market Maker other than a Specialist that submits a quote pursuant to Rule 1017 in any option series when the Specialist's quote has not been submitted shall be required to submit continuous, two-sided quotes in such option series until such time as the Specialist submits his/her quote, after which the Phlx Electronic Market Maker that submitted such quote shall be obligated to submit quotations pursuant to Rule 1014(b)(ii)(D). This is also substantially unchanged.[33]

The Exchange is proposing to state in Rule 1017(d)(iv) that the Opening Process will stop and an option series will not open if the ABBO becomes crossed or when the requisite number of Valid Width Quotes pursuant to Rule 1017(d)(i) are no longer present. Once each of these conditions no longer exists, the Opening Process in the affected option series will start again pursuant to Rule 1017(f)–(k). All eligible opening interest will continue to be considered during the Opening Process when the process is re-started. The Exchange is amending Rule 1017 to add this detail, which the Exchange believes is implied from the conditions that trigger the Opening Process.

Overall, as explained above, new Rule 1017(d) is the same as current Rule 1017(k), except the reference at the end of paragraph (k) to Intermarket Sweep Orders (''ISOs'') [34] will now appear in new subparagraph (k)(C)(3)(i) and a reference is being added to the Immediate-or-Cancel (''IOC'') designation. In addition, the proposed Rule 1017(d) is more closely tied to specific time periods, like 9:25 a.m. for the receipt of quote and Opening Sweeps, and 9:30 a.m. for the beginning of the actual Opening Process. The proposed rule also reflects that the ABBO cannot be crossed because it is indicative of uncertainty in the marketplace of where the option series should be valued. In this case, the Exchange will wait for the ABBO to become uncrossed before initiating the Opening Process to ensure that there is stability in the marketplace in order to assist the Exchange in determining the Opening Price. These additions are intended to provide additional detail to the rule that the Exchange believes will be helpful to the reader.

New Rule 1017(e) states that the procedure described in this Rule may be used to reopen an option after a trading halt. This is currently in Rule 1017(h). The Exchange is adding that if there is a trading halt or pause in the underlying security, the Opening Process will start again irrespective of the specific times listed in Rule 1017(d). This is because these times relate to the normal market opening at 9:30 a.m. Most of this language is in Rule 1017 at current paragraph (h), except the aforementioned reference to specific times provides additional detail.

Opening With a PBBO

New Rule 1017(f) will now be titled ''Opening with a PBBO (No Trade)'' and provide that if there are no opening quotes or orders that lock or cross each other and no routable orders crossing the ABBO, the system will open with an opening quote by disseminating the Exchange's best bid and offer among quotes and orders (''PBBO'') that exist in the system at that time, unless the following three conditions exist: (i) A Zero Bid Market; (ii) no ABBO; and (iii) no Quality Opening Market. If all of these conditions exist, the Exchange will calculate an Opening Quote Range pursuant to paragraph (j) and conduct the Price Discovery Mechanism or ''PDM'' pursuant to paragraph (k) below. These three conditions exist in the system today, but do not appear in Rule 1017. The existence of all three conditions being present at the same time is very rare. The Exchange believes that when all three of these conditions exist, further price discovery is warranted to validate or perhaps update the Potential Opening Price and to attract additional interest to perhaps render an opening trade possible, because: (i) A Zero Bid Market reflects a lack of buying interest that could benefit from price discovery; (ii) the lack of an ABBO means there is no external check on the Exchange's market for that options series; and (iii) the lack of a Quality Opening Market indicates that the Exchange's market is wide. If no quotes or orders lock/cross each other, nothing matches and there can be no trade. This is the same as Rule 1017(l)(i). The Exchange believes that when these conditions exist, it is difficult to arrive at a reasonable and expected price.

Further Opening Processes

If an opening did not occur pursuant to proposed Rule 1017(f) and there are opening Valid Width Quotes or orders that lock or cross each other, the system will calculate the Pre-Market BBO. This new rule text is located in new Rule 1017(g), which is the same as current Rule 1017(l)(ii), except the term Pre-Market BBO is now specifically defined in proposed Rule 1017(a)(vii).

Proposed new Rule 1017 (h) describes the general concept of how the system calculates the Potential Opening Price under all circumstances once the Opening Process is triggered. Specifically, the system will take into consideration all Valid Width Quotes,

[32] *See* proposed Rule 1017(d)(iii).

[33] *See* proposed Rule 1017(d)(iv).

[34] Current Rule 1017(k), which is being deleted, provides: Any order volume that is routed to away markets pursuant to this Rule 1017 will be marked as an ISO.

Opening Sweeps and orders (except AON interest that cannot be satisfied) [35] for the option series and identify the price at which the maximum number of contracts can trade (''maximum quantity criterion''). This concept of maximizing the number of contracts that can trade currently appears in current Rule 1017(l)(ii), and is intended to find the most reasonable and suitable price, relying on the maximization to reflect the best price. However, current Rule 1017(l)(ii) states that if the Opening Price calculation leaves no imbalance, the Exchange will open at that price, executing marketable trading interest, as long as the Opening Price includes only Exchange interest. This only occurs under certain circumstances, which is now explained in new Rule 1017(i).

The Exchange proposal further states that when two or more Potential Opening Prices would satisfy the maximum quantity criterion and leave no contracts unexecuted, the system takes the highest and lowest of those prices and takes the mid-point; if such mid-point is not expressed as a permitted minimum price variation, it will be rounded to the minimum price variation that is closest to the closing price for the affected series from the immediately prior trading session. If there is no closing price from the immediately prior trading session, the system will round up to the minimum price variation to determine the Opening Price.[36] This is similar to current Rule 1017 (l)(ii)(B).

If two or more Potential Opening Prices for the affected series would satisfy the maximum quantity criterion and leave contracts unexecuted, the Opening Price will be either the lowest executable bid or highest executable offer of the largest sized side.[37] This, again, bases the Potential Opening Price on the maximum quantity that is executable. The Potential Opening Price is limited by the away market price that cannot be satisfied with the Exchange routable interest.[38] The Exchange does not open with a trade that trades through another market. The Exchange is amending Rule 1017 to provide detail to the rule not contemplated by the current language. This process, importantly, breaks a tie by considering the largest sized side and away markets, which are relevant to determining a fair Opening Price.

The system applies certain boundaries to the Potential Opening Price to help ensure that the price is a reasonable one by identifying the quality of that price; if a well-defined, fair price can be found within these boundaries, the option series can open at that price without going through a further price discovery mechanism. Accordingly, new Rule 1017(i),[39] entitled ''Opening with Trade,'' will state at Rule 1017(i)(A) the Exchange will open the option series for trading at the following Opening Price if any of these conditions occur: (i) The Potential Opening Price is at or within the best of the Pre-Market BBO and the ABBO; (ii) the Potential Opening Price is at or within the non-zero bid ABBO if the Pre-Market BBO is crossed; or (iii) where there is no ABBO, the Potential Opening Price is at or within the Pre-Market BBO which is also a Quality Opening Market.

These boundaries serve to validate the quality of the Opening Price. This concept is defined in current Rule 1017(l)(ii) in a limited manner, which provides that, ''If the price is within the highest quote bid and lowest quote offer and leaves no imbalance, the Exchange will open at that price, executing marketable trading interest, as long as the opening price includes only Exchange interest.'' New Rule 1017(i) provides that the Exchange will open with a trade as long as it is within the defined boundaries regardless of any imbalance. The Exchange believes that since the Opening Price can be determined within a well-defined boundary and not trading through other markets, it is fair to open the market immediately with a trade and to have the remaining interest available to be executed in the displayed market. Using a boundary-based price counterbalances opening faster at a less bounded and perhaps less expected price and reduces the possibility of leaving an imbalance.

If there is more than one Potential Opening Price which meets the conditions set forth in proposed Rule 1017(i)(A), where (1) no contracts would be left unexecuted and (2) any value used for the mid-point calculation (which is described in Rule 1017(h)) that crosses either: the Pre-Market BBO or the ABBO, then the Exchange will open the option series for trading with an execution and use the best price which the Potential Opening Price crosses as a boundary price for the purpose of the mid-point calculation.[40] The proposed rule now better explains the boundary as well as the price basis for the mid-point calculation for immediate opening with a trade, which improves the detail included in the rule. The Exchange believes that this process is logical because it seeks to select a fair and balanced price.

Proposed Rule 1017(j) will provide that the system will calculate an Opening Quote Range (''OQR'') for a particular option series that will be utilized in the PDM. The OQR is an additional type of boundary beyond the boundaries mentioned in Rule 1017 at proposed paragraph (i). OQR is intended to limit the Opening Price to a reasonable, middle ground price and thus reduce the potential for erroneous trades during the Opening Process. Although the Exchange applies other boundaries such as the BBO, the OQR is outside of that and provides a price that can satisfy more size without becoming unreasonable.

Specifically, to determine the minimum value for the OQR, an amount, as defined in a table to be determined by the Exchange,[41] will be subtracted from the highest quote bid among Valid Width Quotes on the Exchange and on the away market(s), if any, except as provided in proposed Rule1017(j)(3) and (4).[42] To determine the maximum value for the OQR, an amount, as defined in a table to be determined by the Exchange, will be added to the lowest quote offer among Valid Width Quotes on the Exchange and on the away market(s), if any, except as provided in proposed Rule 1017(j)(3) and (4).[43] However, if one or more away markets have disseminated opening quotes that are not crossed, and there are Valid Width Quotes on the Exchange that cross each other or that cross away market quotes, then the minimum value for the OQR will be the highest quote bid among quotes on away market(s).[44] In addition, the maximum value for the OQR will be the lowest quote offer among quotes on away market(s).[45] And if, however, there are opening quotes on the Exchange that cross each other, and there is no away market in the affected option series, the minimum value for the OQR will be the lowest quote bid among Valid Width Quotes on the Exchange, and the maximum value for the OQR will be the highest quote offer among Valid Width Quotes on the Exchange.[46] This is the same as existing Rule 1017(l)(iii) and (iv), except that the new Rule 1017(j) combines those concepts into a single provision.

[35] *See* proposed Rule 1017(b).

[36] *See* proposed Rule 1017(h)(A).

[37] *See* proposed Rule 1017(h)(B).

[38] *See* proposed Rule 1017(h)(C).

[39] The deletion of current paragraph (i) is discussed below.

[40] *See* proposed Rule 1017(i)(B).

[41] The table will be available on the Exchange's Web site.

[42] *See* proposed Rule 1017(j)(1).

[43] *See* proposed Rule 1017(j)(2).

[44] *See* proposed Rule 1017(j)(3)(a).

[45] *See* proposed Rule 1017(j)(3)(b).

[46] *See* proposed Rule 1017(j)(4)(a) and (b).

If there is more than one Potential Opening Price possible where no contracts would be left unexecuted, any price used for the mid-point calculation (which is described in new Rule 1017(h)) that is through the OQR will be restricted to the OQR price on that side of the market for the purposes of this calculation. This, in Rule 1017(j) at new subparagraph (5), continues the theme of relying on both maximizing executions and looking at the correct side of the market to determine a fair price.

New Rule 1017(j) (6) deals with the situation where there is an away market price involved. If there is more than one Potential Opening Price possible where no contracts would be left unexecuted and any price used for the mid-point calculation (which is described in new Rule 1017(h)) is an away market price when contracts will be routed, the system will use the away market price as the Potential Opening Price. Because the system may need to route to other markets it uses the away market price as the Opening Price.

If non-routable interest can be maximum executable against Exchange interest after routable interest has been determined by the system to satisfy the away market, then the Potential Opening Price is the price at which the maximum volume, excluding the volume which will be routed to an away market, may be executed on the Exchange as described in Rule 1017 at new paragraph (h). The system will consider routable Customer interest in price/time priority to satisfy the away market.[47] This is consistent with the price/time handling of Customer interest outside of the Opening Process.[48] This continues the theme of trying to satisfy the maximum amount of interest during the Opening Process.

If the Exchange has not opened pursuant to proposed Rule 1017 paragraphs (f) or (i), the Exchange will conduct a PDM pursuant to new Rule 1017(k). The PDM is the process by which the Exchange seeks to identify an Opening Price having not been able to do so following the process outlined thus far. The principles behind the PDM are, just like above, to satisfy the maximum number of contracts possible by identifying a price that may leave unexecuted contracts. However, the PDM applies a new, wider boundary to identify the Opening Price and the PDM involves seeking additional liquidity.

Currently, the price discovery process, known as the ''imbalance process'' in current Rule 1017, is triggered only by unexecuted contracts at the price at which the maximum number of contracts can trade. Instead, the situations in proposed Rule 1017(f) and (j) also result in the initiation of an imbalance process.[49] The Exchange believes that conducting the price discovery process in these situations protects opening orders from receiving a random price that does not reflect the totality of what is happening in the markets on the opening and also further protects opening interest from receiving a potentially erroneous execution price on the opening. Opening immediately has the benefit of speed and certainty, but that benefit must be weighed against the quality of the execution price and whether orders were left unexecuted. The Exchange believes that the proposed rule strikes an appropriate balance.

In addition, the current rule takes away market interest into account at the beginning of the imbalance process, while the proposed rule attempts to open using Exchange interest only to determine an Opening Price, provided certain conditions contained in new paragraph (i) are present to ensure participants receive a quality execution in the opening. This is reflected beginning in current Rule 1017(l)(ii)(C). The proposed rule does not consider away market liquidity until the price discovery process. As a result, the Exchange might open without routing if all of the conditions described above are met. The Exchange believes that the benefit of this process is a more rapid opening with quality execution prices.

Specifically, new Rule 1017(k)(A) provides that the system will broadcast an Imbalance Message (which includes the symbol, side of the imbalance (unmatched contracts), size of matched contracts, size of the imbalance, and price of the affected series (which must be within the Pre-Market BBO) to participants, and begin an ''Imbalance Timer,'' not to exceed three seconds. The Imbalance Message is intended to attract additional liquidity, much like an auction is, using an auction message and timer.[50] The Imbalance Timer will be for the same number of seconds for all options traded on the Exchange. This is the same as the existing rule, except that the Exchange is adding more detail to this provision, to provide that the price in the imbalance message must be within the Pre-Market BBO. This is intended, as some of the other boundaries applied in the Opening Process, to help ensure that the price is reasonable in light of the price discovery needed to determine an Opening Price.

New Rule 1017(k)(B), states that any new interest received by the system will update the Potential Opening Price. This amendment adds detail to the rule. If during or at the end of the Imbalance Timer, the Opening Price is at or within the OQR the Imbalance Timer will end and the system will execute at the Opening Price if the executions consist of Exchange interest only without trading through the ABBO and without trading through the limit price(s) of interest within OQR which is unable to be fully executed at the Opening Price. If no new interest comes in during the Imbalance Timer and the Opening Price is at or within OQR, the Exchange will open at the end of the Imbalance Timer. This reflects that the Exchange is seeking to identify a price on the Exchange without routing away, yet which price may not trade through another market and the quality of which is addressed by applying the OQR boundary.

Currently, Rule 1017(l)(vi)(B) provides that if opening quotes, Opening Sweeps and orders submitted during the Imbalance Timer, or other changes to the ABBO, would allow the entire imbalance amount to trade at the Exchange at or within the OQR without trading through the ABBO, the Imbalance Timer will end and the system will execute at the appropriate Opening Price. Accordingly, the current rule takes away market prices and volume into account at this step, while the system functionality does not. This is intended to foster trading on the Exchange before routing away.

Next, current Rule 1017(l)(vi)(C) is being reorganized with additional detail, and introduces the process of routing away. Provided the option series has not opened pursuant to proposed Rule 1017(k)(B), the system will send a second Imbalance Message with a Potential Opening Price that is bounded by the OQR (without trading through the limit price(s) of interest within OQR which is unable to be fully executed at the Opening Price) and includes away market volume in the size of the imbalance to participants; and concurrently initiate a Route Timer, not to exceed one second.[51] The Route

[47] *See* proposed Rule 1017(j)(7).

[48] *See* Rule 1014(vii) [sic].

[49] Today, in these situations, the option series would not open immediately. Rather an imbalance would occur where there is unexecutable trading interest at a certain price.

[50] *See* COOP and COLA descriptions in Rule 1080.07.

[51] The Route Timer is a brief timer that operates as a pause before an order is routed to an away market. The Route Timer is currently set at 200 milliseconds, which the Exchange has determined is a reasonable time period to gather additional interest on the Exchange before routing away. The

Timer is intended to give Exchange users an opportunity to respond to an Imbalance Message before any opening interest is routed to away markets and, thereby, maximize trading on the Exchange. If during the Route Timer, interest is received by the system which would allow the Opening Price to be within OQR without trading through other markets and without trading through the limit price(s) of interest within OQR which is unable to be fully executed at the Opening Price, the system will trade and the Route Timer will end. The system will monitor quotes received during the Route Timer period and make ongoing corresponding changes to the permitted OQR to reflect them.[52] This is being changed to eliminate the requirement that there be no imbalance, which means it is more likely that an Opening Price will be discovered. It also widens the boundary of available Opening Prices, which should similarly increase the likelihood that an Opening Price can be determined. The Route Timer, like the Imbalance Timer, is intended to permit responses to be submitted and considered by the system in calculating the Potential Opening Price. The system does not route away until the Route Timer ends.

Proposed Rule 1017(k)(C)(3) will provide that when the Route Timer expires, if the Potential Opening Price is within OQR (without trading through the limit price(s) of interest within OQR that is unable to be fully executed at the Opening Price), the system will determine if the total number of contracts displayed at better prices than the Exchange's Potential Opening Price on away markets (''better priced away contracts'') would satisfy the number of marketable contracts available on the Exchange. This is largely unchanged in terms of applying the OQR as a boundary before considering away markets. The Exchange is adding reference to the limit price, because the limit price of interest within the OQR serves as a boundary as well. This protects the unexecuted interest and should result in a fairer price. The Exchange is adding rule text to state that the Exchange will open the option by routing and/or trading on the Exchange, pursuant to proposed Rule 1017(k)(C)(3)(i)–(iii).

Proposed Rule 1017(k)(C)(3)(i) will provide that if the total number of contracts displayed at better prices than the Exchange's Potential Opening Price on away markets (''better priced away contracts'') would satisfy the number of marketable contracts available on the Exchange on either the buy or sell side, the system will route all marketable contracts on the Exchange to such better priced away markets as ISO IOC orders, and determine an opening PBBO that reflects the interest remaining on the Exchange. The system will price any contracts routed away to other markets at the Exchange's Opening Price or proposed Rule 1017(k)(C)(3)(ii) or (iii) described hereinafter. Currently, Rule 1017 states that contracts routed away are priced at the better away market price. This is incorrect. Routing away at the Exchange's Opening Price is intended to achieve the best possible price available at the time the order is received by the away market.

Proposed Rule 1017(k)(C)(3)(ii)[53] will provide that if the total number of better priced away contracts would not satisfy the number of marketable contracts the Exchange has, the system will determine how many contracts it has available at the Exchange Opening Price. If the total number of better priced away contracts plus the number of contracts available at the Exchange Opening Price would satisfy the number of marketable contracts on the Exchange on either the buy or sell side, the system will contemporaneously route a number of contracts that will satisfy interest at other markets at prices better than the Phlx Opening Price, and trade available contracts on the Exchange at the Exchange Opening Price. The system will price any contracts routed to other markets at the better of the Exchange Opening Price or the order's limit price pursuant to Rule 1017(k)(vi)(C)(3)(ii) [sic] at the better of the Exchange Opening Price or the order's limit price. Currently, the rule states that the Exchange will execute only at the Opening Price, but in actuality the system uses the better of the Opening Price or the order's limit price to route to away markets. This continues with the theme of maximum possible execution of the interest in Phlx or away markets. The addition of the reference to the buy or sell side is intended to provide additional detail and accuracy to the description.[54]

Proposed Rule 1017(k)(C)(3)(iii)[55] will provide that if the total number of better priced away contracts plus the number of contracts available at the Exchange Opening Price plus the contracts available at other markets at the Exchange Opening Price would satisfy the number of marketable contracts the Exchange has on either the buy or sell side, the system will contemporaneously route a number of contracts that will satisfy interest at other markets at prices better than the Exchange Opening Price (pricing any contracts routed to other markets at the better of the Exchange Opening Price or the order's limit price), trade available contracts on the Exchange at the Exchange Opening Price, and route a number of contracts that will satisfy interest at other markets at prices equal to the Exchange Opening Price. Much of this appears in the current rule but is supplemented by the reference to the order's limit price, as discussed above. This provision, like the existing one, is intended to introduce routing to away markets potentially both at a better price than the Exchange Opening Price as well as at the Exchange Opening Price to access as much liquidity as possible to maximize the number of contracts able to be traded as part of the Opening Process. The Exchange routes at the better of the Exchange's Opening Price or the order's limit price to first ensure the order's limit price is not violated. Routing away at the Exchange's Opening Price is intended to achieve the best possible price available at the time the order is received by the away market.

Proposed Rule 1017(k)(C)(4)[56] is proposed to state that the system may send up to two additional Imbalance Messages[57] (which may occur while the Route Timer is operating) bounded by OQR and reflecting away market interest in the volume. The reference to two additional Imbalance Messages is intended to replace in a clearer way the current reference to repeating the ''Imbalance Process'' (a term no longer being used in this rule) three times. The reference to the OQR and away market interest, again, amends the rule by adding detail to make clear that both are boundaries. These boundaries are intended to assist in determining a reasonable price at which an option series might open.

This provision is proposed to further state that after the Route Timer has expired, the processes in proposed Rule 1017(k)(C)(3) will repeat (except no new Route Timer will be initiated). No new Route Timer is initiated because the Exchange believes that after the Route Timer has been initiated and subsequently expired, no further delay

Exchange has only changed this timer a few times over the past several years.

[52] *See* proposed Rule 1017(k)(C)(1) and (2).

[53] This is currently subparagraph 4.

[54] This addition is proposed in several places in Rule 1017 for the same reason.

[55] This is currently subparagraph 5.

[56] This is currently subparagraph 6.

[57] The first two Imbalance Message always occur, while the next two may or may not occur based on whether or not the Exchange has been able to open before repeating the Imbalance Process.

is needed before routing contracts if at any point thereafter the Exchange is able to satisfy the total number of marketable contracts the Exchange has by executing on the Exchange and routing to other markets.

Proposed Rule 1017(k)(vi)(C)(5) [sic],[58] entitled ''Forced Opening,'' will describe what happens as a last resort in order to open an options series when the processes described above have not resulted in an opening of the options series. Under this process, called a Forced Opening, after all additional Imbalance Messages have occurred pursuant to proposed Rule 1017(k)(4),[59] the system will open as many contracts as possible by routing to other markets at prices better than the Exchange Opening Price for their disseminated size, trading available contracts on the Exchange at the Exchange Opening Price bounded by OQR (without trading through the limit price(s) of interest within OQR which is unable to be fully executed at the Opening Price). The system will also route contracts to other markets at prices equal to the Exchange Opening Price at their disseminated size. In this situation, the system will price any contracts routed to other markets at the better of the Exchange Opening Price or the order's limit price. Any unexecuted contracts from the imbalance not traded or routed will be cancelled back to the entering participant if they remain unexecuted and priced through the Opening Price, unless the member that submitted the original order has instructed the Exchange in writing to re-enter the remaining size, in which case the remaining size will be automatically submitted as a new order. Currently, the rule provides that before the order is cancelled back or reentered, it will be displayed in the Exchange quote at the Opening Price for the remaining size for a period not to exceed ten seconds; this does not occur since the Exchange has set this period of time to zero seconds. The Exchange is amending this rule to add the boundaries of OQR and limit prices within the OQR to provide additional detail. A majority of this paragraph is not being amended. These boundaries are intended to ensure a quality Opening Price as well as protect the unexecutable interest entered with a limit price which may not be able to be fully executing at the Opening Price.

Although much of new Rule 1017(k)(vi)(C)(5) [sic] is the same as current subparagraph (7), the Exchange is proposing to delete the sentence that provides that during the display time period, the system will disseminate, on the opposite side of the market from remaining unexecuted contracts: (i) A non-firm bid for the price and size of the next available bid(s) on the Exchange if the imbalance is a sell imbalance, or (ii) a non-firm offer for the price and size of the next available offer(s) on the Exchange if the imbalance is a buy imbalance. This language is obsolete, because this does not occur as there is currently no display time period.

Proposed Rule 1017(k)(viii), currently Rule 1017(l)(viii), as amended, provides that the system will give priority to market orders first in time priority, then to resting limit orders at the Opening Price. Market orders have priority because they are considered to be the most aggressively priced, consistent with price priority. The Exchange is proposing to amend the existing rule text which provides that limit orders are treated as market orders, because they are not. The Exchange proposes to state that limit orders are prioritized based on their limit price and capacity (participant type) as they are during normal trading (outside the opening). Accordingly, the Exchange is proposing to amend this rule text to state that the system will give priority to market orders first in time, then to resting limit orders. Further, the allocation provisions of Rule 1014(g)(vii) will apply.

The Exchange proposes to delete rule text in current Rule 1017(i), which is incorrect. It currently provides that a limit order to buy which is at a higher price than the price at which the option is to be opened and a limit order to sell which is at a lower price than the price at which the option is to be opened, shall be treated as market orders. The Exchange proposes to remove this rule text. The Exchange continues to treat these orders as limit orders, which is consistent with their handling during normal trading. The Exchange does not believe that limit orders should be handled differently on the opening and believes that this is consistent with users' expectations. Presumably, market participants choose to enter limit orders for the protection associated with a limit price, and they understand that market orders may be executed before limit orders as a matter of priority, which is an acceptable outcome because they are not willing to take the risks associated with market orders.[60]

The Exchange proposes to amend Rule 1017 to add new section (k)(F) which would provide that when an option series opens, the system disseminates the price and size of the PBBO. This amendment adds more detail to the rule. The Exchange must necessarily disseminate the PBBO not just on the opening but throughout the day.

The Exchange proposes to delete current Rule 1017(l)(ix) which provides for a brief delay to calculate the opening. The current rule provides that the period will not exceed .25 of one second, but it has long been set at zero. The Exchange's technology does not require a delay in order to open and therefore the provision is obsolete.

The Exchange also proposes to delete current Rule 1017(l)(x), which deals with when the ABBO becomes crossed. The impact of the ABBO on the Exchange's opening is now discussed throughout the proposed rule and therefore this provision is unnecessary.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[61] in general, and furthers the objectives of Section 6(b)(5) of the Act,[62] in particular, in that it is designed to promote just and equitable principles of trade. Specifically, the changes to paragraphs (a) through (e) and (g) amend the current rule by adding details concerning the manner in which the Opening Process occurs in an option series. The amendment also adds detail to the rule and removes outdated language. The proposed rule is also re-organized in a more logical way and deletes ''reserved'' paragraphs, all of which improves the readability of the rule. For all of these reasons, paragraph (a), which adopts the term ''Opening Process'' to be used throughout the rule and which defines it, along with several other new definitions, should promote just and equitable principles of trade.

The proposed additions to Rule 1017(b) promote just and equitable principles of trade because the new language spells out in greater detail what interest is included in the Opening Process, which, in turn, helps investors determine what to submit. New Rule 1017(b) will specifically state that AON interest that can be satisfied will be considered for execution in determining the Opening Price throughout the Opening Process. The rule is currently silent on the eligibility of AON interest on the opening. It is consistent with the Act to include AON interest on the opening because this contingency market or limit order will execute in its entirety or not at all, provided that this interest can be satisfied. The Exchange

[58] This is currently subparagraph 7.

[59] The reference to subparagraph (4) helps link these provisions.

[60] *See* Rule 1014(g)(vii).

[61] 15 U.S.C. 78f(b).

[62] 15 U.S.C. 78f(b)(5).

believes that AON should be included, similar to other orders, if it can be satisfied. This treatment is consistent with the treatment of AON in other market sessions.

The additions to Rule 1017(d) regarding the 9:25 a.m. trigger and providing that orders entered at any time before an options series opens are included in the Opening Process should promote just and equitable principles of trade, because a reasonable time period has been selected after which eligible interest is included balanced against accepting as much interest as possible to result in a robust Opening Process. The 9:25 a.m. trigger is intended to tie the option Opening Process to quoting in the underlying security; it presumes that option quotes submitted before any indicative quotes have been disseminated for the underlying security may not be reliable or intentional. Therefore, the Exchange has chosen a reasonable timeframe at which to begin utilizing option quotes, based on the Exchange's experience with when underlying quotes start becoming available. In addition, the Exchange is proposing to state in proposed Rule 1017(d)(ii) that the underlying security, including indexes, must be open on the primary market for a certain time period for all options to be determined by the Exchange. The Exchange is proposing that the time period be no less than 100 milliseconds and no more than 5 seconds. The Exchange currently applies a minimal delay of 500 milliseconds. This proposal is consistent with the Act because it is intended to permit the price of the underlying security to settle down and not flicker back and forth among prices after its opening. It is common for a stock to fluctuate in price immediately upon opening; such volatility reflects a natural uncertainty about the ultimate Opening Price, while the buy and sell interest is matched. The Exchange is proposing a range of no less than 100 milliseconds and no more than 5 seconds in order to ensure that it has the ability to adjust the period for which the underlying security must be open on the primary market. The Exchange may determine that in periods of high/low volatility that allowing the underlying to be open for a longer/shorter period of time may help to ensure more stability in the marketplace prior to initiating the Opening Process. Rule 1017(e) specifically describes the manner in which a trading halt would impact a reopening process. This paragraph is based on existing Rule 1017(h). This rule text makes clear that a reopening is not tied to the 9:25 a.m. time period of Rule 1017(d). This language should promote just and equitable principles of trade by specifically addressing the manner in which a reopening will occur after a trading halt.

The Exchange believes that new Rule 1017(f) promotes just and equitable principles of trade, because the proposed conditions involving Zero Bid Markets, no ABBO and no Quality Opening Market trigger the price discovery mechanism rather than an immediate opening in order to validate the Opening Price against away markets or by attracting additional interest to address the specific condition. This is consistent with the Act because it should avoid opening executions in very wide or unusual markets where an opening execution price cannot be validated. This process will occur if there are no routable orders that cross the ABBO.

Similarly, new Rule 1017(h) promotes just and equitable principles of trade, because it better describes how the system calculates the Potential Opening Price, which should provide a better understanding of this part of the process, which has many elements. Once the price at which the maximum number of contracts can be executed is determined, applying additional criteria promotes just and equitable principles of trade, because it helps arrive at a price that is logical and reasonable in light of away markets and other interest present in the system. Where there are no away markets, applying the boundary of a Quality Opening Market promotes just and equitable principles of trade also to help arrive at a reasonable Opening Price. When choosing between multiple Opening Prices when some contracts would remain unexecuted, using the lowest bid or highest offer of the largest sized side of the market promotes just and equitable principles of trade because it uses size as a tie breaker. The Exchange's method for determining the Potential Opening Price and Opening Price is consistent with the Act because it seeks to arrive at reasonable price in light of interest present in the system and away market interest. The Exchange's method seeks to validate the Opening Price and avoid opening executions in very wide or unusual markets where validation cannot occur.

Proposed new Rule 1017(i) promotes just and equitable principles of trade by establishing when the Exchange opens immediately and which conditions are relevant, based on the Potential Opening Price determined in Rule 1017(h). The rule text in Rule 1017(i) concerning opening with a trade, is consistent with the Act because it enables an immediate opening to occur within a certain boundary without need for the price discovery process. The boundary provides protections and ensures a reasonable Opening Price. Throughout the Opening Process, there is no different impact to any particular participant; executions occur at the most reasonable price possible regardless of participant type.

The OQR described in proposed Rule 1017(j) promotes just and equitable principles of trade by establishing a reasonable boundary to be applied during the PDM. The OQR operates the same way today and serves to provide a level of protection for potential opening executions. This is consistent with the Act because OQR continues to act as a protection for the Opening Price because it protects away market prices and also protects against extreme volatility which may impact the Opening Price.

New Rule 1017(j)(5) concerning more than one Potential Opening Price is consistent with the Act because it provides price protection because it forces the Potential Opening Price to fall within the OQR boundary. Specifically, the mid-point calculation balances the price among interest participating in the Opening when there is more than one price at which the maximum number of contracts could execute. Limiting the mid-point calculation to the OQR when a price would otherwise fall outside of the OQR ensures the final mid-point price will be within the protective OQR boundary.

New Rule 1017(j)(6) deals with the situation where there is more than one Potential Opening Price and an away market price involved. If there is more than one Potential Opening Price possible where no contracts would be left unexecuted and any price used for the mid-point calculation is an away market price when contracts will be routed, the system will use the away market price as the Potential Opening Price. This result is consistent with the Act, because the system may need to route to other markets and therefore it uses the away market price as the Opening Price. These boundaries serve to validate the quality of the Opening Price. OQR is intended to limit the Opening Price to a reasonable, middle ground price and thus reduce the potential for erroneous trades during the Opening Process. Although the Exchange applies other boundaries such as the Pre-Market BBO, the OQR is outside of that and provides a price that can maximize the number of executions at a reasonable price. The PDM in new Rule 1017(k) reflects what is generally known as an imbalance process. The

process is intended to attract liquidity to improve the price at which an option series will open as well as to maximize the number of contracts that can be executed on the opening. The Exchange believes that this is consistent with just and equitable principles of trade. The Exchange is adding various references to the applicable boundaries throughout this paragraph, as explained above, which should help investors receive reasonable prices, which is the case throughout the Opening Process. In addition, the handling of routing on the opening should promote just and equitable principles of trade by incorporating away markets into the process in a clearer and more detailed away. The PDM also promotes just and equitable principles of trade by taking into account whether all interest can be fully executed, which helps investors by including as much interest as possible in the Opening Process.

The current rule takes away market interest into account at the beginning of the imbalance process, while the proposed rule proposes to open using Exchange interest only within the Pre-Market BBO to determine an Opening Price, provided certain conditions contained in new Rule 1017(i) are present to ensure participants receive a quality execution in the opening. This is reflected beginning in current Rule 1017(l)(ii)(C). It is consistent with the Act to not consider away market liquidity until the price discovery process occurs because this proposed process provides for a swift, yet conservative opening. The Exchange is bounded by the Pre-Market BBO when determining an Opening Price. The away market prices would be considered, albeit not immediately.

The Exchange believes that amending the rule text of current Rule 1017(l)(viii) to describe the manner in which limit orders are executed in comparison to market orders promotes just and equitable principles of trade because it provides investors with the proper method in which the system will execute orders at the opening. It is consistent with the Act to execute market orders before limit order because those order types are by definition at the best price.

The Exchange believes that the deletion of current Rule 1017(l)(ix) promotes just and equitable principles of trade because eliminating an obsolete timer will provide investors with accurate information concerning the operation of the Exchange's opening. Deleting the timer is consistent with the Act because the timer is no longer necessary and its removal results in potentially faster processing of interest received after the opening occurs.

Similarly, the Exchange believes that the deletion of current Rule 1017(l)(x) promotes just and equitable principles of trade, because the proposed rule will continue to describe the impact of a crossed ABBO, but in specific parts of the rule, where appropriate, which adds more context and clarity to the description of the opening. The Exchange is not adding this concept to the rule, rather just relocating the concept within the rule. It is consistent with the Act to terminate the opening process when the ABBO becomes crossed because it protects against potential pricing anomalies in the market.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposal does not change the intense competition that exists among the options markets for options business including on the opening. Nor does the Exchange believe that the proposal will impose any burden on intra-market competition; the Opening Process involves many types of participants and interest.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) by order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2016–79 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR-Phlx-2016–79. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2016–79 and should be submitted on or before September 12, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[63]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19896 Filed 8–19–16; 8:45 am]

BILLING CODE 8011–01–P

[63] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Bird/Other Wildlife Strike Report

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. Wildlife strike data are collected to develop standards and monitor hazards to aviation.

DATES: Written comments should be submitted by September 21, 2016.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Ronda Thompson at (202) 267–1416, or by email at: *Ronda.Thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0045.

Title: Bird/Other Wildlife Strike Report.

Form Numbers: FAA Form 5200–7.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 3, 2016 (81 FR 26616). There was 1 comment. 14 CFR 139.337—Wildlife Hazard Management requires that wildlife strike data is collected to develop standards and monitor hazards to aviation. Data identify wildlife strike control requirements and provide in-service data on aircraft component failure. The FAA form 5200–7, Bird/Other Wildlife Strike Report, is most often completed by the pilot-in-charge of an aircraft involved in a wildlife collision or by Air Traffic Control Tower personnel, or other airline or airport personnel who have knowledge of the incident.

Respondents: Approximately 7,666 pilots, air traffic control personnel, or other airline or airport personnel.

Frequency: Information is collected as needed.

Estimated Average Burden per Response: 5 minutes.

Estimated Total Annual Burden: 613 hours.

Issued in Washington, DC, on August 17, 2016.

Ronda Thompson,

FAA Information Collection Clearance Officer, Performance, Policy & Records Management Branch, ASP–110.

[FR Doc. 2016–20004 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Application for Employment With the Federal Aviation Administration

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information collected is used to evaluate the qualifications of applicants for a variety of positions within the FAA.

DATES: Written comments should be submitted by September 21, 2016.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

PUBLIC COMMENTS INVITED: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Ronda Thompson at (202) 267–1416, or by email at: *Ronda.Thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0597.

Title: Application for Employment with the Federal Government.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 3, 2016 (81 FR 26615). There were no comments. Under the provisions of Public Law 104–50, the Federal Aviation Administration (FAA) was given the authority and the responsibility for developing and implementing its own personnel system. The agency requests certain information needed to determine basic eligibility for employment and potential eligibility for veteran's preference and Veteran's Readjustment Act appointments. In addition, occupation specific questions assist the FAA in determining candidates' qualifications so that only the best-qualified candidates may be hired for the many aviation safety-related occupations.

Respondents: Approximately 118,000 annually.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 1.5 hours.

Estimated Total Annual Burden: 177,000 hours.

Issued in Washington, DC, on August 17, 2016.

Ronda Thompson,

FAA Information Collection Clearance Officer, Performance, Policy & Records Management Branch, ASP–110.

[FR Doc. 2016–20006 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Release From Federal Surplus Property and Grant Assurance Obligations at Redding Municipal Airport (RDD), Redding, California

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of request to release airport land.

SUMMARY: The Federal Aviation Administration (FAA) proposes to rule and invites public comment on the application for a release of approximately 1.10 acres of airport property at the Redding Municipal Airport (RDD), Redding, California from all conditions contained in the Surplus Property Deed and Grant Assurances because the parcel of land is not needed for airport purposes. The land requested to be released is separated from the airport by Airport Road and located outside the airport fence at the southwest corner of the airport property. The release will allow the City of Redding to sell the property at its fair market value, thereby benefiting the Airport and serving the interest of civil aviation. The proposed use will be compatible with the airport and will not interfere with the airport or its operation.

DATES: Comments must be received on or before September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Comments on the request may be mailed to the FAA at the following address: James W. Lomen, Manager, Federal Aviation Administration, San Francisco Airports District Office, **Federal Register** Comment, 1000 Marina Boulevard, Suite 220, Brisbane, CA 94005. In addition, one copy of the comment submitted to the FAA must be mailed to Mr. Rod Dinger, Airport Director, Redding Municipal Airport, 6751 Woodrum Circle, Suite 200, Redding, CA 96002.

SUPPLEMENTARY INFORMATION: In accordance with the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR 21), Public Law 106–181 (Apr. 5, 2000; 114 Stat. 61), this notice must be published in the **Federal Register** 30 days before the Secretary may waive any condition imposed on a federally obligated airport by surplus property conveyance deeds or grant agreements.

The following is a brief overview of the request:

The City of Redding, California requested a release from Federal surplus property and grant assurance obligations for approximately 1.10 acres of airport land to allow for its sale. The property was originally acquired pursuant to the Surplus Property Act of 1944 and was deeded to the City of Redding on June 6, 1949. The parcel of land is located on the southwest side of the airport along Meadow View Drive and Airport Road. The property is separated from the airfield by Airport Road and the airport perimeter fence.

The parcel of land is undeveloped, has no structural improvements, and has not been used for aviation purposes for over 20 years. The City of Redding will sell the 1.10 acres of property at fair market value and redeveloped for commercial business purposes.

The sales proceeds will be devoted to airport operations and capital projects. The reuse of the property will not interfere with the airport or its operation and will thereby serve the interests of civil aviation.

Issued in Brisbane, California, on August 10, 2016.

James W. Lomen,

Manager, San Francisco Airports District Office, Western-Pacific Region.

[FR Doc. 2016–20001 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

EUROCAE WG–96/RTCA SC–236 Joint Plenary #1 Standards for Wireless Avionics Intra-Communication System (WAIC) Within 4200–4400 MHz

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

ACTION: Notice.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of EUROCAE WG–96/RTCA SC–236 Joint Plenary #1 Standards for Wireless Avionics Intra-Communication System (WAIC) within 4200–4400 MHz.

Please inform *adrian.cioranu@eurocae.net* of your intention to attend the meeting. Please inform also *peter.anders@airbus.com,* the host of the meeting.

Find information direction & maps: *https://goo.gl/maps/rkHxCEfN1sL2.*

DATES: The meeting will be held Wednesday, September 21st through Friday, September 23rd 2016.

ADDRESSES: The meeting will be held at: ZAL Zentrum für Angewandte Luftfahrtforschung ZAL, Hamburg, Hein-Saß-Weg 22, 21129 Hamburg, Germany.

FOR FURTHER INFORMATION CONTACT: Adrian Cioranu at *Adrian.cioranu@eurocae.net,* +33 1 40 92 79 31 or Rebecca Morrison at *rmorrison@rtca.org* or (202) 330–0654, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the EUROCAE WG–96/RTCA SC–236 Joint Plenary #1 Standards for Wireless Avionics Intra-Communication System (WAIC) within 4200–4400 MHz. The agenda will include the following:

September 21, 2016 (9:30–17:00), September 22, 2016 (9:00–17:00), and September 23, 2016 (9:00–13:00)

Welcome/Administrative Duties

1. Presentation of RTCA/EUROCAE Joint Committee Organization and Coordination
2. IPR/Membership Call-Out and Introductions
3. Acceptance of Meeting Minutes for the First Plenary of SC–236
4. Presentation of the goals of content for the MOPS
5. Discussion of Structure of Joint Committees
6. Break-out into Initial Working Groups
7. Reports of the Plans for the Working Groups
8. Review of Action Items
9. Plan for next meeting
10. Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on August 17, 2016.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2016–19944 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2016–0069]

Commercial Driver's Licenses; Proposed Pilot Program To Allow Persons Between the Ages of 18 and 21 With Military Driving Experience To Operate Commercial Motor Vehicles in Interstate Commerce

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of proposed pilot program; request for comments.

SUMMARY: As required by section 5404 of the Fixing America's Surface Transportation (FAST) Act, FMCSA proposes a pilot program to allow a limited number of individuals between the ages of 18 and 21 to operate commercial motor vehicles (CMVs) in interstate commerce if they have received specified heavy-vehicle driver training while in military service and are sponsored by a participating motor carrier. During the 3-year pilot program, the safety records of these younger drivers (the study group) would be compared to the records of a control group of comparable size, comprised of drivers who are 21 years of age or older and who have comparable training and experience in driving vehicles requiring a commercial driver's license (CDL). The control group would consist of volunteer drivers who meet specified criteria and are employed by a participating carrier. The comparison of the two groups' performance would help to determine whether age is a critical safety factor. FMCSA also proposes criteria for a working group to consult with the Agency in conducting, monitoring, and evaluating the pilot program. Further, the Agency outlines procedural steps and a data collection plan, and requests comments on these elements.

DATES: Comments must be received on or before September 21, 2016.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2016–0069 using any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov*. Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 1–202–493–2251

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the *Privacy Act* heading below.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy*.

FOR FURTHER INFORMATION CONTACT: Mr. Selden Fritschner, CDL Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, by email at *Selden.Fritschner@dot.gov,* or by telephone at 202–366–0677. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials. In this notice, FMCSA requests certain information, but comments are not limited to responses to those requests.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2016–0069), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online, by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov,* put the docket number, ''FMCSA–2016–0069'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this notice as being available in the docket, go to *www.regulations.gov* and insert the docket number, ''FMCSA–2016–0069'' in the ''Keyword'' box and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

On June 9, 1998, the President signed the Transportation Equity Act for the 21st Century (TEA–21) (Pub. L. 105–178, 112 Stat. 107). Section 4007 of TEA–21 amended 49 U.S.C. 31315 and 31136(e) to give the Secretary of Transportation (the Secretary) authority to grant waivers and exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs) and to conduct pilot programs. A waiver is limited to a period of 3 months and may be granted without requesting public comment. By contrast, an exemption may remain in effect for up to 5 years [1] and may be renewed. The Secretary must provide the public with an opportunity to

[1] Section 5206 of the Fixing America's Surface Transportation (FAST) Act amended 49 U.S.C. 31315(b)(2) to extend the maximum duration of an exemption from 2 years to 5 years, effective October 1, 2015.

comment on each exemption request prior to granting or denying it.

Section 4007 also authorizes pilot programs in which one or more exemptions are granted to allow for the testing of innovative alternatives to certain FMCSRs. FMCSA must publish in the **Federal Register** a detailed description of each pilot program, including the exemptions being considered, and provide notice and an opportunity for public comment before the effective date of the program. The Agency is required to ensure that the safety measures in the pilot programs are designed to achieve a level of safety that is equivalent to, or greater than, the level of safety that would be achieved through compliance with the safety regulations. The maximum duration of pilot programs is 3 years from the starting date.

At the conclusion of each pilot program, FMCSA must report to Congress its findings, conclusions, and recommendations, including suggested amendments to laws and regulations that would enhance motor carrier, CMV, and driver safety, and improve compliance with the FMCSRs.

Section 4007 was implemented through an interim final rule (IFR) on December 8, 1998 (63 FR 67600) and codified at 49 CFR part 381. The IFR was finalized on August 20, 2004 (69 FR 51589). The final rule established procedures applicants must follow to request waivers and apply for exemptions from the FMCSRs and procedures to propose and manage pilot programs.

Section 5404 of the FAST Act (Pub. L. 114–94, 129 Stat. 1312, 1549, Dec. 4, 2015) requires the Secretary of Transportation to conduct a commercial driver pilot program to ''. . . study the feasibility, benefits, and safety impacts of allowing a covered driver to operate a commercial motor vehicle in interstate commerce.'' A ''covered driver'' is defined as a member or former member of the armed forces or reserve and national guard components between the ages of 18 and 21, who is qualified in a Military Occupational Specialty to operate a CMV or similar vehicle. A driver participating in the program may not transport passengers or hazardous cargo, or operate a vehicle in a ''special configuration.''

Section 5404 requires the pilot program to collect and analyze data regarding crashes involving covered drivers participating in the program, and drivers under the age of 21 operating CMVs in intrastate commerce. (See Section VIII of this notice.)

Section 5404 also requires the Secretary to ''. . . conduct, monitor, and evaluate . . .'' the pilot program in consultation with a working group consisting of representatives of the armed forces, industry, drivers, safety advocacy organizations, and State licensing and enforcement officials. The working group must review the data collected and make recommendations to the Secretary regarding the feasibility, benefits, and safety impacts of allowing a covered driver to operate in interstate commerce. (See Section V of this notice.)

III. Background

Applicable Regulations

Drivers of CMVs engaged in interstate commerce must be at least 21 years of age (49 CFR 391.11(b)(1)). This includes CMVs for which CDLs are required, as well as certain other CMVs for which a CDL is not required.

In the May 9, 2011, final rule on ''Commercial Driver's License Testing and Commercial Learner's Permit Standards'' (76 FR 26854), the Agency set a minimum age of 18 for an individual to obtain a commercial learner's permit (CLP) prior to obtaining a CDL. An 18-year-old CLP holder is allowed to drive in *intrastate commerce* only. Therefore, the proposed pilot program requires that participating drivers be provided relief from sections of 49 CFR parts 383 and 391 concerning minimum age requirements.

Prior Younger Driver Pilot Program Efforts

In the early 1970s, the Federal Highway Administration (FHWA), FMCSA's predecessor agency, examined the subject of the minimum age of CMV drivers as part of a comprehensive overhaul of the driver qualification requirements. FHWA conducted a literature review and analyzed crash statistics and psychological data. The result was a 1975 report titled ''Minimum Age Requirements of the Federal Motor Carrier Safety Regulations.'' A copy of the report is filed in the docket identified at the beginning of this notice. The Agency found that most drivers under the age of 21 ''lack the general maturity, skill and judgment that is necessary in handling commercial motor vehicles.'' The report concluded that there was no support for lowering the age limit of 21.

Subsequently, on October 2, 2000, the Truckload Carriers Association (TCA) petitioned FMCSA to conduct a younger driver pilot program. Motor carriers, truck driver training schools, a trade association, and an insurance company joined in the petition asking FMCSA to authorize a pilot program to determine if CMV drivers under age 21 could operate CMVs safely in interstate commerce. Petitioners stated that this pilot would address the shortage of CMV drivers in the trucking industry. Petitioners also asserted that recruiting young persons as truck drivers would be easier if they could be approached immediately after graduation from high school.

The pilot program proposed by TCA would have involved a minimum of 48 weeks of intensive classroom and driving instruction and supervision that was designed to lead to full-time employment as an interstate CMV driver. Each younger driver (18 to 21 years of age) would attend a truck driver training school approved by the Professional Truck Driver Institute for a minimum of 22 weeks and receive 8 weeks of training in a motor carrier's ''driver finishing'' program. This would be followed by 18 weeks of team driving with an older, more experienced driver. Younger drivers would be required to pass the performance standards of the entire 48-week program and reach the age of 19 to begin solo driving.

On February 20, 2001, FMCSA published a notice asking six questions about the proposed pilot program and requesting public comment on the TCA petition (66 FR 10935). FMCSA received more than 1,600 comments. Very few commenters presented data either for or against the program. More than 90 percent of the commenters were opposed, most on the basis that individuals under the age of 21 lacked the maturity and judgment to operate a CMV. None explained how interstate drivers under 21 would diminish safety when most States have concluded that intrastate drivers under 21 do not do so. Very few truck drivers and motor carriers commented, but most of them also opposed the pilot program.

The following language appeared in the Senate Report accompanying the Fiscal Year (FY) 2003 Department of Transportation Appropriations bill: ''Given the fact that young drivers are overrepresented in motor vehicle crashes, the Committee is not convinced of the merits of this proposal. Prior to the approval of such a pilot program, the Committee directs the FMCSA Administrator to conduct a thorough analysis of the safety ramifications and whether there's a genuine shortage of truck drivers to warrant such a waiver of the Federal safety regulations.'' [Senate Report No. 107–224, July 26, 2002].

On June 9, 2003 (68 FR 34467, 34468), FMCSA denied the TCA petition stating that ''the Agency does not have sufficient information at this time to

make a determination that the safety measures in the pilot program are designed to achieve a level of safety equivalent to, or greater than, the level of safety provided by complying with the minimum 21-year age requirement to operate a CMV.''

IV. Structure of the Proposed Pilot Program

The purpose of this proposed 3-year pilot program is to determine whether persons under the age of 21 can safely operate CMVs in interstate commerce, and to enhance opportunities for persons with relevant military training to enter the CMV industry. While many *intrastate* CMV drivers are already in this age group, the Agency is not aware of any studies or published reports comparing their safety performance with that of drivers over 21, either interstate or intrastate. This pilot program proposes to utilize a study group of drivers under the age of 21, who have trained on and operated heavy vehicles while in military service. Because many service personnel leave active duty while close to or over the age of 21, it is likely that most study group members would be reservists or National Guard members. Persons who meet the qualifications described later in this notice may apply to a participating motor carrier for study group sponsorship, which, if approved, would allow the individual to operate a CMV in interstate commerce for that carrier before age 21. To have a statistically valid sample of drivers under the age of 21, approximately 200 study group participants are desired. When these individuals reach the age of 21, they would no longer participate in the pilot program and would be replaced by new study group members meeting the eligibility requirements. The length of time during which replacement study group members will be added will be determined by FMCSA based on the statistical and administrative needs of the pilot data collection plan.

Participating carriers that meet the qualifications described later in this notice would sponsor study group members and perform other duties related to the pilot, such as filing certain reports and recruiting existing drivers to participate as control group members. To reduce the administrative effort involved, FMCSA anticipates that a fairly small number of carriers would be selected to participate.

The control group of older drivers would be needed to form a baseline of comparison for the safety records of the younger study group drivers. The control group participants would be 21 years of age and older, would have received formal CMV driving training comparable to that of the study group members, and would have similar lengths of driving experience. These control group members working for the same participating carriers would volunteer as the study group members. As a participating carrier receives approval from FMCSA for a qualifying younger employee to be in the study group, the carrier would then submit a qualifying, existing employee for inclusion in the control group. In this manner, an approximately equal number of drivers would be accepted by FMCSA for each group.

Carriers would be required to install and operate electronic logging devices (ELDs) on all vehicles operated by study and control group drivers. Data from these devices, such as vehicle miles traveled (VMT), is essential to analyze driving safety records.

In addition to identification data for all participants, FMCSA would gather safety data for all study and control group drivers during the pilot, such as crashes and driving and inspection violations. Because the amount of data of this nature that can be collected in 3 years may be comparatively small, FMCSA would also consider requesting participating carriers that have onboard monitoring systems (OBMSs) to share that data. The safety-critical events (SCEs) [2] recorded by OBMSs may provide valuable information on drivers' operating performance. The use of OBMSs would be based on the willingness of carriers and drivers to participate and the existing equipment in the carrier's cabs. FMCSA specifically seeks comments on this option.

FMCSA would reserve the right to select the carriers to participate and continue in the pilot, as well as to approve the members of the study and control groups.

V. Management of the Proposed Pilot Program; the Working Group

Section 5404 of the FAST Act requires the Secretary to ''. . . conduct, monitor, and evaluate . . .'' the pilot program in consultation with a working group consisting of representatives of the armed forces, industry, drivers, safety advocacy organizations, and State licensing and enforcement officials. The organization and appointment of this working group would take place under existing Departmental policies and procedures.

FMCSA would designate a project manager for the pilot program and review applications for this program. Approved participating carriers would be publicly announced on the Agency's Web site to encourage potential study group members (*i.e.,* drivers) to apply through the identified carriers for participation. Approved carriers would be able to assist potential study group drivers (whom they sponsor) with completion of the application and participation agreement. When a carrier receives notification that a qualifying study group member has been approved by FMCSA, the carrier would then submit a form and agreement for a control group driver. In this manner, the number of drivers in each group would be similar; *i.e.,* about 200 in the study group and 200 in the control group. FMCSA would develop the applications, agreements, and forms to be used by interested carriers and potential study and control group members.

Eligibility requirements and procedural matters are discussed later in this notice.

VI. Proposed Eligibility Criteria To Participate

A. Motor Carriers

Details of each requirement for motor carriers summarized below would be published if the pilot program is approved. Interested motor carriers would be required to:

- Volunteer during the announced application period.
- Be able to supply control group drivers in numbers matching the study group drivers to be employed.
- Agree to comply with all pilot program procedures.
- Agree to submit required pilot program data and reports.
- Purchase, install and operate an ELD in each truck used in the pilot program study.
- Monitor and report safety records of study and control group members as required by FMCSA.
- Have a good safety record, to include appropriate Safety Measurement System (SMS) status, registration, operating authority, financial responsibility, and other Agency records.

B. Under-21 Applicants (Study Group Drivers)

Details of each requirement for study group applicants summarized below would be published if the pilot program is approved. Interested drivers would be required to:

- Volunteer.
- Be 18, 19, or 20 years of age as of the date they are approved by FMCSA for participation.

[2] Safety-critical events include crashes, near-crashes, and crash-relevant conflicts.

• Have certification from a military service of training and experience in driving heavy vehicles while in military service, as described in Section IX of this notice.
• Agree to the release of specific information to FMCSA for purposes of the pilot.
• Agree to the use of ELDs.
• Have no disqualifications, suspensions, or license revocations within past 3 years; or be under any out-of-service order.
• Meet all FMCSR requirements (except age) for operating a CMV in interstate commerce.
• Operate primarily in interstate commerce if selected.
• Not transport passengers or hazardous materials, or operate double- or triple-trailer combinations or cargo tank vehicles while participating in the pilot, regardless of any license endorsements held.

C. Control Group Drivers

Details of each requirement for control group drivers summarized below would be published if the pilot program is approved. Control group drivers would be required to:
• Volunteer.
• Possess a valid CDL.
• Be a full-time driver for participating motor carrier.
• Have no disqualifications, suspensions, or license revocations within past 3 years; or be under any out-of-service order.
• Agree to the use of ELDs.
• Agree to release of specified information for pilot program.
• Have training and experience comparable to study group drivers, regardless of the source.
• Be 21 to 26 years old at time of acceptance into the pilot.

VII. Application Process

A. Motor Carriers

• Contact the pilot project manager to arrange a brief no-obligation preliminary interview via telephone.
• Complete and file with FMCSA the application for participation that is proposed to include identification information on the carrier; number of study/control group participants the carrier is willing to sponsor; nature of duties of study and control group drivers, to include reporting typical hours worked and miles traveled.
• Designate a pilot program coordinator.

B. Under-21 Applicants (Study Group Drivers)

• Obtain from commanding officer, or his or her official designee, a certification [3] that the applicant had formal training and experience in the operation of heavy motor vehicles while in military service.
• Contact approved participating carrier(s) to determine the availability of positions and their qualification requirements.
• Complete any documents prescribed by FMCSA for participation.

C. Control Group Drivers

• Participating carriers would solicit qualifying volunteer drivers from among existing employees in numbers equal to study group participants; and
• Complete any documents prescribed by FMCSA for participation.

VIII. Data Collection Plan

Details of the data collection plan for this proposed pilot program would be developed based on comments to the docket and further review by analysts. The factors to be collected from each participating driver before and during the pilot program may include, but are not limited to, (1) details of any past CMV driving experience and demographic information, to assess qualification for participation in the study and/or control groups; (2) crashes (to be specified); (3) any traffic citations or warnings received while driving a CMV; (4) any violations or warnings listed on a CMV inspection report when the participating driver was operating the vehicle, and (5) detailed 24-hour records of activity to include CMV hours-of-service logs or electronic records. Some of this information normally should be automatically reported to FMCSA; however, due to possibility of delays in reporting and inaccurate data in some instances, the participating carrier would be asked to collect the information from all participating drivers and report it to FMCSA in a designated format. Other information that may be needed, such as VMT, would also be collected through the participating carrier. Every effort would be made to minimize the burden on the carrier in collecting and reporting this data.

IX. Armed Forces Heavy-Vehicle Driver Training Programs

Four branches of the Department of Defense—the Army, Air Force, Navy, and Marine Corps—provide specific training dedicated to operating heavy-duty vehicles. There are three basic job training classifications with additional training for other types of heavy-duty specialty vehicles (*e.g.,* gasoline haulers, construction vehicles, and military equipment transport oversize/overweight [non-track vehicles]).

There are four core training programs for heavy vehicle operations, based on the occupational specialty code of the service member:
• Army—88M—Motor Transport Operator.
• Air Force—2T1—Vehicle Operations.
• Marine Corps—3531—Motor Vehicle Operator.
• Navy—EO—Equipment Operator.

These four are not the only occupational specialty codes that the Agency may designate to participate in the pilot. Comments and data are requested for additional military occupational specialty codes or equivalent that should be included.

Army—88M Training

The 88M Instructor Training Manual is 142 pages long. The student manual—*STP 55–88M14–SM–TG Soldier's Manual and Trainer's Guide 88M, Motor Transport Operator*—is 229 pages long and includes 4 levels of training. The 6-week core curriculum of the Army 88M course contains a total of 221 hours of training, including:
• Lecture—32 classroom hours.
• Practical application—road driving—189 hours.

Motor Transport Operators are primarily responsible for operating wheeled vehicles to transport personnel and cargo. Motor Transport Operator duties include: Interior components/controls and indicators; basic vehicle control; driving vehicles over all types of roads and terrain, traveling alone or in convoys; braking, coupling, backing, and alley docking; adverse/tactical driving operations; pre-trip inspections; reading load plans; checking oil, fuel and other fluid levels, as well as tire pressure; operations in automatic and manual modes; crash prevention; safety check procedures; basic vehicle maintenance and repairs; transporting hazardous materials; and keeping mileage records.

Air Force—2T1—Vehicle Operations

The Air Force *Tractor Trailer Plan of Instruction* (POI) is 226 pages long. The minimum length of instruction for the basic school is 84 hours, including 22 hours of classroom and 62 hours of hands-on activity, both alone on a training pad and on the road with an instructor. The core curriculum is based on the material in the *American Association of Motor Vehicle Administrators (AAMVA) CDL Manual—2005 edition (2014 revised).* Students participating in the basic 2T1 curriculum learn general principles in

[3] Form to be developed.

the classroom. Specialized training occurs at the installation using the *Tractor Trailer Plan of Instruction.* A minimum of 40 hours over-the-road time is expected on each vehicle/trailer type.

Topics covered in the Air Force Vehicle Operations course include: Overview of training and Federal requirements; Federal motor vehicle safety standards; tractor/trailer design; hazards and human factors relative to the environment where used; safety clothing and equipment; driving safely; pre- and post-trip vehicle inspection; basic vehicle control; shifting gears; managing space and speed; driving in mountains, fog, winter, very hot weather, and at night; railroad crossings; defensive awareness to avoid hazards and emergencies; skid control and recovery; what to do in case of a crash; fires; staying alert and fit to drive; hazardous materials—rules for all commercial drivers; preparing, inspecting, and transporting cargo safely; inspecting and driving with air brakes; driving combination vehicles safely; and coupling and uncoupling.

Marine Corps—3531—Motor Vehicle Operator

The core curriculum of the Marine Corps 3531 course—TM 11240–15/3G contains three training areas:

- Lecture—24 classroom hours.
- Demonstration—classroom/training pad—35 hours.
- Practical application—road driving—198 hours.

Instructional breakout includes:

- *Demonstration:* 35 hours.
- *Guided discussion:* 1.5 hours.
- *Lecture:* 24 hours.
- *Performance examination:* 62 hours.
- *Practical application (individual):* 198 hours.
- *Written examination:* 7 hours.

Classroom instruction includes lectures, demonstration, and practice time for the specific tasks identified. Each classroom session includes written and performance evaluations to ensure students have mastered all of the learning objectives for the specialty proficiency. Training includes both simulators and actual vehicle operation. Practical training includes on-the-road and skills operations, ground guide procedures, and operating a vehicle with a towed load. Students practice their driving and backing, with and without a trailer. Instructors ride with the students as they operate on approved road routes. Specific training areas (pads) are set aside for the students to practice their backing skills and ground guide procedures safely.

The Marine Corps training curriculum also includes emergency procedures and cargo loading.

Navy—EO—Equipment Operator

The core curriculum of the USN Heavy Vehicle Operator (Truck Driver) (EO) course (53–3032.00) is designed to train Navy personnel how to operate passenger and cargo vehicles to rated capacity. They palletize, containerize, load and safely transport various types of cargo and demonstrate knowledge and skills for qualifying as a driver journeyman. The complete program covers topics including:

- Hazardous materials transportation
- Line haul planning
- Manual tractor-truck operations
- Vehicle Recovery Operations

The course is taught over 160 hours including 30 hours classroom and 130 hours lab (behind the wheel). By completing this course, the Navy driver will be able to:

1. Perform the duties of normal, non-combat conditions driving in accordance with the local state driver licensing agency's CDL driver handbook;

2. Manage hazardous petroleum, oils and lubricants (POL) material required during line haul and worksite activities, to support normal, non-combat operations;

3. Perform preventive maintenance on a non- or up-armored manual truck tractor with drop-neck trailer, consisting of pre-start, during-operations, and after-operations equipment checks, to support normal, non-combat operations, in accordance with local State Driver License Agency CDL handbooks;

4. Operate vehicle controls of a non- or up-armored manual truck-tractor, to support normal, non-combat operations; and

5. Be proficient with the components and controls of a drop-neck trailer relative to a detached/attached gooseneck and a coupled/uncoupled trailer.

Other topics covered within the Navy EO training program include:

- Development and maintenance of operational records
- Operation of high mobility multi-purpose wheeled vehicles
- Weight distribution and load securement
- Loading bulk and container cargo
- Preventive maintenance
- Pre- and post- trip vehicle safety inspections

X. Paperwork Reduction Act

The proposed pilot program would require participating motor carriers to collect, maintain, and report to FMCSA certain information about their employed/sponsored drivers who are participating in the pilot program. This would include identifying information and safety performance data for use in analyzing the drivers' safety history. The Agency would develop forms to promote uniformity in the data collected by the pilot carriers.

The Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) prohibits agencies from conducting information collection (IC) activities until they analyze the need for the collection of information and how the collected data would be managed. Agencies must also analyze whether technology could be used to reduce the burden imposed on those providing the data. The Agency must estimate the time burden required to respond to the IC requirements, such as the time required to complete a particular form. The Agency submits its IC analysis and burden estimate to the Office of Management and Budget (OMB) as a formal information collection request (ICR); the Agency cannot conduct the information collection until OMB approves the ICR.

FMCSA asks for comment on the IC requirements of this proposal. The Agency's analysis of these comments would be used in devising the Agency's estimate of the IC burden of the pilot program. Comments can be submitted to the docket as outlined under **ADDRESSES** at the beginning of this notice. Specifically, the Agency asks for comment on: (1) How useful the information is and whether it can help FMCSA perform its functions better; (2) how the Agency can improve the quality of the information being collected; (3) the accuracy of FMCSA's estimate of the burden of this IC; and (4) how the Agency can minimize the burden of collection.

Because this is a proposed pilot program in which certain aspects—such as the content of forms and reports—have not been finalized, the Agency is not posting possible IC burden data at this time. If the pilot program is to be implemented, this information would be posted at a later date and additional comments would be taken.

XI. Removal From the Program

FMCSA reserves the right to remove any motor carrier or driver from the pilot program for reasons including, but not limited to, failing to meet any of the requirements of the program.

XII. Request for Public Comments

The following questions identify input desired by FMCSA. Instructions

for filing comments to the public docket are included earlier in this notice. Persons are encouraged to respond wherever possible, but comments are not limited to replies to these questions:

1. Are any additional safeguards needed to ensure that the pilot program provides a level of safety equivalent to that without the age exemption?

2. Would carriers be able to obtain enough volunteer drivers to serve in the control group?

3. Do ''comparable levels of training and experience'' need to be defined more precisely? If so, what levels would you suggest?

4. Are traffic violations, crashes, and inspection violations adequate to allow a comparison of safety records? If not, what other safety performance measures should be included?

5. If drivers reach age 21 while in the study group, should they be removed from the pilot and replaced with a different driver meeting the eligibility criteria?

6. Are the data collection efforts proposed so burdensome for carriers as to discourage their participation?

7. Are there carriers currently using onboard monitoring on all their CMVs that are willing to participate in the study? Is onboard monitoring of pilot program drivers needed to assess their safety performance?

Issued on: August 11, 2016.

T.F. Scott Darling, III,

Administrator.

[FR Doc. 2016–19948 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice To Rescind a Notice of Intent To Prepare an Environmental Impact Statement

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: In this notice, FRA is advising the public that the Notice of Intent (NOI) to prepare a Tier One Environmental Impact Statement (EIS) for the Rochester-Twin Cities Passenger Rail Corridor Investment Plan is rescinded.

FOR FURTHER INFORMATION CONTACT: Andrea E. Martin, Environmental Protection Specialist, FRA, 1200 New Jersey Avenue SE., MS–20, Washington, DC 20590, telephone: (202) 493–6201.

SUPPLEMENTARY INFORMATION: The Minnesota Department of Transportation (MNDOT) and the Olmsted County Regional Railroad Authority (OCRRA) jointly explored the feasibility of a high-speed rail connection to serve anticipated travel demand between the State's two largest economies, Rochester and the Twin Cities. FRA published the NOI to prepare a Tier One EIS for the Rochester-Twin Cities Passenger Rail Corridor Investment Plan in the **Federal Register** on May 13, 2013; and MNDOT and OCRRA issued a final scoping decision document and alternatives analysis report in 2015. MNDOT and its partner OCRRA decided to suspend the voluntary EIS due to public funding constraints and private sector actions to undertake a similar project. Therefore, FRA is issuing this notice rescinding its NOI to prepare a Tier One EIS for the Rochester-Twin Cities Passenger Rail Corridor Investment Plan.

Issued in Washington, DC, on August 16, 2016.

Jamie Rennert,

Office Director, Office of Program Delivery.

[FR Doc. 2016–19917 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Port Performance Freight Statistics Working Group

AGENCY: Bureau of Transportation Statistics (BTS), Office of the Assistant Secretary for Research and Technology (OST–R), U.S. Department of Transportation (USDOT).

ACTION: Port Performance Freight Statistics Working Group: Notice of public meetings.

SUMMARY: This notice announces two upcoming public meetings of the Port Performance Freight Statistics Working Group (hereafter, ''Working Group''). The Working Group will provide advice and recommendations to the BTS Director pursuant to Section 6018 of the *Fixing America's Surface Transportation (FAST) Act* on matters related to port performance measures, including: Specifications and data measurements to be used in the Port Performance Freight Statistics Program established under subsection 6018(a); and a process for the Department to collect timely and consistent data, including identifying safeguards to protect proprietary information described in subsection 6018(b)(2). The Working Group will operate in accordance with the provisions of the *Federal Advisory Committee Act (FACA)* and the rules and regulations issued in implementation of that Act.

DATES: The meetings will be held on September 23, 2016, and October 21, 2016, from 9:00 a.m. to 4:30 p.m., Eastern Standard Time.

ADDRESSES: The meetings will be at the U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Any person requiring accessibility accommodations should contact Matthew Chambers at (202) 366–1270 or via email at: *portstatistics@dot.gov.*

FOR FURTHER INFORMATION CONTACT: U.S. Department of Transportation, Office of the Assistant Secretary for Research and Technology, Bureau of Transportation Statistics, Attn: Port Performance Freight Statistics Working Group, 1200 New Jersey Avenue SE., Room # E32–342, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Background: The Port Performance Freight Statistics Working Group has been created in accordance with Section 6018 of the FAST Act (Pub. L. 114–94; Dec. 4, 2015; 129 Stat. 1312). The Working Group supports the BTS Port Performance Freight Statistics Program, which has the goal ''to provide nationally consistent measures of performance'' of the nation's largest ports, and to report annually to Congress on port capacity and throughput.

The Working Group is established in the FAST Act to provide recommendations to the BTS Director on matters related to port performance measures; to identify a standard for port data; to specify standards for consistent port performance measures; to recommend statistics for measuring port capacity and throughput; and to develop a process to collect timely and consistent data. The FAST Act also identifies the membership of the Working Group, and sets a due date for recommendations to the BTS Director of December 4, 2016.

Agenda: During the meetings, U.S. Department of Transportation (hereafter, ''Department'') staff will provide updates of the Department's progress in implementing its Port Performance Freight Statistics Program and related provisions. The Working Group will discuss its development of a list of tasks and subtasks that:

(a) Identify a generally accepted industry standard for port data collection and reporting.

(b) Specify standards for collecting data and reporting nationally consistent port performance measures.

(c) Make recommendations for statistics measuring on U.S. port capacity and throughput.

(d) Develop a process for the Department to collect timely and consistent data, including identifying safeguards to protect proprietary information.

The final meeting agendas will be posted on the BTS Web site at *www.bts.gov/port_performance* in advance of the meetings.

Public Participation: The meetings will be open to the public on a first-come, first-serve basis, especially because space is limited. Members of the public who wish to attend the meetings in-person are asked to send RSVPs, including name, affiliation, and contact information to *portstatistics@dot.gov,* in order to request a seat and to facilitate entry. RSVPs are requested by September 19, 2016, for the September 23, 2016, meeting; and by October 17, 2016, for the October 21, 2016, meeting. Any person requiring accessibility accommodation, such as sign language interpretation, should contact Matthew Chambers at (202) 366–1270 or via email at: *portstatistics@dot.gov* five (5) business days before the meeting.

Written Comments: Persons who wish to submit written comments for consideration by the Working Group must send them via email to *portstatistics@dot.gov* or mail to Matthew Chambers, Designated Federal Officer, Port Performance Freight Statistics Working Group, 1200 New Jersey Avenue SE., Room # E32–342, Washington, DC 20590. Please note that all written comments will be made available for public inspection. Written comments must be received on or before September 19, 2016, for the September 23, 2016, meeting; and on or before October 17, 2016, for the October 21, 2016, meeting.

Issued in Washington, DC, on August 16, 2016.

Rolf R. Schmitt,

Deputy Director, Bureau of Transportation Statistics.

[FR Doc. 2016–19947 Filed 8–19–16; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

[Docket No. TTB–2016–0001]

Proposed Information Collections; Comment Request (No. 60)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB); Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of our continuing effort to reduce paperwork and respondent burden, and as required by the Paperwork Reduction Act of 1995, we invite comments on the proposed or continuing information collections listed below in this notice.

DATES: We must receive your written comments on or before October 21, 2016.

ADDRESSES: As described below, you may send comments on the information collections listed in this document using the ''*Regulations.gov*'' online comment form for this document, or you may send written comments via U.S. mail or hand delivery. TTB no longer accepts public comments via email or fax.

- *http://www.regulations.gov:* Use the comment form for this document posted within Docket No. TTB–2016–0001 on ''*Regulations.gov*,'' the Federal e-rulemaking portal, to submit comments via the Internet;
- *U.S. Mail:* Michael Hoover, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005.
- *Hand Delivery/Courier in Lieu of Mail:* Michael Hoover, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 400, Washington, DC 20005.

Please submit separate comments for each specific information collection listed in this document. You must reference the information collection's title, form or recordkeeping requirement number, and OMB number (if any) in your comment.

You may view copies of this document, the information collections listed in it and any associated instructions, and all comments received in response to this document within Docket No. TTB–2016–0001 at *https://www.regulations.gov.* A link to that docket is posted on the TTB Web site at *https://www.ttb.gov/forms/comment-on-form.shtml.* You may also obtain paper copies of this document, the information collections described in it and any associated instructions, and any comments received in response to this document by contacting Michael Hoover at the addresses or telephone number shown below.

FOR FURTHER INFORMATION CONTACT: Michael Hoover, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; telephone 202–453–1039, ext. 135; or email *informationcollections@ttb.gov* (please *do not* submit comments on this notice to this email address).

SUPPLEMENTARY INFORMATION:

Request for Comments

The Department of the Treasury and its Alcohol and Tobacco Tax and Trade Bureau (TTB), as part of their continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to comment on the proposed or continuing information collections listed below in this notice, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Comments submitted in response to this notice will be included or summarized in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments are part of the public record and subject to disclosure. Please do not include any confidential or inappropriate material in your comments.

For each information collection listed below, we invite comments on: (a) Whether the information collection is necessary for the proper performance of the agency's functions, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the information collection's burden; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the information collection's burden on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide the requested information.

Information Collections Open for Comment

Currently, we are seeking comments on the following information collections (forms, recordkeeping requirements, or questionnaires):

Title: Marks on Equipment and Structures (TTB REC 5130/3), and Marks and Labels on Containers of Beer (TTB REC 5130/4).

OMB Number: 1513–0086.

TTB Recordkeeping Numbers: REC 5130/3 and 5130/4.

Abstract: Under the authority of chapter 51 of the Internal Revenue Code of 1986, as amended (26 U.S.C. chapter 51), the TTB regulations require marks, signs, and suitable measuring devices on brewery equipment and structures in order to identify the use and capacity of brewery equipment and structures, tank contents, and taxpaid and nontaxpaid beer. To identify products for purposes

of administering the IRC's excise tax provisions, the TTB regulations also require marks, brands, and labels on kegs, cans, bottles, and cases of beer. These marks, brands, and labels identify the name or trade name of the brewer, the place of production of the beer, the contents of the container, and the nature of the product (beer, ale, etc.).

Current Actions: TTB is submitting this collection as a revision. The information collection remains unchanged. However, TTB is increasing the estimated number of respondents due to an increase in the number of brewers regulated by TTB. While TTB is increasing the number or respondents, there is no increase in the estimated total annual burden hours for this information collection because markings on and suitable measuring devices for brewery equipment and structures and marking and labeling containers of beer are usual and customary business practices, and would be undertaken even without the TTB regulatory requirements to do so.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses and other for-profits.

Estimated Number of Respondents: 5,864.

Estimated Total Annual Burden Hours: 1 (one).

Title: Formula and Process for Domestic and Imported Alcohol Beverages.

OMB Number: 1513–0122.

TTB Form Number: TTB F 5100.51.

Abstract: TTB F 5100.51 (in all formats, including its online equivalent completed using Formulas Online (FONL)) is used by industry members to obtain approval of formulas for alcohol beverage products where the TTB regulations require such approval. The form collect information regarding the person filing, the type of product made, the ingredients used, and the manufacturing process. TTB uses the collected information to ensure appropriate classification of distilled spirits, wine, and malt beverages for labeling and taxation purposes.

Current Actions: TTB is submitting this collection as a revision. TTB F 5100.51 (in all formats, including the FONL version) remains unchanged. However, TTB is adding an additional information collection instrument to this information collection request, the Flavor Ingredient Data Sheet (FIDS). TTB provides the FIDS for respondents to use to disclose the ingredients of certain flavors used in the formulas they submit to TTB for approval. The FIDS helps TTB identify the flavors used for labeling and taxation purposes. Respondents will submit the FIDS as supplemental documents to their paper or online entries. We also are increasing the number of respondents to reflect an increase in the number of alcohol beverage industry members submitting formula requests to TTB, and we are increasing the estimated total annual burden hours to reflect that increase and the addition of the FIDS to this information collection request.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 3,000.

Estimated Total Annual Burden Hours: 34,320.

Title: Surveys for Applications, Permits Online (PONL), Formulas Online (FONL), and COLAs (Certificates of Label Approval) Online.

OMB Number: 1513–0124.

TTB Form Number: None.

Abstract: As part of our efforts to improve customer service, TTB surveys its customers who apply for original or amended permits, submit formula approval requests, and submit requests for certificates of label approval. These surveys assist TTB in identifying potential customer needs and problems, as well as opportunities for improvement in our applications processes, with particular focus on our customers' experiences with TTB's various electronic application systems.

Current Actions: TTB is submitting this collection as a revision. The surveys approved under this OMB control number remain unchanged. However, TTB intends to increase the number of customers it surveys on an annual basis and is, therefore, increasing the number of respondents and the resulting burden hours associated with this information collection. Participation in TTB customer satisfaction surveys is voluntary.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses and other for-profits; individuals.

Estimated Number of Respondents: 50,000.

Estimated Total Annual Burden Hours: 25,000.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Number: 1513–0132.

TTB Form Number: None.

Abstract: This collection of information is necessary to enable TTB to obtain customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders through surveys, usability tests, focus groups, and other evaluative tools approved under this information collection will help ensure that TTB customers and stakeholders have effective, efficient, and satisfying experiences with TTB's programs and Web site.

Current Actions: TTB is submitting this collection as a revision. TTB intends to increase its use of surveys, usability tests, focus groups, and other tools it uses to obtain customer and stakeholder feedback in order to improve its service delivery, programs, and Web site. As a result, TTB is increasing the number of respondents and the resulting burden hours associated with this information collection. Participation in TTB surveys, usability tests, focus groups, and other evaluative tools is voluntary.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses and other for-profits; Non-profits; individuals.

Estimated Number of Respondents: 30,000.

Estimated Total Annual Burden Hours: 30,000.

Dated: August 17, 2016.

Amy R. Greenberg,

Director, Regulations and Rulings Division.

[FR Doc. 2016–19955 Filed 8–19–16; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Proposed Agency Information Collection Activities; Comment Request

Correction

In notice document 2016–19268, appearing on pages 54190 through 54216 in the issue of Monday, August 15, 2016, make the following corrections:

1. On page 54213, at the top of the page, above the table labelled Data Items Removed, insert the heading ''Appendix B'' and, on the following line, insert the heading ''FFIEC 031: Data Items Removed or Change in Reporting Threshold''.

2. On page 54214, above the table labelled Data Items Removed, insert the heading ''Appendix C'' and, on the following line, insert the heading

''FFIEC 041: Data Items Removed or Change in Reporting Threshold''.

[FR Doc. C1–2016–19268 Filed 8–19–16; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Revision; Submission for OMB Review; Uniform Interagency Transfer Agent Registration and Amendment Form

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the revision of an information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment on a revision to its collection titled ''Uniform Transfer Agency Registration and Amendment Form.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted on or before September 21, 2016.

ADDRESSES: Because paper mail in the Washington, DC, area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention ''1557–0124, Form TA–1,'' 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to 571–465–4326 or by electronic mail to *prainfo@occ.treas.gov.*

You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling 202–649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comments or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0124, U.S. Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503; by fax to 202–395–6974; or by email to *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, 202–649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219. In addition, copies of the current Form TA–1 reporting form and instructions can be obtained at the Federal Financial Institutions Examination Council Web site (*http://www.ffiec.gov/ffiec_report_forms.htm*).

SUPPLEMENTARY INFORMATION: The OCC is proposing to revise the following information collection:

Report Title: Uniform Interagency Transfer Agent Registration and Amendment Form.

Form Number: Form TA–1.

Frequency of Response: On occasion.

Affected Public: National banks and their subsidiaries, federal savings associations and their subsidiaries.

OMB Control No.: 1557–0124.

Estimated Number of Respondents: registrations: 1; amendments: 10.

Estimated Average Time per Response: registrations: 1.25 hours; amendments: 10 minutes.

Estimated Total Annual Burden: 3 hours.

General Description of Report

Section 17A(c) of the Security Exchange Act of 1934 (the Act) requires all transfer agents for securities registered under section 12 of the Act or, if the security would be required to be registered except for the exemption from registration provided by section 12(g)(2)(B) or section 12(g)(2)(G), to ''fil[e] with the appropriate regulatory agency . . . an application for registration in such form and containing such information and documents . . . as such appropriate regulatory agency may prescribe as necessary or appropriate in furtherance of the purposes of this section.'' [1] In general, an entity performing transfer agent functions for a security is required to register with its appropriate regulatory agency (''ARA'') if the security is registered on a national securities exchange or if the issuer of the security has total assets exceeding $10 million and a class of equity security held of record by 2,000 persons or, for an issuer that is not a bank, BHC, or SLHC, by 500 persons who are not accredited investors.[2] The OCC's 12 CFR 9.20 implements these provisions of the Act.

To accomplish the registration of transfer agents, Form TA–1 was developed in 1975 as an interagency effort by the Securities and Exchange Commission (SEC) and the Federal banking agencies (the OCC, the Board of Governors of the Federal Reserve System, and the Federal Deposit Insurance Corporation). The agencies primarily use the data collected on Form TA–1 to determine whether an application for registration should be approved, denied, accelerated, or postponed, and they use the data in connection with their supervisory responsibilities.

Current Actions

The OCC proposes to revise the reporting instructions for Form TA–1. The proposed revisions remove outdated references to the OTS, clarify the definition of a ''qualifying security'' pursuant to statutory changes, alter the number of Form TA–1 copies that registrants are required to file with their ARA, and make other minor instructional clarifications. The OCC currently requires the filing of an original plus two copies of any registration or amendment. The proposed change is to require the filing of only the original.

Pursuant to statutory changes,[3] the definition of a ''qualifying security'' was altered to include securities registered on a national securities exchange pursuant to section 12(b) of the Act, as well as equity securities registered pursuant to section 12(g)(1) of the Act for issuers that have:

(a) Total assets exceeding $10 million and a class of equity security (other than an exempted security) held of record by either 2,000 persons, or 500 persons

[1] 15 U.S.C. 78q–1.

[2] 15 U.S.C. 78l(g)(1).

[3] *See* Fixing America's Surface Transportation Act section 85001, Pub. L. 114–94, 129 Stat. 1312, 1797 (2010), amending 15 U.S.C. 78a *et seq;* Jumpstart Our Business Startups Act section 501, Pub. L. 112–106, 126 Stat. 306, 325 (2012), amending 15 U.S.C. 78l(g)(1)(A).

who are not accredited investors (as such term is defined by the SEC); and

(b) In the case of an issuer that is a bank, a savings and loan holding company (as defined in section 10 of the Home Owners' Loan Act), or a bank holding company, as such term is defined in section 2 of the Bank Holding Company Act of 1956 (12 U.S.C. 1841), has total assets exceeding $10 million and a class of equity security (other than an exempted security) held of record by 2,000 or more persons.

Legal Basis for the Information Collection

The OCC has determined that Form TA–1 is mandatory and that its collection is authorized by sections 17A(c), 17(a)(3), and 23(a)(1) of the Act, as amended (15 U.S.C. 78q–1(c), 78q(a)(3), and 78w(a)(1)). Additionally, section 3(a)(34)(B) of the Act (15 U.S.C. 78c(a)(34)(B)(ii)) provides that the OCC is the ARA in the case of a national banks and insured Federal savings associations and subsidiaries of such institutions. The registrations are public filings and are not considered confidential.

The OCC needs the information contained in this collection to fulfill its statutory responsibilities. Section 17A(c) of the Act (15 U.S.C. 78q–1(c)), as amended, provides that all those authorized to transfer securities registered under section 12 of the Act (transfer agents) shall register ''by filing with the appropriate regulatory agency . . . an application for registration in such form and containing such information and documents . . . as such appropriate regulatory agency may prescribe to be necessary or appropriate in furtherance of the purposes of this section.'' Section 9.20 of the OCC's regulations (12 CFR 9.20) governs registration of transfer agents. Section 9.20(b) provides that SEC rules pursuant to section 17A of the Act, prescribing operational and reporting requirements for transfer agents, apply to the domestic activities of registered national bank transfer agents.

Request for Comment

On June 10, 2016, the Federal banking agencies published a notice concerning the collection for 60 days of comment, 81 FR 37665. No comments were received. Comments continue to be invited on:

(a) Whether the information collections are necessary for the proper performance of the OCC's functions, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the information collections, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Karen Solomon,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2016–19956 Filed 8–19–16; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Assignment Form

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Assignment Form.

DATES: Written comments should be received on or before October 21, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, 200 Third Street A4–A, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Assignment Form.

OMB Number: 1530–0011.

Transfer of OMB Control Number: The Financial Management Service (FMS) and the Bureau of Public Debt (BPD) have consolidated to become the Bureau of the Fiscal Service (Fiscal Service). Information collection requests previously held separately by FMS and BPD will now be identified by a 1530 prefix, designating Fiscal Service.

Form Number: FS Form 6314.

Abstract: This form is used when an award holder wants to assign or transfer all or part of his/her award to another person. When this occurs, the award holder forfeits all future rights to the portion assigned.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 150.

Estimated Time per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 75.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: August 17, 2016.

Bruce A. Sharp,

Bureau Clearance Officer.

[FR Doc. 2016–19975 Filed 8–19–16; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Direct Deposit, Go Direct, and Direct Express Sign-Up Forms

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995,

Public Law 104–13 (44 U.S.C. 3506(c)(2)(A). Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Direct Deposit, Go Direct, and Direct Express Sign-Up Forms.

DATES: Written comments should be received on or before October 21, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for further information to Bureau of the Fiscal Service, Bruce A. Sharp, 200 Third Street A4–A, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Direct Deposit, Go Direct, and Direct Express Sign-Up Forms.

OMB Number: 1530–0006.

Transfer of OMB Control Number: The Financial Management Service (FMS) and the Bureau of Public Debt (BPD) have consolidated to become the Bureau of the Fiscal Service (Fiscal Service). Information collection requests previously held separately by FMS and BPD will now be identified by a 1530 prefix, designating Fiscal Service.

Form Number: SF–1199A, FS Form 1200, FS Form 1200VADE, FS Form 1201L, FS Form 1201S.

Abstract: This series of forms is used by recipients to authorize the deposit of Federal payments into their accounts at financial institutions. The information on the forms routes the direct deposit payment to the correct account at the financial institution.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households, Business or other Not-for Profit, Federal Government.

Estimated Number of Respondents: 406,715.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 67,786.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: August 17, 2016.

Bruce A. Sharp,

Bureau Clearance Officer.

[FR Doc. 2016–19974 Filed 8–19–16; 8:45 am]

BILLING CODE 4810–35–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: U.S. Treasury Securities State and Local Government Series Early Redemption Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A). Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the U.S. Treasury Securities State and Local Government Series Early Redemption Request.

DATES: Written comments should be received on or before October 21, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, 200 Third Street A4–A, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: U.S. Treasury Securities State and Local Government Series Early Redemption Request.

OMB Number: 1530–0039.

Transfer of OMB Control Number: The Bureau of Public Debt (BPD) and the Financial Management Service (FMS) have consolidated to become the Bureau of the Fiscal Service (Fiscal Service). Information collection requests previously held separately by BPD and FMS will now be identified by a 1530 prefix, designating Fiscal Service.

Form Number: FS Form 5377.

Abstract: The information is requested to process early redemption requests for the owners of State and Local Government Series Securities.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: State or Local Government.

Estimated Number of Respondents: 494.

Estimated Time per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 247.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: August 17, 2016.

Bruce A. Sharp,

Bureau Clearance Officer.

[FR Doc. 2016–19978 Filed 8–19–16; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Request to Reissue United States Savings Bonds

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A). Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting

comments concerning the Request to Reissue United States Savings Bonds.

DATES: Written comments should be received on or before October 21, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, 200 Third Street A4–A, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Request to Reissue United States Savings Bonds.

OMB Number: 1530–0025.

Transfer of OMB Control Number: The Bureau of Public Debt (BPD) and the Financial Management Service (FMS) have consolidated to become the Bureau of the Fiscal Service (Fiscal Service). Information collection requests previously held separately by BPD and FMS will now be identified by a 1530 prefix, designating Fiscal Service.

Form Number: FS Form 4000.

Abstract: The information is requested to support a request to reissue paper (definitive) Series EE, HH, and I United States Savings Bonds; Retirement Plan Bonds; and Individual Retirement Plan Bonds and to indicate the new registration required.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 115,000.

Estimated Time per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 57,500.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: August 17, 2016.

Bruce A. Sharp,

Bureau Clearance Officer.

[FR Doc. 2016–19977 Filed 8–19–16; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Members of Senior Executive Service Performance Review Boards

AGENCY: Internal Revenue Service (IRS), Department of the Treasury (Treasury).

ACTION: Notice.

SUMMARY: The purpose of this notice is to publish the names of those IRS employees who will serve as members on IRS's Fiscal Year 2016 Senior Executive Service (SES) Performance Review Boards.

DATES: This notice is effective September 1, 2016.

FOR FURTHER INFORMATION CONTACT: Cheryl Huffman, IRS, 250 Murall Drive, Kearneysville, WV 25430, (304) 264–5572.

SUPPLEMENTARY INFORMATION: Pursuant to 5 U.S.C. 4314(c)(4), this notice announces the appointment of members to the IRS's SES Performance Review Boards. The names and titles of the executives serving on the boards are as follows:

John M. Dalrymple, Deputy Commissioner for Services and Enforcement

Jeffrey J. Tribiano, Deputy Commissioner for Operations Support

Justin Abold-LaBreche, Initiative Director, Office of Compliance Analytics

David P. Alito, Deputy Division Commissioner, Wage & Investment

Michael C. Beebe, Deputy Director, Return Integrity and Correspondence Services, Wage & Investment

E. Faith Bell, IRS Acting Deputy Human Capital Officer, Human Capital Office

Carol A. Campbell, Director, Return Preparer Office

Daniel B. Chaddock, Associate Chief Information Officer, Enterprise Services, Information Technology

Robert S. Choi, Director, Employee Plans, Tax Exempt & Government Entities

Elia I. Christiansen, Executive Director, Office of Equity, Diversity & Inclusion

Cheryl P. Claybough, Director, Pass Through Entities Practice Area, Large Business & International

James P. Clifford, Director, Accounts Management, Wage & Investment

Kenneth C. Corbin, Director, Return Integrity and Compliance Services, Wage & Investment

Tracy L. DeLeon, Director, Corporate Data, Information Technology

Nanette M. Downing, Assistant Deputy Commissioner, Government Entities/Shared Service, Tax Exempt & Government Entities

Pamela Drenthe, Director, Withholding and International Individual Compliance Practice Area, Large Business & International

Alain Dubois, Deputy Chief, Financial Officer

Elizabeth A. Dugger, Assistant Deputy Commissioner for Operations Support

Nikole C. Flax, Deputy Chief, Appeals

John D. Fort, Deputy Chief, Criminal Investigation

Shelley M. Foster, Director, Examination Field, Small Business/Self-Employed

Karen L. Freeman, Associate Chief Information Officer, Enterprise Operations, Information Technology

Julieta Garcia, Director, Customer Assistance, Relationships and Education, Wage & Investment

Silvana G. Garza, Deputy Chief Information Officer for Operations, Information Technology

Ursula S. Gillis, Chief Financial Officer

Rena C. Girinakis, Deputy National Taxpayer Advocate, Taxpayer Advocate Service

Dietra D. Grant, Director, Field Assistance, Wage & Investment

Darren J. Guillot, Director, Collection—Field, Small Business/Self-Employed

Daniel S. Hamilton, Director, Enterprise Systems Testing, Information Technology

Donna C. Hansberry, Deputy Division Commissioner, Tax Exempt & Government Entities

Barbara Harris, Director, Northeastern Compliance Practice Area, Large Business & International

Nancy E. Hauth, Director, Examination Headquarters, Small Business/Self-Employed

Mary R. Hernandez, Deputy Associate Chief Information Officer, Enterprise Operations, Information Technology

Benjamin D. Herndon, Director, Research, Applied, Analytics & Statistics

Shenita L. Hicks, Director, Examination, Small Business/Self-Employed

John E. Hinding, Director, Cross Border Activities Practice Area, Large Business & International

Debra S. Holland, Commissioner, Wage & Investment

David W. Horton, Assistant Deputy Commissioner Compliance Integration, Large Business & International

Cecil T. Hua, Director, Enterprise Technology Implementation, Information Technology
Robert L. Hunt, Director, Operations Support, Small Business/Self-Employed
Sharon C. James, Associate Chief Information Officer, Cybersecurity, Information Technology
Robin DelRey Jenkins, Director, Collection—Campus, Small Business/Self-Employed
Edward T. Killen, Director, Privacy, Governmental Liaison and Disclosure
Robert M. Leahy Jr., Associate Chief Information Officer, Strategy and Planning, Information Technology
Terry Lemons, Chief, Communications & Liaison
Sunita B. Lough, Commissioner, Tax Exempt & Government Entities
Deborah Lucas-Trumbull, Director, Demand Management and Project Governance, Information Technology
William H. Maglin II, Associate Chief Financial Officer for Financial Management, Chief Financial Officer
Paul J. Mamo, Director, Submission Processing, Wage & Investment
Lee D. Martin, Director, Whistleblower's Office
Erick Martinez, Director of Field Operations—Northern Area, Criminal Investigation
Thomas D. Mathews, Director, Collection—Headquarters, Small Business/Self-Employed
Ivy S. McChesney, Director, Customer Accounts Services, Wage & Investment
Kevin Q. McIver, Chief, Agency-Wide Shared Services
Tina D. Meaux, Director, Central Compliance Practice Area, Large Business & International
Renee A. Mitchell, Director, Collection—Central, Small Business/Self-Employed
Mary E. Murphy, Deputy Commissioner, Small Business/Self-Employed
Frank A. Nolden, Director, Stakeholder, Partnership, Education & Communication, Wage & Investment
Douglas W. O'Donnell, Commissioner, Large Business & International
Kimberly A. Petty, Associate Chief Information Officer, Applications Development, Information Technology
Crystal K. Philcox, Chief of Staff
Sharon R. Porter, Director, Treaty and Transfer Pricing Operations Practice Area, Large Business & International
Mary S. Powers, Director, Operations Support, Wage & Investment
Scott B. Prentky, Director, Collection, Small Business/Self-Employed
Robert A. Ragano, Director, Submission Processing, Information Technology
Daniel T. Riordan, IRS Human Capital Officer, Human Capital Office
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Kathy J. Robbins, Director, Enterprise Activities Practice Area, Large Business & International
Karen M. Schiller, Commissioner, Small Business/Self-Employed
Rene S. Schwartzman, IRS Identity Assurance Executive, Wage & Investment
Rosemary Sereti, Deputy Commissioner, Large Business & International
Theodore D. Setzer, Assistant Deputy Commissioner International, Large Business & International
Verline A. Shepherd, Associate Chief Information Officer for User and Network Services, Information Technology
Nancy A. Sieger, Deputy Associate Chief Information Officer for Applications Development, Information Technology
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Marla L. Somerville, Associate Chief Information Officer, Enterprise Information Technology Program Management Office, Information Technology
Carolyn A. Tavenner, Director, Affordable Care Act, Affordable Care Act Office
Kathryn D. Vaughan, Director, Examination—Campus, Small Business/Self-Employed
Peter C. Wade, Director, Technology Solutions, Small Business/Self-Employed
Kathleen E. Walters, Deputy IRS Human Capital Officer, Human Capital Office
Tina A. Walters, Director, Server Support and Services, Information Technology
Shanna R. Webbers, Chief Procurement Officer
Richard Weber, Chief, Criminal Investigation
Stephen A. Whitlock, Director, Office of Professional Responsibility
Kirsten B. Wielobob, Chief, Appeals
Lavena B. Williams, Director, Eastern Compliance Practice Area, Large Business & International
Johnny E. Witt, Deputy Director, Affordable Care Act Office

This document does not meet the Treasury's criteria for significant regulations.

John M. Dalrymple,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

[FR Doc. 2016–20025 Filed 8–17–16; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

August 17, 2016.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before September 21, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimates, or any other aspect of the information collections, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8117, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Control Number: 1545–NEW.

Type of Review: New collection (request for a new OMB control number).

Title: Country-by-Country Reporting (Form 8975).

Form: Form 8975.

Abstract: Form 8975 is used to provide certain information required to report annual country-by-country reporting by certain United States persons that are the ultimate parent entity of a U.S. multinational enterprise that has annual revenue for the preceding annual accounting period of $850 million or more.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 4,680.

OMB Control Number: 1545–0052.

Type of Review: Extension of a currently approved collection.

Title: Form 990–PF, Return of Private Foundation or Section 4947(a)(1) Nonexempt Charitable Trust Treated as Private Foundation; Form 4720, Return of Certain Excise Taxes on Charities and

Other Persons Under Chapters 41 and 42 for the Internal Revenue Code.

Form: Form 990–PF, Form 4720.

Abstract: Form 990–PF is an annual information return used to figure the tax based on investment income, and to report charitable distributions and activities. It also serves as a substitute for the section 4947(a)(1) nonexempt charitable trust's income tax return, Form 1041, U.S. Income Tax Return for Estates and Trusts, when the trust has no taxable income. Form 4720 is used to figure and pay certain excise taxes in chapters 41 and 42 of the Internal Revenue Code.

Affected Public: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 11,054,637.

OMB Control Number: 1545–0902.

Type of Review: Extension of a currently approved collection.

Title: Form 8288, U.S. Withholding Tax Return for Dispositions by Foreign Persons of U.S. Real Property Interests; Form 8288–A, Statement of Withholding on Dispositions by Foreign Persons of U.S. Real Property Interests.

Form: Form 8288, Form 8288–A.

Abstract: A buyer or other transferee of a U.S. real property interest, and a corporation, qualified investment entity, or fiduciary that is required to withhold tax, must file Form 8288 to report and transmit the amount withheld. Anyone who completes Form 8288 must also complete a Form 8288–A for each person subject to withholding.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 243,675.

OMB Control Number: 1545–1021.

Type of Review: Revision of a currently approved collection.

Title: Asset Acquisition Statement Under Section 1060.

Form: Form 8594.

Abstract: Both the seller and purchaser of a group of assets that makes up a trade or business must use Form 8594 to report such a sale if goodwill or going concern value attaches, or could attach, to such assets; and the purchaser's basis in the assets is determined only by the amount paid for the assets.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 22,910.

OMB Control Number: 1545–1533.

Type of Review: Reinstatement of a previously approved collection.

Title: Revenue Procedure 97–22, 26 CFR 601.105 Examination of returns and claims for refund, credits, or abatement, determination of correct tax liability.

Abstract: Rev. Proc. 97–22 provides guidance to taxpayers that maintain books and records by using an electronic storage system that either images their hardcopy (paper) books and records, or transfers their computerized books and records, to an electronic storage media, such as an optical disk. Records maintained in an electronic storage system that complies with the requirements of this revenue procedure will constitute records within the meaning of § 6001 of the Internal Revenue Code.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 1,000,400.

OMB Control Number: 1545–1718.

Type of Review: Extension of a currently approved collection.

Title: Source of Income from Certain Space and Ocean Activities; Source of Communications Income (TD 9305—final).

Abstract: Treasury Decision (TD) 9305 contains final regulations under section 863(d) governing the source of income from certain space and ocean activities. The collections of information in these final regulations are in §§ 1.863–8(g) and 1.863–9(k). This information is required by the IRS to monitor compliance with the federal tax rules for determining the source of income from space or ocean activities, or from transmission of communications.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 1,250.

OMB Control Number: 1545–2028.

Type of Review: Extension of a currently approved collection.

Title: Fuel Cell Motor Vehicle Credit.

Abstract: Notice 2008–33 provides procedures for manufacturers to follow to certify both that a particular make, model, and model year of fuel cell motor vehicle meets the requirements of section 30B(a)(1) and (b) of the Internal Revenue Code, and the amount of the credit allowable with respect to the vehicle. To certify a vehicle, the manufacturer must submit to the IRS a certification that includes, among other items, the make, model, model year, proposed credit amount and a statement affirming that the vehicle is propelled by power derived from one or more cells that convert chemical energy into electricity.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 200.

OMB Control Number: 1545–2132.

Type of Review: Reinstatement of a previously approved collection.

Title: Form 8933, Carbon Dioxide Sequestration Credit.

Form: Form 8933.

Abstract: Form 8933 is used to claim the carbon dioxide sequestration credit. The credit is allowed for qualified carbon dioxide that is captured and disposed of; or captured, used, and disposed of by the taxpayer in secure geological storage.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 215.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–19985 Filed 8–19–16; 8:45 am]

BILLING CODE 4810–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee: VA National Academic Affiliations Council Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2 that the VA National Academic Affiliations Council will meet via conference call on September 13, 2016, from 2:00 p.m. to 4:00 p.m. EST.

The purpose of the Council is to advise the Secretary on matters affecting partnerships between VA and its academic affiliates.

On September 13, 2016, the Council will discuss the implementation and funding status of the Veterans Access, Choice, and Accountability Act of 2014's Graduate Medical Education expansion plan, explore challenges involving the timely issuance of personal identity verification cards to trainees, and examine the breadth and scope of VA's education program for nursing trainees. The Council will receive public comments from 3:45 p.m. to 4:00 p.m. EST.

Interested persons may attend and/or present oral statements to the Council. The dial in number to attend the conference call is: 1–800–767–1750. At the prompt, enter access code 09462 then press #. Individuals seeking to present oral statements are invited to submit a 1–2 page summary of their comments at the time of the meeting for inclusion in the official meeting record. Oral presentations will be limited to five minutes or less, depending on the number of participants. Interested parties may also provide written comments for review by the Council prior to the meeting or at any time, by email to *Steve.Trynosky@va.gov,* or by

mail to Stephen K. Trynosky J.D., M.P.H., M.M.A.S., Designated Federal Officer, Office of Academic Affiliations (10A2D), 810 Vermont Avenue NW., Washington, DC 20420. Any member of the public wishing to participate or seeking additional information should contact Mr. Trynosky via email or by phone at (202) 461–6723.

Dated: August 16, 2016.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2016–19887 Filed 8–19–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Structural Safety of Department of Veterans Affairs Facilities; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act (5 U.S.C. App. 2) that a meeting of the Advisory Committee on Structural Safety of Department of Veterans Affairs Facilities will be held on September 13–14, 2016, in Room 6W303, 425 I Street NW., Washington, DC. On September 13, the session will be 9:00 a.m. until 5:00 p.m.; and on September 14, the session will be 9:00 a.m. until 1:00 p.m. The meeting is open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on matters of structural safety in the construction and remodeling of VA facilities and to recommend standards for use by VA in the construction and alteration of its facilities.

On September 13, the Committee will review developments in the fields of fire safety issues and structural design as they relate to seismic and other natural hazards impact on the safety of buildings. On September 14, the Committee will receive appropriate briefings and presentations on current seismic, natural hazards, and fire safety issues that are particularly relevant to facilities owned and leased by the Department. The Committee will also discuss appropriate structural and fire safety recommendations for inclusion in VA's construction standards.

No time will be allocated for receiving oral presentations from the public. However, the Committee will accept written comments. Comments should be sent to Donald Myers, Director, Facilities Standards Service, Office of Construction and Facilities Management (003C2B), Department of Veterans Affairs, 425 I Street NW., Washington, DC 20001, or emailed at *donald.myers@va.gov.* Because the meeting will be held in a Government building, anyone attending must be prepared to show a valid photo ID. Please allow 15 minutes before the meeting begins for this process. Those wishing to attend should or seeking additional information should contact Mr. Myers at (202) 632–5388.

Dated: August 17, 2016.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2016–19990 Filed 8–19–16; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

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Book 2 of 2 Books

Pages 56761–57438

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, *et al.*

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; Technical Changes Relating to Costs to Organizations and Medicare Cost Reports; Finalization of Interim Final Rules With Comment Period on LTCH PPS Payments for Severe Wounds, Modifications of Limitations on Redesignation by the Medicare Geographic Classification Review Board, and Extensions of Payments to MDHs and Low-Volume Hospitals; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, and 489

[CMS–1655–F; CMS–16644–F; CMS–1632–F2]

RIN 0938–AS77; 0938–AS88; 0938–AS41

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; Technical Changes Relating to Costs to Organizations and Medicare Cost Reports; Finalization of Interim Final Rules With Comment Period on LTCH PPS Payments for Severe Wounds, Modifications of Limitations on Redesignation by the Medicare Geographic Classification Review Board, and Extensions of Payments to MDHs and Low-Volume Hospitals

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

ACTION: Final rule.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2017. Some of these changes will implement certain statutory provisions contained in the Pathway for Sustainable Growth Reform Act of 2013, the Improving Medicare Post-Acute Care Transformation Act of 2014, the Notice of Observation Treatment and Implications for Care Eligibility Act of 2015, and other legislation. We also are providing the estimated market basket update to apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits for FY 2017.

We are updating the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2017.

In addition, we are making changes relating to direct graduate medical education (GME) and indirect medical education payments; establishing new requirements or revising existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities), including related provisions for eligible hospitals and critical access hospitals (CAHs) participating in the Electronic Health Record Incentive Program; updating policies relating to the Hospital Value-Based Purchasing Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition Reduction Program; implementing statutory provisions that require hospitals and CAHs to furnish notification to Medicare beneficiaries, including Medicare Advantage enrollees, when the beneficiaries receive outpatient observation services for more than 24 hours; announcing the implementation of the Frontier Community Health Integration Project Demonstration; and making technical corrections and changes to regulations relating to costs to related organizations and Medicare cost reports; we are providing notice of the closure of three teaching hospitals and the opportunity to apply for available GME resident slots under section 5506 of the Affordable Care Act.

We are finalizing the provisions of interim final rules with comment period that relate to a temporary exception for certain wound care discharges from the application of the site neutral payment rate under the LTCH PPS for certain LTCHs; application of two judicial decisions relating to modifications of limitations on redesignation by the Medicare Geographic Classification Review Board; and legislative extensions of the Medicare-dependent, small rural hospital program and changes to the payment adjustment for low-volume hospitals.

DATES: *Effective Date:* These final rules are effective on October 1, 2016.

FOR FURTHER INFORMATION CONTACT: Ing Jye Cheng, (410) 786–4548, and Donald Thompson, (410) 786–44487, Operating Prospective Payment, MS–DRGs, Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Issues, Medicare-Dependent Small Rural Hospital (MDH) Program, and Low-Volume Hospital Payment Adjustment Issues.

Michele Hudson, (410) 786–4487, and Emily Lipkin, (410) 786–3633, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Mollie Knight (410) 786–7948, and Bridget Dickensheets, (410) 786–8670, Rebasing and Revising the LTCH Market Basket Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

Jason Pteroski, (410) 786–4681, and Siddhartha Mazumdar, (410) 786–6673, Frontier Community Health Integration Project Demonstration Issues.

Kathryn McCann Smith, (410) 786–7623, Hospital Notification Procedures for Beneficiaries Receiving Outpatient Observation Services Issues; or Stephanie Simons, (206) 615–2420, only for Related Medicare Health Plans Issues.

Lein Han, (617) 879–0129, Hospital Readmissions Reduction Program—Readmission Measures for Hospitals Issues.

Delia Houseal, (410) 786–2724, Hospital-Acquired Condition Reduction Program and Hospital Readmissions Reduction Program—Administration Issues.

Joseph Clift, (410) 786–4165, Hospital-Acquired Condition Reduction Program—Measures Issues.

James Poyer, (410) 786–2261, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Program Administration, Validation, and Reconsideration Issues.

Cindy Tourison, (410) 786–1093, Hospital Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and Readmission Measures for Hospitals Issues.

Kim Spaulding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

James Poyer, (410) 786–2261, PPS-Exempt Cancer Hospital Quality Reporting Issues.

Mary Pratt, (410) 786–6867, Long-Term Care Hospital Quality Data Reporting Issues.

Jeffrey Buck, (410) 786–0407 and Cindy Tourison (410) 786–1093, Inpatient Psychiatric Facilities Quality Data Reporting Issues.

Deborah Krauss, (410) 786–5264, and Lisa Marie Gomez, (410) 786–1175, EHR Incentive Program Clinical Quality Measure Related Issues.

Elizabeth Myers, (410) 786–4751, EHR Incentive Program Nonclinical Quality Measure Related Issues.

Lauren Wu, (202) 690–7151, Certified EHR Technology Related Issues.

Kellie Shannon, (410) 786–0416, Technical Changes Relating to Costs to Organizations and Medicare Cost Reports Issues.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the Internet at: *http://www.gpo.gov/fdsys*.

Tables Available Only Through the Internet on the CMS Web Site

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to the proposed rule and the final rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, some of the IPPS tables and LTCH PPS tables are no longer published in the **Federal Register**. Instead, these tables generally will be available only through the Internet. The IPPS tables for this final rule are available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2017 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download''. The LTCH PPS tables for this FY 2017 final rule are available through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1655–F. For further details on the contents of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this final rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified above should contact Michael Treitel at (410) 786–4552.

Acronyms

3M 3M Health Information System
AAMC Association of American Medical Colleges
ACGME Accreditation Council for Graduate Medical Education
ACoS American College of Surgeons
AHA American Hospital Association
AHIC American Health Information Community
AHIMA American Health Information Management Association
AHRQ Agency for Healthcare Research and Quality
AJCC American Joint Committee on Cancer
ALOS Average length of stay
ALTHA Acute Long-Term Hospital Association
AMA American Medical Association
AMGA American Medical Group Association
AMI Acute myocardial infarction
AOA American Osteopathic Association
APR DRG All Patient Refined Diagnosis Related Group System
APRN Advanced practice registered nurse
ARRA American Recovery and Reinvestment Act of 2009, Public Law 111–5
ASCA Administrative Simplification Compliance Act of 2002, Public Law 107–105
ASITN American Society of Interventional and Therapeutic Neuroradiology
ASPE Assistant Secretary for Planning and Evaluation (DHHS)
ATRA American Taxpayer Relief Act of 2012, Public Law 112–240
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS Bureau of Labor Statistics
CABG Coronary artery bypass graft [surgery]
CAH Critical access hospital
CARE [Medicare] Continuity Assessment Record & Evaluation [Instrument]
CART CMS Abstraction & Reporting Tool
CAUTI Catheter-associated urinary tract infection
CBSAs Core-based statistical areas
CC Complication or comorbidity
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDAC [Medicare] Clinical Data Abstraction Center
CDAD *Clostridium difficile*-associated disease
CDC Centers for Disease Control and Prevention
CERT Comprehensive error rate testing
CDI *Clostridium difficile* [C. difficile] infection
CFR Code of Federal Regulations
CLABSI Central line-associated bloodstream infection
CIPI Capital input price index
CMI Case-mix index
CMS Centers for Medicare & Medicaid Services
CMSA Consolidated Metropolitan Statistical Area
COBRA Consolidated Omnibus Reconciliation Act of 1985, Public Law 99–272
COLA Cost-of-living adjustment
CoP [Hospital] condition of participation
COPD Chronic obstructive pulmonary disease
CPI Consumer price index
CQL Clinical quality language
CQM Clinical quality measure
CY Calendar year
DACA Data Accuracy and Completeness Acknowledgement
DPP Disproportionate patient percentage
DRA Deficit Reduction Act of 2005, Public Law 109–171
DRG Diagnosis-related group
DSH Disproportionate share hospital
EBRT External beam radiotherapy
ECE Extraordinary circumstances exemption
ECI Employment cost index
eCQM Electronic clinical quality measure
EDB [Medicare] Enrollment Database
EHR Electronic health record
EMR Electronic medical record
EMTALA Emergency Medical Treatment and Labor Act of 1986, Public Law 99–272
EP Eligible professional
FAH Federation of American Hospitals
FDA Food and Drug Administration
FFY Federal fiscal year
FPL Federal poverty line
FQHC Federally qualified health center
FR Federal Register
FTE Full-time equivalent
FY Fiscal year
GAF Geographic Adjustment Factor
GME Graduate medical education
HAC Hospital-acquired condition
HAI Healthcare-associated infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCFA Health Care Financing Administration
HCO High-cost outlier
HCP Healthcare personnel
HCRIS Hospital Cost Report Information System
HF Heart failure
HHA Home health agency
HHS Department of Health and Human Services
HICAN Health Insurance Claims Account Number
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HIPC Health Information Policy Council
HIS Health information system
HIT Health information technology
HMO Health maintenance organization
HPMP Hospital Payment Monitoring Program
HSA Health savings account
HSCRC [Maryland] Health Services Cost Review Commission
HSRV Hospital-specific relative value
HSRVcc Hospital-specific relative value cost center
HQA Hospital Quality Alliance
HQI Hospital Quality Initiative
HwH Hospital-within-hospital
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
ICD–10–PCS International Classification of Diseases, Tenth Revision, Procedure Coding System
ICR Information collection requirement
ICU Intensive care unit
IGI IHS Global Insight, Inc.
IHS Indian Health Service
IME Indirect medical education
IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014, Public Law 113–185

I–O Input-Output
IOM Institute of Medicine
IPF Inpatient psychiatric facility
IPFQR Inpatient Psychiatric Facility Quality Reporting [Program]
IPPS [Acute care hospital] inpatient prospective payment system
IRF Inpatient rehabilitation facility
IQR [Hospital] Inpatient Quality Reporting
LAMCs Large area metropolitan counties
LEP Limited English proficiency
LOC Limitation on charges
LOS Length of stay
LTC–DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
LTCH QRP Long-Term Care Hospital Quality Reporting Program
MA Medicare Advantage
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114–10
MAP Measure Application Partnership
MCC Major complication or comorbidity
MCE Medicare Code Editor
MCO Managed care organization
MDC Major diagnostic category
MDH Medicare-dependent, small rural hospital
MedPAC Medicare Payment Advisory Commission
MedPAR Medicare Provider Analysis and Review File
MEI Medicare Economic Index
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MOON Medicare Outpatient Observation Notice
MRHFP Medicare Rural Hospital Flexibility Program
MRSA Methicillin-resistant *Staphylococcus aureus*
MSA Metropolitan Statistical Area
MS–DRG Medicare severity diagnosis-related group
MS–LTC–DRG Medicare severity long-term care diagnosis-related group
MU Meaningful Use [EHR Incentive Program]
MUC Measure under consideration
NAICS North American Industrial Classification System
NALTH National Association of Long Term Hospitals
NCD National coverage determination
NCHS National Center for Health Statistics
NCQA National Committee for Quality Assurance
NCVHS National Committee on Vital and Health Statistics
NECMA New England County Metropolitan Areas
NHSN National Healthcare Safety Network
NOP Notice of Participation
NOTICE Act Notice of Observation Treatment and Implication for Care Eligibility Act, Public Law 114–42
NQF National Quality Forum
NQS National Quality Strategy
NTIS National Technical Information Service
NTTAA National Technology Transfer and Advancement Act of 1991, Public Law 104–113
NUBC National Uniform Billing Code
NVHRI National Voluntary Hospital Reporting Initiative
OACT [CMS'] Office of the Actuary
OBRA 86 Omnibus Budget Reconciliation Act of 1986, Public Law 99–509
OES Occupational employment statistics
OIG Office of the Inspector General
OMB [Executive] Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPM [U.S.] Office of Personnel Management
OQR [Hospital] Outpatient Quality Reporting
O.R. Operating room
OSCAR Online Survey Certification and Reporting [System]
PAC Post-acute care
PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93
PCH PPS-exempt cancer hospital
PCHQR PPS-exempt cancer hospital quality reporting
PMSAs Primary metropolitan statistical areas
POA Present on admission
PPI Producer price index
PPR Potentially Preventable Readmissions
PPS Prospective payment system
PRA Paperwork Reduction Act
PRM Provider Reimbursement Manual
ProPAC Prospective Payment Assessment Commission
PRRB Provider Reimbursement Review Board
PRTFs Psychiatric residential treatment facilities
PSF Provider-Specific File
PSI Patient safety indicator
PS&R Provider Statistical and Reimbursement [System]
PQRS Physician Quality Reporting System
PUF Public use file
QDM Quality data model
QIES ASAP Quality Improvement Evaluation System Assessment Submission and Processing
QIG Quality Improvement Group [CMS]
QIO Quality Improvement Organization
QM Quality measure
QRDA Quality Reporting Document Architecture
RFA Regulatory Flexibility Act, Public Law 96–354
RHC Rural health clinic
RHQDAPU Reporting hospital quality data for annual payment update
RIM Reference information model
RNHCI Religious nonmedical health care institution
RPL Rehabilitation psychiatric long-term care (hospital)
RRC Rural referral center
RSMR Risk-standard mortality rate
RSP Risk-standardized payment
RSSR Risk-standard readmission rate
RTI Research Triangle Institute, International
RUCAs Rural-urban commuting area codes
RY Rate year
SAF Standard Analytic File
SCH Sole community hospital
SCHIP State Child Health Insurance Program
SCIP Surgical Care Improvement Project
SFY State fiscal year
SGR Sustainable Growth Rate
SIC Standard Industrial Classification
SIR Standardized infection ratio
SNF Skilled nursing facility
SNF QRP Skilled Nursing Facility Quality Reporting Program
SNF VBP Skilled Nursing Facility Value-Based Purchasing
SOCs Standard occupational classifications
SOM State Operations Manual
SRR Standardized risk ratio
SSI Surgical site infection
SSI Supplemental Security Income
SSO Short-stay outlier
SUD Substance use disorder
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
TEP Technical expert panel
THA/TKA Total hip arthroplasty/total knee arthroplasty
TMA TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Public Law 110–90
TPS Total Performance Score
UHDDS Uniform hospital discharge data set
UR Utilization review
VBP [Hospital] Value Based Purchasing [Program]
VTE Venous thromboembolism

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This final rule makes payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it makes payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). It also makes policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs.

We are establishing new requirements or revising requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities) that are participating in Medicare, including related provisions for eligible hospitals and critical access hospitals (CAHs) participating in the Electronic Health Record (EHR) Incentive Program. We are updating policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program. We are implementing statutory provisions that require hospitals and CAHs to furnish notification to Medicare beneficiaries, including Medicare Advantage enrollees, when the beneficiaries receive outpatient observation services for more than 24 hours; announcing the implementation of the Frontier Community Health Integration Project Demonstration; and making technical corrections and changes to regulations relating to costs to organizations and Medicare cost reports. In addition, in this final rule, we are providing notice of the closure of three teaching hospitals and the opportunity for hospitals to apply for available graduate medical education resident slots under section 5506 of the Affordable Care Act.

Under various statutory authorities, we are making changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2017 and subsequent fiscal years. These statutory authorities include, but are not limited to, the following:

• Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).

• Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.

• Sections 123(a) and (c) of the BBRA (Pub. L. 106–113) and section 307(b)(1) of the BIPA (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of long-term care hospitals (LTCHs) described in section 1886(d)(1)(B)(iv) of the Act.

• Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.

• Section 1866(k) of the Act, as added by section 3005 of the Affordable Care Act, which establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''

• Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.

• Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase in payments to a subsection (d) hospital for a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.

• Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.

• Section 1886(p) of the Act, as added by section 3008 of the Affordable Care Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.

• Section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act and amended by section 10309 of the Affordable Care Act, which establishes the ''Hospital Readmissions Reduction Program'' effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions.

• Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act for DSH (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured (minus 0.1 percentage points for FY 2014, and minus 0.2 percentage points for FY 2015 through FY 2017); and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.

• Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS with implementation beginning in FY 2016.

• Section 1886(m)(5)(D)(iv) of the Act, as added by section 1206 (c) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which provides for the establishment of a functional status quality measure under the LTCH QRP for change in mobility among inpatients requiring ventilator support.

• Section 1899B of the Act, as added by the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act, Pub. L. 113–185), which imposes data reporting requirements for certain post-acute care providers, including LTCHs.

• Section 1886(d)(12) of the Act, as amended by section 204 of the Medicare Access and CHIP Reauthorization Act of 2015, which extends, through FY 2017, changes to the inpatient hospital payment adjustment for certain low-volume hospitals; and section 1886(d)(5)(G) of the Act, as amended by section 205 of the Medicare Access and CHIP Reauthorization Act of 2015, which extends, through FY 2017, the Medicare-dependent, small rural hospital (MDH) program.

• Section 1886(m)(6)(A)(i) and (E) of the Act, as amended and added by section 231 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), which established a temporary exception to the site neutral payment rate under the LTCH PPS for certain severe wound discharges from certain LTCHs occurring prior to January 1, 2017.

2. Summary of the Major Provisions

a. MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Pub. L. 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. This adjustment represents the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Pub. L. 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Pub. L. 110–90.

While our actuaries estimated that a −9.3 percent adjustment to the

standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in one year, it is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, we made a −0.8 percent recoupment adjustment to the standardized amount in FY 2014, FY 2015, and FY 2016. For FY 2017, we are making an additional −1.5 percent recoupment adjustment to the standardized amount.

b. Adjustment to IPPS Rates Resulting From 2-Midnight Policy

In this final rule, we are making a permanent adjustment of (1/0.998) to the standardized amount, the hospital-specific payment rates, and the national capital Federal rate using our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to prospectively remove the 0.2 percent reduction to the rate put in place in FY 2014 to offset the estimated increase in IPPS expenditures as a result of the 2-midnight policy. In addition, we are making a temporary one-time prospective increase to the FY 2017 standardized amount, the hospital-specific payment rates, and the national capital Federal rate of 0.6 percent by including a temporary one-time factor of 1.006 in the calculation of the standardized amount, the hospital-specific payment rates, and the national capital Federal rate using our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act, to address the effects of the 0.2 percent reduction to the rate for the 2-midnight policy in effect for FYs 2014, 2015, and 2016.

c. Reduction of Hospital Payments for Excess Readmissions

We are making changes to policies for the Hospital Readmissions Reduction Program, which is established under section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FY 2017 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). In this final rule, to align with other quality reporting programs and allow us to post data as soon as possible, we are clarifying our public reporting policy so that excess readmission rates will be posted to the *Hospital Compare* Web site as soon as feasible following the preview period, and we are revising the methodology to include the addition of the CABG applicable condition in the calculation of the readmissions payment adjustment for FY 2017.

d. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this final rule, we are updating one previously adopted measure beginning with the FY 2019 program year; indicating our intent to propose to remove one measure beginning with the FY 2019 program year and our intent to propose to adopt one measure in future rulemaking; adopting two new measures beginning with the FY 2021 program year; updating one previously adopted measure beginning with the FY 2021 program year; and adopting one new measure beginning with the FY 2022 program year. We also are changing the performance period for one previously adopted measure for the FY 2018 program year and changing the name of the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to the Person and Community Engagement domain beginning with the FY 2019 program year. In addition, we are making changes to the immediate jeopardy citation policy.

e. Hospital-Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act, as added under section 3008(a) of the Affordable Care Act, establishes an incentive to hospitals to reduce the incidence of hospital-acquired conditions by requiring the Secretary to make an adjustment to payments to applicable hospitals effective for discharges beginning on October 1, 2014. This 1-percent payment reduction applies to a hospital whose ranking is in the top quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. In this final rule, we are promulgating the following HAC Reduction Program policies: (1) Establishing NHSN CDC HAI data submission requirements for newly opened hospitals; (2) clarifying data requirements for Domain 1 scoring; (3) establishing performance periods for the FY 2018 and FY 2019 HAC Reduction Programs, including revising our regulations to accommodate variable timeframes; (4) adopting the refined PSI 90: Patient Safety and Adverse Events Composite (NQF #0531); and (5) changing the program scoring methodology from the current decile-based scoring to a continuous scoring methodology.

f. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY 2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, DSHs will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of what otherwise would have been paid as Medicare DSH payments, will be paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this final rule, we are updating our estimates of the three factors used to determine uncompensated care payments for FY 2017 and continuing our methodology of using a hospital's share of insured low-income days for purposes of determining Factor 3. For Puerto Rico hospitals, we are using 14 percent of Medicaid days as a proxy for SSI days in the calculation of Factor 3. We are continuing to use the methodology we established in FY 2015 to calculate the uncompensated care payment amounts for merged hospitals such that we combine uncompensated care data for the hospitals that have undergone a merger in order to calculate their relative share of uncompensated care. We are expanding the time period of the data used to calculate the uncompensated care payment amounts to be distributed, from one cost reporting period to three cost reporting periods. At this time, we are not finalizing a future transition to using Worksheet S–10 data to determine the amounts and distribution of uncompensated care payments.

Specifically, we had proposed to use a 3-year transition beginning in FY 2018 where we use a combination of Worksheet S–10 and proxy data until FY 2020 when all data used in computing the uncompensated care payment amounts to be distributed would come from Worksheet S–10. In light of public comments, we believe it would be appropriate to institute certain additional quality control and data improvement measures to the Worksheet S–10 instructions and data prior to moving forward with incorporation of Worksheet S–10 data into the calculation of Factor 3. Consequently, we are not finalizing our proposal to begin to incorporate Worksheet S–10 data into the computation of Factor 3 for FY 2018. In light of the significant concerns expressed by commenters regarding the Worksheet S–10 data, we are postponing the decision regarding when to begin incorporating data from Worksheet S–10 and proceeding with revisions to the cost report instructions for Worksheet S–10. We expect data from the revised Worksheet S–10 to be available to use in the calculation of Factor 3 in the near future, and no later than FY 2021. With regard to how Factor 3 will be computed in FY 2018 and subsequent years, we intend to explore whether there is an appropriate proxy for uncompensated care that could be used to calculate Factor 3 until we determine that data from the revised Worksheet S–10 can be used for this purpose. We will undertake further notice-and-comment rulemaking to address the issue of the appropriate data to use to determine Factor 3 for FY 2018 and subsequent fiscal years.

g. Payments for Capital-Related Costs for Hospitals Located in Puerto Rico

Capital IPPS payments to hospitals located in Puerto Rico are currently computed based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS Federal rate. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. In this final rule, we are revising the calculation of capital IPPS payments to hospitals located in Puerto Rico to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, beginning in FY 2017.

h. Changes to the LTCH PPS

In this final rule, we are revising and rebasing the market basket used under the LTCH PPS (currently the 2009-based LTCH-specific market basket) to reflect a 2013 base year. In addition, in this final rule, we are changing our 25-percent threshold policy by sunsetting our existing regulations at 42 CFR 412.534 and 412.536 and replacing them with a single consolidated 25-percent threshold policy at § 412.538. We also are amending our existing regulations limiting allowable charges to beneficiaries for ''subclause (II)'' LTCHs and making technical corrections to § 412.503. In addition, in this document, we are finalizing an April 21, 2016 interim final rule with comment period relating to a temporary exception from the site neutral payment rate under the LTCH PPS for certain severe wound care discharges from certain LTCHs.

i. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, hospitals are required to report data on measures selected by the Secretary for the Hospital IQR Program in order to receive the full annual percentage increase in payments. In past years, we have established measures for reporting data and the process for submittal and validation of the data.

In this final rule, we are making several changes. First, we are removing 15 measures for the FY 2019 payment determination and subsequent years. Thirteen of these measures are electronic clinical quality measures (eCQMs), two of which we are also removing in their chart-abstracted form, because they are ''topped-out,'' and two others are structural measures.

Second, we are refining two previously adopted measures beginning with the FY 2018 payment determination: (1) The Hospital-level, Risk-standardized Payment Associated with a 30-day Episode-of-Care for Pneumonia (NQF # 2579); and (2) the Patient Safety and Adverse Events Composite (NQF #0531).

Third, we are adding four new claims-based measures: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure; (3) Spinal Fusion Clinical Episode-Based Payment Measure; and (4) Excess Days in Acute Care after Hospitalization for Pneumonia for the FY 2019 payment determination and subsequent years.

Fourth, we summarize public comment we received on potential new quality measures under consideration for future inclusion in the Hospital IQR Program: (1) A refined version of the NIH Stroke Scale for the Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure beginning as early as the FY 2022 payment determination; (2) the National Healthcare Safety Network (NHSN) Antimicrobial Use Measure (NQF #2720); and (3) one or more measures of behavioral health for the inpatient hospital setting, including measures previously adopted for the IPFQR Program (80 FR 46417). Also, we summarize public comment we received on the possibility of future stratification of Hospital IQR Program data by race, ethnicity, sex, and disability on *Hospital Compare,* as well as on potential future hospital quality measures that incorporate health equity.

Fifth, we are modifying our proposal and requiring hospitals to select and submit 8 of the available eCQMs included in the Hospital IQR Program measure set for four quarters of data, on an annual basis, for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination, in order to align the Hospital IQR Program with the Medicare and Medicaid EHR Incentive Programs. Also, we are establishing related eCQM submission requirements beginning with the FY 2019 payment determination.

Sixth, we are modifying the existing validation process for Hospital IQR Program data to include validation of eCQMs beginning with the FY 2020 payment determination.

Seventh, we are updating our Extraordinary Circumstances Extensions or Exemptions (ECE) policy by: (1) Extending the ECE request deadline for non-eCQM circumstances from 30 to 90 calendar days following an extraordinary circumstance, beginning in FY 2017 as related to extraordinary circumstance events that occur on or after October 1, 2016; and (2) establishing a separate submission deadline of April 1 following the end of the reporting calendar year for ECEs related to eCQMs beginning with an April 1, 2017 deadline and applying for subsequent eCQM reporting years.

j. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

Section 3004(a) of the Affordable Care Act amended section 1886(m)(5) of the Act to require the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). This

program applies to all hospitals certified by Medicare as LTCHs. Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the LTCH PPS standard Federal rate for discharges occurring during such fiscal year by 2 percentage points for any LTCH that does not comply with the requirements established by the Secretary.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) amended the Act in ways that affect the LTCH QRP. Specifically, section 2(a) of the IMPACT Act amended title XVIII of the Act by adding section 1899B, titled Standardized Post-Acute Care (PAC) Assessment Data for Quality, Payment, and Discharge Planning. The Act requires that each LTCH submit, for FYs beginning on or after the specified application date (as defined in section 1899B(a)(2)(E) of the Act), data on quality measures specified under section 1899B(c)(1) of the Act and data on resource use and other measures specified under section 1899B(d)(1) of the Act in a manner and within the timeframes specified by the Secretary. In addition, each LTCH is required to submit standardized patient assessment data required under section 1899B(b)(1) of the Act in a manner and within the timeframes specified by the Secretary. Sections 1899B(c)(1) and 1899B(d)(1) of the Act require the Secretary to specify quality measures and resource use and other measures with respect to certain domains no later than the specified application date in section 1899B(a)(2)(E) of the Act that applies to each measure domain and PAC provider setting.

In this final rule, we are specifying three new measures for the FY 2018 payment determination and subsequent years to meet the requirements as set forth by the IMPACT Act. These measures are: (1) MSPB–PAC LTCH QRP; (2) Discharge to Community-PAC LTCH QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for the PAC LTCH QRP. We also are establishing one new quality measure to meet the requirements of the IMPACT Act for the FY 2020 determination and subsequent years. That measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, addresses the IMPACT Act domain of Medication Reconciliation.

In addition, we will publicly report LTCH quality data beginning in fall 2016, on a CMS Web site, such as *Hospital Compare.* Initially, we publicly reported quality data on four quality measures. In this final rule, we are providing that we will publicly report data in 2017 on four additional measures. We are promulgating additional details regarding procedures that will allow individual LTCHs to review and correct their data and information on measures that are to be made public before those measure data are made public. We also will provide confidential feedback reports to LTCHs on their performance on the specified measures, beginning 1 year after the specified application date that applies to such measures and LTCHs.

Finally, we are changing the timing for submission of exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an LTCH from submitting their quality data for the LTCH QRP.

k. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013 through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit must submit to the Secretary data on quality measures as specified by the Secretary. The data must be submitted in a form and manner and at a time specified by the Secretary. In this final rule, for the IPFQR Program, we are making several changes. We are making a technical update to the previously finalized measure, ''Screening for Metabolic Disorders.'' We are finalizing two new measures beginning with the FY 2019 payment determination:

- SUB–3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB–3a Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664); and
- Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF.

In addition, we are finalizing our proposal to include SUB–3: Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and subset measure SUB–3a: Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664) in the list of measures covered by the global sample for the FY 2019 payment determination and subsequent years as proposed. Also, we are finalizing that we will make the data for the IPFQR Program available as soon as possible and announce both the date of the public display of the program's data and the 30-day preview period, which will be approximately 12 weeks before the public display date, via subregulatory methods, as opposed to rulemaking. For the FY 2017 payment determination only, we also are finalizing our proposal that, if it is technically feasible to display the data in December 2016, we would provide data to IPFs for a 2-week preview period that would start on October 1, 2016, as proposed. Moreover, we are finalizing as proposed that as a courtesy, for the FY 2017 payment determination only, if we are able to display the data in December 2016, we would ensure that IPFs have approximately 30 days for review if they so choose by providing IPFs with their data as early as mid-September.

3. Summary of Costs and Benefits

- Adjustment for MS–DRG Documentation and Coding Changes. We are making a −1.5 percent recoupment adjustment to the standardized amount for FY 2017 to implement, in part, the requirement of section 631 of the ATRA that the Secretary make an adjustment totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. This recoupment adjustment represents the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Pub. L. 110–90.

While our actuaries estimated that a −9.3 percent recoupment adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in FY 2014, it is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year. Taking into account the cumulative effects of this adjustment and the adjustments made in FYs 2014, 2015, and 2016, we estimate that we will recover the full $11 billion required under section 631 of the ATRA by the end of FY 2017. We note that section 414 of the MACRA (Pub. L. 114–10), enacted on April 16, 2015, requires us to not make the single positive adjustment we intended to make in FY 2018, but instead make a 0.5 percent positive adjustment for each of FYs 2018 through 2023. The provision under section 414 of the MACRA does not impact our FY 2017 recoupment adjustment, and we will address this MACRA provision in future rulemaking.

- Adjustment to IPPS Payment Rates as a Result of the 2-Midnight Policy. The adjustment to IPPS rates resulting

from the 2-midnight policy will increase IPPS payment rates by (1/0.998) * 1.006 for FY 2017. The 1.006 is a one-time factor that will be applied to the standardized amount, the hospital-specific rates, and the national capital Federal rate for FY 2017 only. Therefore, for FY 2018, we will apply a one-time factor of (1/1.006) in the calculation of the rates to remove this one-time prospective increase.

• Changes to the Hospital Readmissions Reduction Program. For FY 2017 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). Overall, in this final rule, we estimate that 2,588 hospitals will have their base operating DRG payments reduced by their determined proxy FY 2017 hospital-specific readmission adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program will save approximately $528 million in FY 2017, an increase of approximately $108 million over the estimated FY 2016 savings. This increase in the estimated savings for the Hospital Readmissions Reduction Program in FY 2017 as compared to FY 2016 is primarily due to the inclusion of the refinement of the pneumonia readmissions measure, which expanded the measure cohort, along with the addition of the CABG readmission measure, in the calculation of the payment adjustment.

• Value-Based Incentive Payments under the Hospital VBP Program. We estimate that there will be no net financial impact to the Hospital VBP Program for the FY 2017 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS–DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS–DRG payment amount reductions for the FY 2017 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2017 discharges is approximately $1.8 billion.

• Changes to the HAC Reduction Program. In regard to the five changes to existing HAC Reduction Program policies described earlier, because a hospital's Total HAC score and its ranking in comparison to other hospitals in any given year depends on several different factors, any significant impact due to the HAC Reduction Program changes for FY 2017, including which hospitals will receive the adjustment, will depend on actual experience.

• Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care. Under section 1886(r) of the Act (as added by section 3133 of the Affordable Care Act), DSH payments to hospitals under section 1886(d)(5)(F) of the Act are reduced and an additional payment for uncompensated care is made to eligible hospitals beginning in FY 2014. Hospitals that receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the current statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, will be the basis for determining the additional payments for uncompensated care after the amount is reduced for changes in the percentage of individuals that are uninsured and additional statutory adjustments. Each hospital that receives Medicare DSH payments will receive an additional payment for uncompensated care based on its share of the total uncompensated care amount reported by Medicare DSHs. The reduction to Medicare DSH payments is not budget neutral.

For FY 2017, we are providing that the 75 percent of what otherwise would have been paid for Medicare DSH is adjusted to approximately 55.36 percent of the amount to reflect changes in the percentage of individuals that are uninsured and additional statutory adjustments. In other words, approximately 41.52 percent (the product of 75 percent and 55.36 percent) of our estimate of Medicare DSH payments, prior to the application of section 3133 of the Affordable Care Act, is available to make additional payments to hospitals for their relative share of the total amount of uncompensated care. We project that estimated Medicare DSH payments, and additional payments for uncompensated care made for FY 2017, will reduce payments overall by approximately 0.4 percent as compared to overall payments with the estimate of Medicare DSH payments and uncompensated care payments that will be distributed in FY 2016. The additional payments have redistributive effects based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are estimated to receive Medicare DSH payments, and the calculated payment amount is not directly tied to a hospital's number of discharges.

• Update to the LTCH PPS Payment Rates and Other Payment Factors. Based on the best available data for the 420 LTCHs in our data base, we estimate that the changes to the payment rates and factors that we are presenting in the preamble and Addendum of this final rule, which includes the second year under the transition of the statutory application of the new site neutral payment rate required by section 1886(m)(6)(A) of the Act, the update to the LTCH PPS standard Federal payment rate for FY 2017, the update to the LTCH PPS adjustment for differences in area wage levels (which includes the update to the labor-related share based on the revised and rebased LTCH PPS market basket) and estimated changes to the site neutral payment rate and short-stay outlier (SSO) and high-cost outlier (HCO) payments will result in an estimated decrease in payments from FY 2016 of approximately $376 million.

• Hospital Inpatient Quality Reporting (IQR) Program. In this final rule, we are removing 15 measures for the FY 2019 payment determination and subsequent years. We are adding 4 new claims-based measures to the Hospital IQR Program for the FY 2019 payment determination and subsequent years. We also are modifying our proposal and requiring hospitals to report on 8 of the available Hospital IQR Program electronic clinical quality measures that align with the Medicare and Medicaid EHR Incentive Programs for four quarters of data on an annual basis for the FY 2019 and FY 2020 payment determination. In addition, we are modifying the existing validation process for the Hospital IQR Program data to include a random sample of up to 200 hospitals for validation of eCQMs. We estimate that our policies for the adoption and removal of measures will result in a total hospital cost decrease of $50.4 million across 3,300 IPPS hospitals.

• Changes Related to the LTCH QRP. In this final rule, we are specifying four quality measures for the LTCH QRP. We estimate that the total cost related to one of these proposed measures, the Drug Regimen Review Conducted with Follow-up for Identified Issues-PAC measure, would be $3,080 per LTCH annually, or $1,330,721 for all LTCHs annually. We also estimate that while there will be some additional burden associated with our expansion of data collection for the measure NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (77 FR

53624 through 53627), this burden has been previously accounted for in PRA submissions approved under OMB control number 0938–1163. For a detailed explanation, we refer readers to section I.M. of Appendix A (Economic Analyses) of this final rule. There is no additional burden for the three other claims-based measures being adopted. Overall, we estimate the total cost for the 13 previously adopted measures and the 4 new measures will be $27,905 per LTCH annually or $12,054,724 for all LTCHs annually. These estimates are based on 432 LTCHs that are currently certified by Medicare. This is an average increase of 14 percent over the burden for FY 2016. This increase includes all quality measures that LTCHs are required to report, with the exception of the four new measures for FY 2017. Section VIII.C. of the preamble of this final rule includes a detailed discussion of the policies.

• Changes to the IPFQR Program. In this final rule, we are adding two new measures beginning with the FY 2019 payment determination and for subsequent years. One of these measures, the 30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF measure, is calculated from administrative claims data. For the second measure, we estimate that our policies will result in total costs of $11,834,748 for 1,684 IPFs nationwide.

B. Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment that considers the amount of uncompensated care beginning on October 1, 2013.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2017. Through and including FY 2006, an MDH received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate was exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. For discharges occurring on or after October 1, 2007, but before October 1, 2017, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years).

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the

IPPS. These hospitals and units are: inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; cancer hospitals; and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are now included as part of the IPPS annual update document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006, all LTCHs are paid 100 percent of the Federal rate. Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, based on a rolling effective date that is linked to the date on which a given LTCH's Federal FY 2016 cost reporting period begins, LTCHs are paid for LTCH discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR Part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v)(1)(A) of the Act and existing regulations under 42 CFR parts 413 and 415.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

C. Summary of Provisions of Recent Legislation Implemented in This Final Rule

1. American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240)

The American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240), enacted on January 2, 2013, made a number of changes that affect the IPPS. In this final rule, we are making policy changes to implement section 631 of the ATRA, which amended section 7(b)(1)(B) of Public Law 110–90 and requires a recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring in FY 2014 through FY 2017 to fully offset $11 billion (which represents the amount of the increase in aggregate payments from FYs 2008 through 2013 for which an adjustment was not previously applied).

2. Pathway for SGR Reform Act of 2013 (Pub. L. 113–67)

The Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) introduced new payment rules in the LTCH PPS. Under section 1206 of this law, discharges in cost reporting periods beginning on or after October 1, 2015 under the LTCH PPS will receive payment under a site neutral rate unless the discharge meets certain patient-specific criteria. In this final rule, we are providing clarifications to prior policy changes that implemented provisions under section 1206 of the Pathway for SGR Reform Act.

3. Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185)

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act (Pub. L. 113–185), enacted on October 6, 2014, made a number of changes that affect the Long-Term Care Quality Reporting Program (LTCH QRP). In this final rule, we are continuing to implement portions of section 1899B of the Act, as added by section 2 of the IMPACT Act, which, in part, requires LTCHs, among other postacute care providers, to report standardized patient assessment data, data on quality measures, and data on resource use and other measures.

4. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) extended the MDH program and changes to the payment adjustment for low-volume hospitals through FY 2017. In this final rule, we are updating the low-volume hospital payment adjustment for FY 2017 under the extension of the temporary changes to the low-volume hospital payment adjustment provided for by section 204 of Public Law 114–10. We also are finalizing in this FY 2017 IPPS/LTCH PPS final rule the provisions of the FY 2016 IPPS/LTCH PPS interim final rule with comment period (80 FR 49594 through 49597) that implemented sections 204 and 205 of Public Law 114–10.

5. The Consolidated Appropriations Act, 2016 (Pub. L. 114–113)

The Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, made changes that affect the IPPS and the LTCH PPS. Section 231 of Public Law 114–113 amended section 1886(m)(6) of the Act to provide for a temporary exception to the site neutral payment rate under the LTCH PPS for certain severe wound discharges from certain LTCHs occurring prior to January 1, 2017. This provision was implemented in an interim final rule with comment period that appeared in the **Federal Register** on April 21, 2016 (81 FR 23428 through 23438). We are finalizing that interim final rule with comment period in section VII.B.3. of this FY 2017 IPPS/LTCH PPS final rule. Section 601 of Public Law 114–113 made changes to the payment calculation for operating IPPS payments for hospitals located in Puerto Rico. Section 602 of Public Law 114–113 specifies that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also applies the adjustments to the applicable percentage increase under the statute for Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. In this final rule, we are making conforming changes to our regulations to reflect the provisions of section 601 of Public Law 114–113, which increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016.

6. The Notice of Observation Treatment and Implication for Care Eligibility Act (the NOTICE Act) (Pub. L. 114–42)

The Notice of Observation Treatment and Implication for Care Eligibility Act (the NOTICE Act) (Pub. L. 114–42) enacted on August 6, 2015, amended section 1866(a)(1) of the Act by adding new subparagraph (Y) that requires hospitals and CAHs to provide written notification and an oral explanation of such notification to individuals receiving observation services as outpatients for more than 24 hours at the hospitals or CAHs. In this final rule, we are implementing the provisions of Public Law 114–42.

D. Issuance of a Notice of Proposed Rulemaking

In the proposed rule that appeared in the **Federal Register** on April 27, 2016 (81 FR 24946), we set forth proposed payment and policy changes to the Medicare IPPS for FY 2017 operating costs and for capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS, including proposed changes relating to payments for IME and direct GME to certain hospitals that continue to be excluded from the IPPS and paid on a reasonable cost basis. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2017.

Below is a summary of the major changes that we proposed to make:

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we included—

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2017.
- Proposed application of the documentation and coding adjustment for FY 2017 resulting from implementation of the MS–DRG system.
- Proposed recalibrations of the MS–DRG relative weights.
- A discussion of the FY 2017 status of new technologies approved for add-on payments for FY 2016 and a presentation of our evaluation and analysis of the FY 2017 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to the proposed rule, we proposed to make revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed included, but were not limited to, the following:

- The proposed FY 2017 wage index update using wage data from cost reporting periods beginning in FY 2013.
- Calculation of the proposed occupational mix adjustment for FY 2017 based on the 2013 Occupational Mix Survey.
- Analysis and implementation of the proposed FY 2017 occupational mix adjustment to the wage index for acute care hospitals.
- Proposed application of the rural floor, the proposed imputed floor, and the proposed frontier State floor.
- Transitional wage indexes relating to the continued use of the revised OMB labor market area delineations based on 2010 Decennial Census data.
- Proposed revisions to the wage index for acute care hospitals based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Notification regarding the proposed CMS ''lock-in'' date for urban to rural reclassifications under § 412.103.
- The proposed adjustment to the wage index for acute care hospitals for FY 2017 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Determination of the labor-related share for the proposed FY 2017 wage index.
- Solicitation of Comments on Treatment of Overhead and Home Office Costs in the Wage Index Calculation

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs

In section IV. of the preamble of the proposed rule, we discussed proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed conforming changes to our regulations to reflect the changes to operating payments for subsection (d) Puerto Rico hospitals in accordance with the provisions of section 601 of Public Law 114–113.
- Proposed changes to the inpatient hospital update for FY 2017.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- Proposed payment adjustment for low-volume hospitals for FY 2017.
- The statutorily required IME adjustment factor for FY 2017.
- Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.
- Proposed changes to the rules for payment adjustments under the Hospital Readmissions Reduction Program based on hospital readmission measures and the process for hospital review and correction of those rates for FY 2017.
- Proposed changes to the requirements and provision of value-based incentive payments under the Hospital Value-Based Purchasing Program.

• Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2017.
• Proposed changes relating to direct GME and IME payments to urban hospitals with rural track training programs.
• Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality adjustment for the demonstration program.
• Proposed implementation of the Notice of Observation Treatment and Implications for Care Eligibility Act (the NOTICE Act) for hospitals and CAHs.
• Proposed technical changes and corrections to regulations relating to cost to related organizations and Medicare cost reports.

4. Proposed FY 2017 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to the proposed rule, we discussed the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2017. In addition, we discussed proposed changes to the calculation of capital IPPS payments to hospitals located in Puerto Rico to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, beginning in FY 2017.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VI. of the preamble of the proposed rule, we discussed—
• Proposed changes to payments to certain excluded hospitals for FY 2017.
• Proposed implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

6. Proposed Changes to the LTCH PPS

In section VII. of the preamble of the proposed rule, we set forth—
• Proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2017.
• Proposals to sunset our existing 25-percent threshold policy regulations, and replace them with single consolidated 25 percent threshold policy regulation.
• Proposed changes to the limitation on charges to beneficiaries and related billing requirements for ''subclause (II)'' LTCHs to align those LTCH PPS payment adjustment policies with the limitation on charges policies applied in the TEFRA payment context.
• Proposed technical corrections to certain definitions to correct and clarify their use under the application of the site neutral payment rate and proposed additional definitions in accordance with our proposed modifications to the 25-percent policy.
• Proposed rebasing and revising of the LTCH market basket to update the LTCH PPS, effective for FY 2017.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section VIII. of the preamble of the proposed rule, we addressed—
• Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program as a condition for receiving the full applicable percentage increase.
• Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).
• Proposed changes to the requirements under the LTCH Quality Reporting Program (LTCH QRP).
• Proposed changes to the requirements under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program.
• Proposed changes relating to clinical quality measures for the Medicare Electronic Health Record (EHR) Incentive Program and eligible hospitals and CAHs.

8. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In section V. of the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2017 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We proposed to establish the threshold amounts for outlier cases. In addition, we addressed the update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2017 for certain hospitals excluded from the IPPS.

9. Determining Prospective Payment Rates for LTCHs

In the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2017 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2017. We proposed to establish the adjustments for wage levels, the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates. We also provided the estimated market basket update to apply to the ceiling used to determine payments under the existing payment adjustment for ''subclause (II)'' LTCHs for cost reporting periods beginning in FY 2017.

10. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected acute care hospitals, CAHs, LTCHs, PCHs, and IPFs.

11. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provided our recommendations of the appropriate percentage changes for FY 2017 for the following:

• A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
• Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
• The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

12. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2016 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We addressed these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2016 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's Web site at: *http://www.medpac.gov*.

E. Finalization of Interim Final Rule With Comment Period on the Temporary Exception to the Site Neutral Payment Rate Under the LTCH PPS for Certain Severe Wound Discharges From Certain LTCHs Required by the Consolidated Appropriations Act, 2016 and Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board

In the interim final rule with comment period that appeared in the **Federal Register** on April 21, 2016 (CMS–1664–IFC; 81 FR 23428 through 23438), we addressed provisions relating to (1) a temporary exception to the site neutral payment rate under the LTCH PPS for certain severe wound discharges from certain LTCHs; and (2) application of two judicial decisions relating to modifications of the limitations on redesignation by the Medicare Geographic Classification Review Board.

In response to the section of the interim final rule with comment period on the temporary exception to the site neutral payment rate under the LTCH PPS for certain severe wound discharges from certain LTCHs, we received 22 timely pieces of correspondence. In section VII.B.3. of the preamble of this final rule, we summarize our policies and these public comments, present our responses, and finalize our policies regarding this temporary exception.

In response to the section of the interim final rule with comment period on modification of limitations on redesignation by the MGCRB, we received 7 timely pieces of correspondence. In section III,J,2. of the preamble of this final rule, we summarize these public comments, present our responses, and finalize these provisions.

F. Finalization of Interim Final Rule With Comment Period Implementing Legislative Extensions Relating to the Payment Adjustment for Low-Volume Hospitals and the Medicare-Dependent, Small Rural Hospital (MDH) Program

In the interim final rule with comment period that appeared in the **Federal Register** on August 17, 2015, as part of the FY 2017 IPPS/LTCH PPS final rule, we addressed the legislative extensions relating to the payment adjustment for low-volume hospitals and the MDH program (CMS–1632–IFC; 80 FR 49594). In response to this interim final rule with comment period, we received 14 timely pieces of correspondence. However, all of the correspondence included public comments that were outside the scope of the provisions of the interim final rule with comment period. We are finalizing this interim final rule with comment in section IV.N. of the preamble of this final rule.

II. Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. MS–DRG Reclassifications

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011, 2012, 2013, 2014, 2015, and 2016 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; and 80 FR 49342, respectively).

C. Adoption of the MS–DRGs in FY 2008

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

D. FY 2017 MS–DRG Documentation and Coding Adjustment

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (As a result of this final rule, for FY 2017, there are 757 MS–DRGs.) By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percent to the national standardized amount. We provided for phasing in this −4.8 percent adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percent for FY 2008, −1.8 percent for FY 2009, and −1.8 percent for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Public Law 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percent for FY 2008 and −0.9 percent for FY 2009, and we finalized the FY 2008 adjustment through rulemaking, effective October 1, 2007 (72 FR 66886).

For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent, and we finalized that adjustment through rulemaking effective October 1, 2008 (73 FR 48447). The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period, which reflected the amendments made by section 7(a) of Public Law 110–90, are cumulative. As a result, the −0.9 percent documentation and coding adjustment for FY 2009 was in addition to the −0.6 percent adjustment for FY 2008, yielding a combined effect of −1.5 percent.

2. Adjustment to the Average Standardized Amounts Required by Public Law 110–90

a. Prospective Adjustment Required by Section 7(b)(1)(A) of Public Law 110–90

Section 7(b)(1)(A) of Public Law 110–90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, the Secretary shall make an appropriate adjustment under section 1886(d)(3)(A)(vi) of the Act.

Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as the payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 reflected the change that occurred in those years.

b. Recoupment or Repayment Adjustments in FYs 2010 Through 2012 Required by Section 7(b)(1)(B) Public Law 110–90

If, based on a retroactive evaluation of claims data, the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different from the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an additional adjustment to the standardized amounts under section 1886(d) of the Act. This adjustment must offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustment applied under section 7(a) of Public Law 110–90. This adjustment is in addition to making an appropriate adjustment to the standardized amounts under section 1886(d)(3)(A)(vi) of the Act as required by section 7(b)(1)(A) of Public Law 110–90. That is, these adjustments are intended to recoup (or repay, in the case of underpayments) spending in excess of (or less than) spending that would have occurred had the prospective adjustments for changes in documentation and coding applied in FY 2008 and FY 2009 matched the changes that occurred in those years. Public Law 110–90 requires that the Secretary only make these recoupment or repayment adjustments for discharges occurring during FYs 2010, 2011, and 2012.

3. Retrospective Evaluation of FY 2008 and FY 2009 Claims Data

In order to implement the requirements of section 7 of Public Law 110–90, we performed a retrospective evaluation of the FY 2008 data for claims paid through December 2008 using the methodology first described in the FY 2009 IPPS/LTCH PPS final rule (73 FR 43768 and 43775) and later discussed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43768 through 43772). We performed the same analysis for FY 2009 claims data using the same methodology as we did for FY 2008 claims (75 FR 50057 through 50068). The results of the analysis for the FY 2011 IPPS/LTCH PPS proposed and final rules, and subsequent evaluations in FY 2012, supported that the 5.4 percent estimate accurately reflected the FY 2009 increases in documentation and coding under the MS–DRG system. We were persuaded by both MedPAC's analysis (as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50064 through 50065)) and our own review of the methodologies proposed by various commenters that the methodology we employed to determine the required documentation and coding adjustments was sound.

As in prior years, the FY 2008, FY 2009, and FY 2010 MedPAR files are available to the public to allow independent analysis of the FY 2008 and FY 2009 documentation and coding effects. Interested individuals may still order these files through the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/* by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This CMS Web page describes the file and provides directions and further detailed instructions for how to order.

Persons placing an order must send the following: a Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check (refer to the Web site for the required payment amount) to:

Mailing address if using the U.S. Postal Service: Centers for Medicare & Medicaid Services, RDDC Account, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520.

Mailing address if using express mail: Centers for Medicare & Medicaid Services, OFM/Division of Accounting—RDDC, 7500 Security Boulevard, C3–07–11, Baltimore, MD 21244–1850.

4. Prospective Adjustments for FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Public Law 110–90

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43767 through 43777), we opted to delay the implementation of any documentation and coding adjustment until a full analysis of case-mix changes based on FY 2009 claims data could be completed. We refer readers to the FY 2010 IPPS/RY LTCH PPS final rule for a detailed description of our proposal, responses to comments, and finalized policy. After analysis of the FY 2009 claims data for the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50073), we found a total prospective documentation and coding effect of 5.4 percent. After accounting for the −0.6 percent and the −0.9 percent documentation and coding adjustments in FYs 2008 and 2009, we found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of −3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Public Law 110–90 to make an adjustment to the average standardized amounts in order to eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments. Unlike section 7(b)(1)(B) of Public Law 110–90, section 7(b)(1)(A) does not specify when we must apply the prospective adjustment, but merely requires us to make an ''appropriate'' adjustment. Therefore, as we stated in the FY 2011 IPPS/LTCH

PPS final rule (75 FR 50061), we believed the law provided some discretion as to the manner in which we applied the prospective adjustment of −3.9 percent. As we discussed extensively in the FY 2011 IPPS/LTCH PPS final rule, it has been our practice to moderate payment adjustments when necessary to mitigate the effects of significant downward adjustments on hospitals, to avoid what could be widespread, disruptive effects of such adjustments on hospitals. Therefore, we stated that we believed it was appropriate to not implement the −3.9 percent prospective adjustment in FY 2011 because we finalized a −2.9 percent recoupment adjustment for that fiscal year. Accordingly, we did not propose a prospective adjustment under section 7(b)(1)(A) of Public Law 110–90 for FY 2011 (75 FR 23868 through 23870). We noted that, as a result, payments in FY 2011 (and in each future fiscal year until we implemented the requisite adjustment) would be higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51489 and 51497), we indicated that, because further delay of this prospective adjustment would result in a continued accrual of unrecoverable overpayments, it was imperative that we implement a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we implemented a −2.0 percent prospective adjustment to the standardized amount instead of the full −3.9 percent.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53276), we completed the prospective portion of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 by finalizing a −1.9 percent adjustment to the standardized amount for FY 2013. We stated that this adjustment would remove the remaining effect of the documentation and coding changes that do not reflect real changes in case-mix that occurred in FY 2008 and FY 2009. We believed that it was imperative to implement the full remaining adjustment, as any further delay would result in an overstated standardized amount in FY 2013 and any future fiscal years until a full adjustment was made.

We noted again that delaying full implementation of the prospective portion of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated. These overpayments could not be recovered by CMS, as section 7(b)(1)(B) of Public Law 110–90 limited recoupments to overpayments made in FY 2008 and FY 2009.

5. Recoupment or Repayment Adjustment Authorized by Section 7(b)(1)(B) of Public Law 110–90

Section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an adjustment to the standardized amounts under section 1886(d) of the Act to offset the estimated increase or decrease in aggregate payments for FY 2008 and FY 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustments applied under section 7(a) of Public Law 110–90. This determination must be based on a retrospective evaluation of claims data. Our actuaries estimated that there was a 5.8 percentage point difference resulting in an increase in aggregate payments of approximately $6.9 billion. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50062 through 50067), we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012 would be necessary in order to meet the requirements of section 7(b)(1)(B) of Public Law 110–90 to adjust the standardized amounts for discharges occurring in FYs 2010, 2011, and/or 2012 to offset the estimated amount of the increase in aggregate payments (including interest) in FYs 2008 and 2009.

It is often our practice to phase in payment rate adjustments over more than one year in order to moderate the effect on payment rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, in the FY 2011 IPPS/LTCH PPS final rule, we made an adjustment to the standardized amount of −2.9 percent, representing approximately half of the aggregate adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. An adjustment of this magnitude allowed us to moderate the effects on hospitals in one year while simultaneously making it possible to implement the entire adjustment within the timeframe required under section 7(b)(1)(B) of Public Law 110–90 (that is, no later than FY 2012). For FY 2012, in accordance with the timeframes set forth by section 7(b)(1)(B) of Public Law 110–90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we completed the recoupment adjustment by implementing the remaining −2.9 percent adjustment, in addition to removing the effect of the −2.9 percent adjustment to the standardized amount finalized for FY 2011 (76 FR 51489 and 51498). Because these adjustments, in effect, balanced out, there was no year-to-year change in the standardized amount due to this recoupment adjustment for FY 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53276), we made a final +2.9 percent adjustment to the standardized amount, completing the recoupment portion of section 7(b)(1)(B) of Public Law 110–90. We note that with this positive adjustment, according to our estimates, all overpayments made in FY 2008 and FY 2009 have been fully recaptured with appropriate interest, and the standardized amount has been returned to the appropriate baseline.

6. Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

Section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represents the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. As discussed earlier, this delay in implementation resulted in overstated payment rates in FYs 2010, 2011, and 2012. The resulting overpayments could not have been recovered under Public Law 110–90.

Similar to the adjustments authorized under section 7(b)(1)(B) of Public Law 110–90, the adjustment required under section 631 of the ATRA is a one-time recoupment of a prior overpayment, not a permanent reduction to payment rates. Therefore, we anticipated that any adjustment made to reduce payment rates in one year would eventually be offset by a positive adjustment in 2018, once the necessary amount of overpayment was recovered. However, section 414 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, Public Law 114–10, enacted on April 16, 2015, replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. We stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49345) that we will address this MACRA provision in future rulemaking.

As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), our actuaries estimated that a −9.3 percent adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by

section 631 of the ATRA in FY 2014. It is often our practice to phase in payment rate adjustments over more than one year, in order to moderate the effect on payment rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, and after consideration of the public comments we received, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), we implemented a −0.8 percent recoupment adjustment to the standardized amount in FY 2014. We stated that if adjustments of approximately −0.8 percent are implemented in FYs 2014, 2015, 2016, and 2017, using standard inflation factors, we estimate that the entire $11 billion will be accounted for by the end of the statutory 4-year timeline. As estimates of any future adjustments are subject to slight variations in total savings, we did not provide for specific adjustments for FYs 2015, 2016, or 2017 at that time. We stated that we believed that this level of adjustment for FY 2014 was a reasonable and fair approach that satisfies the requirements of the statute while mitigating extreme annual fluctuations in payment rates.

Consistent with the approach discussed in the FY 2014 rulemaking for recouping the $11 billion required by section 631 of the ATRA, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49874) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49345), we implemented additional −0.8 percent recoupment adjustments to the standardized amount in FY 2015 and FY 2016, respectively. We estimated that these adjustments, combined with leaving the prior −0.8 percent adjustments in place, would recover up to $2 billion in FY 2015 and another $3 billion in FY 2016. When combined with the approximately $1 billion adjustment made in FY 2014, we estimated that approximately $5 to $6 billion would be left to recover under section 631 of the ATRA by the end of FY 2016.

However, as indicated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24966), due to lower than previously estimated inpatient spending, we determined that an adjustment of −0.8 percent in FY 2017 would not recoup the $11 billion under section 631 of the ATRA. Based on the FY 2017 President's Budget, our actuaries estimated for the proposed rule that FY 2014 through FY 2016 spending subject to the documentation and coding recoupment adjustment in the absence of the −0.8 percent adjustments made in FYs 2014 through 2016 would have been $123.783 billion in FY 2014, $124.361 billion in FY 2015, and $127.060 billion in FY 2016. As shown in the following table, the amount recouped in each of those fiscal years is therefore calculated as the difference between those amounts and the amounts determined to have been spent in those years with the −0.8 percent adjustment applied, namely $122.801 billion in FY 2014, $122.395 billion in FY 2015, and $124.059 billion in FY 2016. This yields an estimated total recoupment through the end of FY 2016 of $5.950 billion.

RECOUPMENT MADE UNDER SECTION 631 OF THE AMERICAN TAXPAYER RELIEF ACT OF 2012

[ATRA]

	IPPS Spending* (billions)	Cumulative adjustment factor	Adjusted IPPS spending (billions)	Recoupment amount (billions)
FY 2014	$122.801	1.00800	$123.783	$0.98
FY 2015	122.395	1.01606	124.361	1.97
FY 2016	124.059	1.02419	127.060	3.00
Total				5.95

*Based on FY 2017 President's Budget, including capital, IME, and DSH payments.

These estimates and the estimate of FY 2017 spending subject to the documentation and coding recoupment adjustment also are included in a memorandum from the Office of the Actuary that we made publicly available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* on the FY 2017 IPPS Proposed Rule Home Page. A description of the President's Budget for FY 2017 is currently available on the OMB Web site at: *https://www.whitehouse.gov/omb/budget.*

For the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24967), our actuaries estimated that the FY 2017 spending subject to the documentation and coding recoupment adjustment (including capital, IME, and DSH payment) would be $129.625 billion in the absence of any documentation and recoupment adjustments from FY 2014 through FY 2017. Therefore, at the time of issuance of the FY 2017 proposed rule, our actuaries estimated that, to the nearest tenth of a percent, the FY 2017 documentation and coding adjustment factor that will recoup as closely as possible $11 billion from FY 2014 through FY 2017 without exceeding this amount is −1.5 percent. This adjustment factor yields an estimated spending amount in FY 2017 of $124.693 billion, calculated as $129.625/(1.008*1.008*1.008*1.015). We indicated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24967) that this estimated proposed −1.5 percent adjustment factor would be updated for the final rule based on the FY 2017 President's Budget Midsession Review. We noted that, based on updated estimates, the necessary adjustment factor to the nearest tenth of a percent could be different than our actuaries' estimate of −1.5 percent.

Comment: MedPAC reiterated its previous support for the recovery of past overpayments due to documentation and coding. MedPAC stated that the law stipulates the amount of the recovery and the timing of the recovery. MedPAC also stated that CMS has little discretion and is proceeding as required by law.

Response: We appreciate MedPAC's support for our proposal.

Comment: The vast majority of commenters urged CMS to use its older estimate of the required adjustment for FY 2017 of −0.8 percentage point, rather than its updated proposed estimate of −1.5 percentage points. Commenters argued that the ATRA does not require CMS to update the initial FY 2017 estimate discussed in the FY 2014 final rule with more recent data, that the law allows CMS to continue using the older analysis, and that revisiting the actual recoupments for the preceding fiscal years is not consistent with the ATRA. The commenters' bases for this argument included that it would be a better interpretation of the statute and it is more consistent with CMS' approach regarding its use of estimates for outlier payments. The commenters also stated

that CMS should take into account any savings in Medicare Advantage (MA) payments when determining the $11 billion recoupment or otherwise adjust the $11 billion for policies that have been implemented since the passage of the ATRA. Many commenters also believed that the proposed −1.5 percent adjustment was inconsistent with Congressional intent in the ATRA and the MACRA, which they asserted reflected Congress' expectation that the final reduction would be 0.8 percentage points or at least statutorily limited the difference between the negative recoupment adjustments under the ATRA and the positive adjustments under the MACRA. Commenters further stated that if CMS does finalize its proposed adjustment under the ATRA for FY 2017, it should make an offsetting adjustment in FY 2018 to address the difference between the FY 2017 adjustment and the positive adjustments provided for under the MACRA.

Response: We believe our proposed adjustment for FY 2017 is most consistent with the requirement under section 631 of the ATRA to make an adjustment to ''fully offset'' $11 billion by FY 2017. While we recognize that the commenters have advocated for alternative interpretations of the legislation, we believe the most straightforward reading is that the ATRA requires us to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. If we were to use the older estimate of a −0.8 percent adjustment for FY 2017, we would only recoup an estimated $10.1 billion, which we do not believe would be consistent with the requirement under the ATRA to offset $11 billion by FY 2017. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49345) and prior rules, because estimates of future adjustments were subject to variations in total estimated savings, we did not address the specific amount of the final adjustment required under section 631 of the ATRA for FY 2017 at that time.

In response to comments that we should take into account any savings in MA payments when determining the $11 billion recoupment or otherwise adjust the $11 billion for policies that have been implemented since the passage of the ATRA, we note that our approach for estimating the FY 2017 adjustment is consistent with our historic approach for estimating adjustments to address documentation and coding effects. There is no evidence in the legislative language that, in determining the adjustments necessary to achieve the $11 billion offset required under the ATRA, CMS should include impacts on MA payments or make adjustments for policies that have been implemented since the passage of the ATRA. We also believe that the commenters' suggestion should be evaluated in the context of MedPAC's comment and prior comments on this issue that we should recover past overpayments due to changes in documentation and coding. As stated previously, the $11 billion recoupment under the ATRA represents the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Adopting an interpretation that reduces the amount of our proposed FY 2017 adjustment creates a greater differential by the end of FY 2017 between the payment increases that occurred due to documentation and coding and the amount recovered. We do not believe increasing this differential would be an appropriate policy. We also note that it has been our consistent practice in implementing the ATRA to not account for MA discharges or savings and find no indication or expectation under the MACRA to change this approach.

With respect to the additional issues of Congressional intent raised by commenters, we disagree that the ATRA and the MACRA, in conjunction, somehow ratify a −0.8 percent adjustment for FY 2017 or statutorily limit the difference between the adjustments under the ATRA and adjustments under the MACRA. As commenters have noted, even if we did adopt an adjustment of −0.8 percent for FY 2017, the cumulative effect of our ATRA adjustment would be −3.2 percentage points, while the MACRA only requires cumulative positive adjustments of +3.0 percent, leaving a −0.2 percent gap between our ATRA adjustments and the MACRA adjustments. It is not clear to us that the MACRA provision was intended to augment or limit CMS' separate obligation, pursuant to the ATRA, to fully offset $11 billion by FY 2017 under section 7(b)(1)(A)(ii) of the TMA, when that language was not changed by the MACRA and, as noted, the MACRA would not fully restore even an estimated −3.2 percent adjustment. Moreover, limiting the ATRA adjustment in this manner would create a greater differential by the end of FY 2017 between the payment increases that occurred due to documentation and coding and the amount recovered.

With regard to the comments stating that if CMS finalizes its proposed adjustment under ATRA for FY 2017, it should make an offsetting adjustment in FY 2018, as we indicated in the proposed rule, we will address the adjustments for FY 2018 and later years in future rulemaking.

Comment: One commenter objected to CMS' use of actuarial assumptions as the basis for determining the level of adjustment required under ATRA. The commenter questioned the variance in the figures for OACT's 2013 and 2016 estimates and stated that OACT's most recent estimate could not be externally replicated. The commenter stated that there should be much greater certainty in the estimate before imposing the higher adjustment proposed for FY 2017. Other commenters requested that CMS reexamine the assumption and estimates made by OACT.

Response: While the OACT memorandum containing the estimates acknowledges the uncertainty in the estimates, it also states that the results shown are OACT's latest and best estimates for Medicare payments for FYs 2014–2017, and that OACT believes that the spending estimates presented, as well as the assumptions used to develop the estimates, are reasonable. We also note that, as explained in OACT's memorandum and the proposed rule, the estimate from the proposed rule was based on the FY 2017 President's Budget, subject to certain adjustments. As discussed in the memorandum, the major changes in the projections were due to lower updates to hospital payments than were assumed in 2013, mostly due to the lower than expected market basket adjustments and a lower number of discharges than assumed in 2013. These changes caused the spending levels to be lower than the 2013 projections. However, in 2013, when CMS made the original projections, everything that was included for 2014 through 2017 was a projection (except for the 2014 update). Now when we make the current projection, we have actual updates for the whole period through 2017, and we have complete data for the number of discharges for 2014 and 2015 and for part of 2016. For that reason, the current projections of spending for 2014 through 2017 are calculated with greater precision than the projections that were done in 2013. For additional information on the specific economic assumptions used in the President's FY 2017 Budget, we refer readers to the OMB Web site at: *https://www.whitehouse.gov/omb/budget*. The estimates for this final rule are similarly based on the Midsession Review of the President's FY 2017 Budget. For additional information on the specific economic assumptions used in the

Midsession Review of the President's FY 2017 Budget, we refer readers to the ''Midsession Review of the President's FY 2017 Budget'' available on the OMB Web site at: *https://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/17msr.pdf*, under ''Economic Assumptions.'' For a general overview of the principal steps involved in projecting future costs and utilization, we refer readers to the ''2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS Web site at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html?redirect=/reportstrustfunds/* under ''Downloads.'' As we did with the proposed adjustment, we are making available on the CMS Web site a memorandum containing our actuaries' estimates relating to our finalized adjustment (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* on the FY 2017 IPPS Final Rule Home Page).

After consideration of the public comments we received, we are finalizing our proposal without modification. For this final rule, based on updated estimates by the Office of the Actuary using the Midsession Review of the President's FY 2017 Budget, we are making an −1.5 percent adjustment as the final adjustment required under section 631 of the ATRA, and when combined with the effects of previous adjustments made in FY 2014, FY 2015, and FY 2016, we estimate will satisfy the recoupment under section 631 of the ATRA. In other words, our actuaries currently estimate that, to the nearest tenth of a percent, the FY 2017 documentation and coding adjustment factor that will recoup as closely as possible $11 billion from FY 2014 through FY 2017 without exceeding this amount is −1.5 percent. As we stated earlier, the estimates by our actuaries related to this finalized adjustment are included in a memorandum that we are making publicly available on the CMS Web site.

The updated table from our actuaries based on the Midsession Review of the President's FY 2017 Budget is below. The interpretation of the table and the calculations are the same as those described in the proposed rule (81 FR 24966 through 24967), except for the update from the FY 2017 President's Budget to the FY 2017 President's Budget Midsession Review.

RECOUPMENT MADE UNDER SECTION 631 OF THE AMERICAN TAXPAYER RELIEF ACT OF 2012

[ATRA]

	IPPS Spending* (billions)	Cumulative adjustment factor	Adjusted IPPS spending (billions)	Recoupment amount (billions)
FY 2014	$122.84	1.00800	$123.82	$0.98
FY 2015	122.48	1.01606	124.45	1.97
FY 2016	124.02	1.02419	127.02	3.00
FY 2017	126.40	1.03956	131.40	5.00
Total				10.95

*Based on FY 2017 President's Budget Midsession Review, including capital, IME, and DSH payments.

For this FY 2017 IPPS/LTCH PPS final rule, our actuaries estimate that the FY 2017 spending subject to the documentation and coding recoupment adjustment (including capital, IME, and DSH payment) would be $131.40 billion in the absence of any documentation and recoupment adjustments from FY 2014 through FY 2017 based on the FY 2017 President's Budget Midsession Review. Therefore our actuaries estimated that, to the nearest tenth of a percent, the FY 2017 documentation and coding adjustment factor that will recoup as closely as possible $11 billion from FY 2014 through FY 2017 without exceeding this amount is −1.5 percent. This adjustment factor yields an estimated spending amount in FY 2017 of $126.4 billion, calculated as $131.4/(1.008*1.008*1.008*1.015).

As stated in the proposed rule, once the recoupment was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA replaced the single positive adjustment we intended to make in 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. The provision under section 414 of the MACRA does not impact our FY 2017 adjustment, as discussed above. As noted previously, while we received public comments on adjustments for FY 2018 and later fiscal years, we will address these adjustments in future rulemaking as we indicated in the proposed rule.

E. Refinement of the MS–DRG Relative Weight Calculation

1. Background

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for a detailed discussion of our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS–DRGs.

As we implemented cost-based relative weights, some public commenters raised concerns about potential bias in the weights due to ''charge compression,'' which is the practice of applying a higher percentage charge markup over costs to lower cost items and services, and a lower percentage charge markup over costs to higher cost items and services. As a result, the cost-based weights would undervalue high-cost items and overvalue low-cost items if a single cost-to-charge ratio (CCR) is applied to items of widely varying costs in the same cost center. To address this concern, in August 2006, we awarded a contract to the Research Triangle Institute, International (RTI) to study the effects of charge compression in calculating the relative weights and to consider methods to reduce the variation in the CCRs across services within cost centers. For a detailed summary of RTI's findings, recommendations, and public comments that we received on the report, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48452 through 48453). In addition, we refer readers to RTI's July 2008 final report titled ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights'' (available at: *http://www.rti.org/reports/cms/HHSM-*

500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf).

In the FY 2009 IPPS final rule (73 FR 48458 through 48467), in response to the RTI's recommendations concerning cost report refinements, we discussed our decision to pursue changes to the cost report to split the cost center for Medical Supplies Charged to Patients into one line for ''Medical Supplies Charged to Patients'' and another line for ''Implantable Devices Charged to Patients.'' We acknowledged, as RTI had found, that charge compression occurs in several cost centers that exist on the Medicare cost report. However, as we stated in the FY 2009 IPPS final rule, we focused on the CCR for Medical Supplies and Equipment because RTI found that the largest impact on the MS–DRG relative weights could result from correcting charge compression for devices and implants. In determining the items that should be reported in these respective cost centers, we adopted the commenters' recommendations that hospitals use revenue codes established by the AHA's National Uniform Billing Committee to determine the items that should be reported in the ''Medical Supplies Charged to Patients'' and the ''Implantable Devices Charged to Patients'' cost centers. Accordingly, a new subscripted line for ''Implantable Devices Charged to Patients'' was created in July 2009. This new subscripted cost center has been available for use for cost reporting periods beginning on or after May 1, 2009.

As we discussed in the FY 2009 IPPS final rule (73 FR 48458) and in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527), in addition to the findings regarding implantable devices, RTI found that the costs and charges of computed tomography (CT) scans, magnetic resonance imaging (MRI), and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI also concluded that both the IPPS and the OPPS relative weights would better estimate the costs of those services if CMS were to add standard cost centers for CT scans, MRIs, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the costs from charges on claims data. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create standard cost centers for CT scans, MRIs, and cardiac catheterization, and to require that hospitals report the costs and charges for these services under new cost centers on the revised Medicare cost report Form CMS–2552–10. (We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a detailed discussion of the reasons for the creation of standard cost centers for CT scans, MRIs, and cardiac catheterization.) The new standard cost centers for CT scans, MRIs, and cardiac catheterization are effective for cost reporting periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10.

In the FY 2009 IPPS final rule (73 FR 48468), we stated that, due to what is typically a 3-year lag between the reporting of cost report data and the availability for use in ratesetting, we anticipated that we might be able to use data from the new ''Implantable Devices Charged to Patients'' cost center to develop a CCR for ''Implantable Devices Charged to Patients'' in the FY 2012 or FY 2013 IPPS rulemaking cycle. However, as noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43782), due to delays in the issuance of the revised cost report Form CMS 2552–10, we determined that a new CCR for ''Implantable Devices Charged to Patients'' might not be available before FY 2013. Similarly, when we finalized the decision in the FY 2011 IPPS/LTCH PPS final rule to add new cost centers for CT scans, MRIs, and cardiac catheterization, we explained that data from any new cost centers that may be created will not be available until at least 3 years after they are first used (75 FR 50077). In preparation for the FY 2012 IPPS/LTCH PPS rulemaking, we checked the availability of data in the ''Implantable Devices Charged to Patients'' cost center on the FY 2009 cost reports, but we did not believe that there was a sufficient amount of data from which to generate a meaningful analysis in this particular situation. Therefore, we did not propose to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for ''Implantable Devices Charged to Patients'' for use in calculating the MS–DRG relative weights for FY 2012. We indicated that we would reassess the availability of data for the ''Implantable Devices Charged to Patients'' cost center for the FY 2013 IPPS/LTCH PPS rulemaking cycle and, if appropriate, we would propose to create a distinct CCR at that time.

During the development of the FY 2013 IPPS/LTCH PPS proposed and final rules, hospitals were still in the process of transitioning from the previous cost report Form CMS–2552–96 to the new cost report Form CMS–2552–10. Therefore, we were able to access only those cost reports in the FY 2010 HCRIS with fiscal year begin dates on or after October 1, 2009, and before May 1, 2010; that is, those cost reports on Form CMS–2552–96. Data from the Form CMS–2552–10 cost reports were not available because cost reports filed on the Form CMS–2552–10 were not accessible in the HCRIS. Further complicating matters was that, due to additional unforeseen technical difficulties, the corresponding information regarding charges for implantable devices on hospital claims was not yet available to us in the MedPAR file. Without the breakout in the MedPAR file of charges associated with implantable devices to correspond to the costs of implantable devices on the cost report, we believed that we had no choice but to continue computing the relative weights with the current CCR that combines the costs and charges for supplies and implantable devices. We stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53281 through 53283) that when we do have the necessary data for supplies and implantable devices on the claims in the MedPAR file to create distinct CCRs for the respective cost centers for supplies and implantable devices, we hoped that we would also have data for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization, which could then be finalized through rulemaking. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53281), we stated that, prior to proposing to create these CCRs, we would first thoroughly analyze and determine the impacts of the data, and that distinct CCRs for these new cost centers would be used in the calculation of the relative weights only if they were first finalized through rulemaking.

At the time of the development of the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27506 through 27507), we had a substantial number of hospitals completing all, or some, of these new cost centers on the FY 2011 Medicare cost reports, compared to prior years. We stated that we believed that the analytic findings described using the FY 2011 cost report data and FY 2012 claims data supported our original decision to break out and create new cost centers for implantable devices, MRIs, CT scans, and cardiac catheterization, and we saw no reason to further delay proposing to implement the CCRs of each of these cost centers. Therefore, beginning in FY 2014, we proposed a policy to calculate the MS–DRG relative weights using 19 CCRs,

creating distinct CCRs from cost report data for implantable devices, MRIs, CT scans, and cardiac catheterization.

We refer readers to the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27507 through 27509) and final rule (78 FR 50518 through 50523) in which we presented data analyses using distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. The FY 2014 IPPS/LTCH PPS final rule also set forth our responses to public comments we received on our proposal to implement these CCRs. As explained in more detail in the FY 2014 IPPS/LTCH PPS final rule, we finalized our proposal to use 19 CCRs to calculate MS–DRG relative weights beginning in FY 2014—the then existing 15 cost centers and the 4 new CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. Therefore, beginning in FY 2014, we calculate the IPPS MS–DRG relative weights using 19 CCRs, creating distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

2. Discussion of Policy for FY 2017

Consistent with our established policy, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24968), we stated that we calculated the proposed MS–DRG relative weights for FY 2017 using two data sources: the MedPAR file as the claims data source and the HCRIS as the cost report data source. We adjusted the charges from the claims to costs by applying the 19 national average CCRs developed from the cost reports. The description of the calculation of the 19 CCRs and the MS–DRG relative weights for FY 2017 is included in section II.G. of the preamble of this final rule.

Comment: One commenter recommended that CMS work with stakeholders to update cost reporting instructions and improve the accuracy and validity of the national average CCRs. The commenter expressed concern that the differences between hospitals' use of nonstandard cost center codes and CMS' procedures for mapping and rolling up nonstandard codes to the standard cost centers will continue to result in invalid CCRs and inaccurate payments. The commenter stressed the need for flexibility in cost reporting, to accommodate any new or unique services that certain hospitals may provide, which may not be easily captured through the cost reporting software. Finally, the commenter again recommended, as it had done in response to prior IPPS rules, that CMS pay particular attention to data used for CT scanand MRI cost centers; the commenter believed that the hospital payment rates established by CMS from the CT scan and MRI CCRs simply do not correlate with resources used for these capital-intensive services.

Response: We appreciate the commenter's desire to increase the accuracy and validity of the CCRs. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49347 through 49350), we noticed inconsistencies in hospital cost reporting of nonstandard cost centers and were concerned about the implication that some of these discrepancies might have on the aspects of the IPPS that rely on CCRs. While we did not propose any changes to the methodology or data sources for the FY 2016 CCRs and relative weights, we stated in that final rule that we would continue to explore ways in which we can improve the accuracy of the cost report data and calculated CCRs used in the cost estimation process and that, to the extent possible, we will continue to seek stakeholder input in efforts to limit the impact on providers. We also note that the concern regarding hospitals' use of nonstandard cost center codes and CMS' procedures for mapping and rolling up nonstandard codes to the standard cost centers does not specifically apply to the standard CT scan and MRI cost centers. Although these centers were previously nonstandard cost centers, they were implemented as standard cost centers in Form CMS–2552–10. Therefore, many of the issues relating to inconsistent coding and issues with information ''rollup'' would not be specifically relevant for the CT scan and MRI standard cost centers. We have previously addressed stakeholder concerns related to the flexibility of cost reporting and accuracy of the CT scan and MRI standard cost centers in setting the IPPS relative weights. For a detailed discussion of the CT scan and MRI standard cost centers, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50520 through 50523), and the FY 2011 IPPS/LTCH PPS final rule (7 FR 50077 through 50079).

Consistent with our established policy, we calculated the final MS–DRG relative weights for FY 2017 using two data sources: the MedPAR file as the claims data source and the HCRIS as the cost report data source. We adjusted the charges from the claims to costs by applying the 19 national average CCRs developed from the cost reports. As we did with the FY 2016 IPPS/LTCH PPS final rule, we are providing the version of the HCRIS from which we calculated these 19 CCRs on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2017 IPPS Final Rule Home Page'' or ''Acute Inpatient Files for Download.''

F. Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the Official ICD–10–CM and ICD–10–PCS Guidelines for Coding and Reporting. The ICD–10 coding system was initially adopted for transactions conducted on or after October 1, 2013, as described in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification: Modifications to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS Final Rule published in the **Federal Register** on January 16, 2009 (74 FR 3328 through 3362) (hereinafter referred to as the ''ICD–10–CM and ICD–10–PCS final rule''). However, the Secretary of Health and Human Services (the Secretary) issued a final rule that delayed the compliance date for ICD–10 from October 1, 2013, to October 1, 2014. That final rule, entitled ''Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD–10–CM and ICD–10–PCS Medical Data Code Sets,'' CMS–0040–F, was published in the **Federal Register** on September 5, 2012 (77 FR 54664) and is available for viewing on the Internet at: *http://www.gpo.gov/fdsys/pkg/FR-2012-09-05/pdf/2012-21238.pdf*. On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted, which specified that the Secretary may not adopt ICD–10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human

Services released a final rule in the **Federal Register** on August 4, 2014 (79 FR 45128 through 45134) that included a new compliance date that required the use of ICD–10 beginning October 1, 2015. The rule also required HIPAA-covered entities to continue to use ICD–9–CM through September 30, 2015.

The anticipated move to ICD–10 necessitated the development of an ICD–10–CM/ICD–10–PCS version of the MS–DRGs. CMS began a project to convert the ICD–9–CM-based MS–DRGs to ICD–10 MS–DRGs. In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received public comments on the creation of the ICD–10 version of the MS–DRGs to be implemented at the same time as ICD–10 (75 FR 50127 and 50128). While we did not propose an ICD–10 version of the MS–DRGs in the FY 2011 IPPS/LTCH PPS proposed rule, we noted that we have been actively involved in converting current MS–DRGs from ICD–9–CM codes to ICD–10 codes and sharing this information through the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee. We undertook this early conversion project to assist other payers and providers in understanding how to implement their own conversion projects. We posted ICD–10 MS–DRGs based on Version 26.0 (FY 2009) of the MS–DRGs. We also posted a paper that describes how CMS went about completing this project and suggestions for other payers and providers to follow. Information on the ICD–10 MS–DRG conversion project can be found on the ICD–10 MS–DRG Conversion Project Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We have continued to keep the public updated on our maintenance efforts for ICD–10–CM and ICD–10–PCS coding systems, as well as the General Equivalence Mappings that assist in conversion through the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee. Information on these committee meetings can be found on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*.

During FY 2011, we developed and posted Version 28.0 of the ICD–10 MS–DRGs based on the FY 2011 MS–DRGs (Version 28.0) that we finalized in the FY 2011 IPPS/LTCH PPS final rule on the CMS Web site. This ICD–10 MS–DRGs Version 28.0 also included the CC Exclusion List and the ICD–10 version of the hospital-acquired conditions (HACs), which was not posted with Version 26. We also discussed this update at the September 15–16, 2010 and the March 9–10, 2011 meetings of the ICD–9–CM Coordination and Maintenance Committee. The minutes of these two meetings are posted on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*.

We reviewed comments on the ICD–10 MS–DRGs Version 28 and made updates as a result of these comments. We called the updated version the ICD–10 MS–DRGs Version 28–R1. We posted a Definitions Manual of ICD–10 MS–DRGs Version 28–R1 on our ICD–10 MS–DRG Conversion Project Web site. To make the review of Version 28–R1 updates easier for the public, we also made available pilot software on a CD–ROM that could be ordered through the National Technical Information Service (NTIS). A link to the NTIS ordering page was provided on the CMS ICD–10 MS–DRGs Web site. We stated that we believed that, by providing the ICD–10 MS–DRGs Version 28–R1 Pilot Software (distributed on CD–ROM), the public would be able to more easily review and provide feedback on updates to the ICD–10 MS–DRGs. We discussed the updated ICD–10 MS–DRGs Version 28–R1 at the September 14, 2011 ICD–9–CM Coordination and Maintenance Committee meeting. We encouraged the public to continue to review and provide comments on the ICD–10 MS–DRGs so that CMS could continue to update the system.

In FY 2012, we prepared the ICD–10 MS–DRGs Version 29, based on the FY 2012 MS–DRGs (Version 29.0) that we finalized in the FY 2012 IPPS/LTCH PPS final rule. We posted a Definitions Manual of ICD–10 MS–DRGs Version 29 on our ICD–10 MS–DRG Conversion Project Web site. We also prepared a document that describes changes made from Version 28 to Version 29 to facilitate a review. The ICD–10 MS–DRGs Version 29 was discussed at the ICD–9–CM Coordination and Maintenance Committee meeting on March 5, 2012. Information was provided on the types of updates made. Once again the public was encouraged to review and comment on the most recent update to the ICD–10 MS–DRGs.

CMS prepared the ICD–10 MS–DRGs Version 30 based on the FY 2013 MS–DRGs (Version 30) that we finalized in the FY 2013 IPPS/LTCH PPS final rule. We posted a Definitions Manual of the ICD–10 MS–DRGs Version 30 on our ICD–10 MS–DRG Conversion Project Web site. We also prepared a document that describes changes made from Version 29 to Version 30 to facilitate a review. We produced mainframe and computer software for Version 30, which was made available to the public in February 2013. Information on ordering the mainframe and computer software through NTIS was posted on the ICD–10 MS–DRG Conversion Project Web site. The ICD–10 MS–DRGs Version 30.0 computer software facilitated additional review of the ICD–10 MS–DRGs conversion.

We provided information on a study conducted on the impact of converting the MS–DRGs to ICD–10. Information on this study is summarized in a paper entitled ''Impact of the Transition to ICD–10 on Medicare Inpatient Hospital Payments.'' This paper was posted on the CMS ICD–10 MS–DRGs Conversion Project Web site and was distributed and discussed at the September 15, 2010 ICD–9–CM Coordination and Maintenance Committee meeting. The paper described CMS' approach to the conversion of the MS–DRGs from ICD–9–CM codes to ICD–10 codes. The study was undertaken using the ICD–9–CM MS–DRGs Version 27.0 (FY 2010), which was converted to the ICD–10 MS–DRGs Version 27.0. The study estimated the impact on aggregate payment to hospitals and the distribution of payments across hospitals. The impact of the conversion from ICD–9–CM to ICD–10 on Medicare MS–DRG hospital payments was estimated using FY 2009 Medicare claims data. The study found a hospital payment increase of 0.05 percent using the ICD–10 MS–DRGs Version 27.

CMS provided an overview of this hospital payment impact study at the March 5, 2012 ICD–9–CM Coordination and Maintenance Committee meeting. This presentation followed presentations on the creation of ICD–10 MS–DRGs Version 29.0. A summary report of this meeting can be found on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*. At this March 2012 meeting, CMS announced that it would produce an update on this impact study based on an updated version of the ICD–10 MS–DRGs. This update of the impact study was presented at the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting. The study found that moving from an ICD–9–CM-based system to an ICD–10 MS–DRG replicated system would lead to DRG reassignments on only 1 percent of the 10 million MedPAR sample records used in the study. Ninety-nine percent of the records did not shift to another MS–DRG when using an ICD–10 MS–DRG system. For the 1 percent of the records that shifted, 45 percent of the shifts were to a higher-weighted MS–DRG, while 55 percent of the shifts were

to lower-weighted MS–DRGs. The net impact across all MS–DRGs was a reduction by 4/10000 or minus 4 pennies per $100. The updated paper is posted on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Downloads'' section. Information on the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting can be found on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*. This update of the impact paper and the ICD–10 MS–DRG Version 30 software provided additional information to the public who were evaluating the conversion of the MS–DRGs to ICD–10 MS–DRGs.

CMS prepared the ICD–10 MS–DRGs Version 31 based on the FY 2014 MS–DRGs (Version 31) that we finalized in the FY 2014 IPPS/LTCH PPS final rule. In November 2013, we posted a Definitions Manual of the ICD–10 MS–DRGs Version 31 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that described changes made from Version 30 to Version 31 to facilitate a review. We produced mainframe and computer software for Version 31, which was made available to the public in December 2013. Information on ordering the mainframe and computer software through NTIS was posted on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Related Links'' section. This ICD–10 MS–DRGs Version 31.0 computer software facilitated additional review of the ICD–10 MS–DRGs conversion. We encouraged the public to submit to CMS any comments on areas where they believed the ICD–10 MS–DRGs did not accurately reflect grouping logic found in the ICD–9–CM MS–DRGs Version 31.

We reviewed public comments received and developed an update of ICD–10 MS–DRGs Version 31, which we called ICD–10 MS–DRGs Version 31–R. We posted a Definitions Manual of the ICD–10 MS–DRGs Version 31–R on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that describes changes made from Version 31 to Version 31–R to facilitate a review. We continued to share ICD–10 MS–DRG conversion activities with the public through this Web site.

CMS prepared the ICD–10 MS–DRGs Version 32 based on the FY 2015 MS–DRGs (Version 32) that we finalized in the FY 2015 IPPS/LTCH PPS final rule. In November 2014, we made available a Definitions Manual of the ICD–10 MS DRGs Version 32 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that described changes made from Version 31–R to Version 32 to facilitate a review. We produced mainframe and computer software for Version 32, which was made available to the public in January 2015. Information on ordering the mainframe and computer software through NTIS was made available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Related Links'' section. This ICD–10 MS–DRGs Version 32 computer software facilitated additional review of the ICD–10 MS–DRGs conversion. We encouraged the public to submit to CMS any comments on areas where they believed the ICD–10 MS–DRGs did not accurately reflect grouping logic found in the ICD–9–CM MS–DRGs Version 32. We discussed five requests from the public to update the ICD–10 MS–DRGs Version 32 to better replicate the ICD–9–CM MS–DRGs in section II.G.3., 4., and 5. of the preamble of the FY 2016 IPPS/LTCH PPS final rule. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24351), we proposed to implement the MS–DRG code logic in the ICD–10 MS–DRGs Version 32 along with any finalized updates to the ICD–10 MS–DRGs Version 32 for the final ICD–10 MS–DRGs Version 33. In the proposed rule, we proposed the ICD–10 MS–DRGs Version 33 as the replacement logic for the ICD–9–CM based MS–DRGs Version 32 as part of the proposed MS–DRG updates for FY 2016. We invited public comments on how well the ICD–10 MS–DRGs Version 32 replicated the logic of the MS–DRGs Version 32 based on ICD–9–CM codes.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49356 through 49357 and 49363 through 49407), we addressed the public comments we received on the replication in the ICD–10 MS–DRGs Version 32 of the logic of the MS–DRGs Version 32 based on ICD–9–CM codes. We refer readers to that final rule for a discussion of the changes we made in response to public comments.

b. Basis for FY 2017 MS–DRG Updates

CMS encourages input from our stakeholders concerning the annual IPPS updates when that input is made available to us by December 7 of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2017, comments and suggestions should have been submitted by December 7, 2015. The comments that were submitted in a timely manner for FY 2017 are discussed in this section of the final rule. Interested parties should submit any comments and suggestions for FY 2018 by December 7, 2016, via the new CMS MS–DRG Classification Change Requests Mailbox located at: *MSDRGClassification Change@cms.hhs.gov*.

Following are the changes we proposed to the MS–DRGs for FY 2017 in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24971 through 25016). We invited public comment on each of the MS–DRG classification proposed changes as well as our proposals to maintain certain existing MS–DRG classifications discussed in the proposed rule. In some cases, we proposed changes to the MS–DRG classifications based on our analysis of claims data. In other cases, we proposed to maintain the existing MS–DRG classification based on our analysis of claims data. For the FY 2017 proposed rule, our MS–DRG analysis was based on claims data from the December 2015 update of the FY 2015 MedPAR file, which contains hospital bills received through September 30, 2015, for discharges occurring through September 30, 2015. In our discussion of the proposed MS–DRG reclassification changes, we referred to our analysis of claims data from the ''December 2015 update of the FY 2015 MedPAR file.''

In this FY 2017 IPPS/LTCH PPS final rule, we summarize the public comments we received on our proposals, present our responses, and state our final policies. For this FY 2017 final rule, we did not perform any further MS–DRG analysis of claims data. Therefore, all of the data analysis is based on claims data from the December 2015 update of the FY 2015 MedPAR file, which contains hospital bills received through September 30, 2015, for discharges occurring through September 30, 2015.

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modification to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay

and rely on the judgment of our clinical advisors to decide whether patients are clinically distinct or similar to other patients in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In our examination of the claims data, we apply the following criteria established in FY 2008 (72 FR 47169) to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG is warranted:

- A reduction in variance of costs of at least 3 percent.
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup.
- At least 500 cases are in the CC or MCC subgroup.
- There is at least a 20-percent difference in average costs between subgroups.
- There is a $2,000 difference in average costs between subgroups.

In order to warrant creation of a CC or MCC subgroup within a base MS–DRG, the subgroup must meet all five of the criteria.

We note that some of the issues evaluated for the FY 2017 MS–DRGs update continue to relate to the need for the ICD–10 MS–DRGs to accurately replicate the logic of the ICD–9–CM based version of the MS–DRGs. Replication is important because both the logic for the MS–DRGs and the data source used to calculate and develop proposed relative payment weights are based on the same MedPAR claims data. In other words, as the logic for the proposed and final FY 2017 ICD–10 MS–DRGs is based upon the FY 2015 ICD–9–CM MedPAR claims data, the data source used to calculate and develop the proposed and final FY 2017 relative payment weights is also based on the FY 2015 ICD–9–CM MedPAR claims data, including any MS–DRG classification changes discussed in the proposed rule and this final rule. This is consistent with how the current FY 2016 relative payment weights are based on the ICD–9–CM diagnosis and procedure codes from the FY 2014 MedPAR claims data that were grouped through the ICD–9–CM version of the FY 2016 GROUPER Version 33. We note that we made the MS–DRG GROUPER and Medicare Code Editor (MCE) ICD–9–CM Software Version 33 available to the public for use in analyzing ICD–9–CM data to create relative payment weights using ICD–9–CM data on our CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html?DLSort=0&DLEntries=10&DLPage=1&DLSortDir=ascending*. Therefore, as discussed in section II.G. of the preamble of this final rule, ICD–9–CM data were used for computing the proposed and final FY 2017 MS–DRG relative payment weights. As we did for FY 2016, we note that, for FY 2017, we have made the MS–DRG GROUPER and Medicare Code Editor (MCE) ICD–9–CM Software Version 34 available to the public for use in analyzing ICD–9–CM data to create relative payment weights using ICD–9–CM data on our CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2017-IPPS-Final-Rule-Home-Page.html*. If the ICD–9 and ICD–10 versions of MS–DRGs cease to be replications of each other, the relative payment weights computed using the ICD–9 claims data and MS–DRGs would be inconsistent with the relative payment weights assigned for the ICD–10 MS–DRGs, causing unintended payment redistributions. Thus, if the findings of our data analyses and the recommendations of our clinical advisors supported modifications to the current ICD–10 MS–DRG structure, prior to proposing any changes, we first evaluated whether the requested change could be replicated in the ICD–9–CM MS–DRGs. If the answer was ''yes,'' from a replication perspective, the change was considered feasible. If the answer was ''no,'' we examined whether the change in the ICD–10 MS–DRGs was likely to cause a significant number of patient cases to change or ''shift'' ICD–10 MS–DRGs. If relatively few patient cases would be impacted, we evaluated if it would be feasible to propose the change even though it could not be replicated by the ICD–9 MS–DRGs because it would not cause a material payment redistribution. For the ICD–10 MS–DRG classification change requests that could not be replicated in ICD–9–CM and that would cause a significant number of patient cases to shift MS–DRG assignment, we considered other alternatives.

Comment: Some commenters requested that CMS make the FY 2017 finalized MS–DRG GROUPER logic proposals retroactive to October 1, 2015 for current FY 2016 claims. One commenter stated that if the corrected replication issues were retroactive to October 1, 2015, private payers would be able to appropriately adjust claims that had an inappropriate MS–DRG assignment.

Response: We acknowledge the commenters' request. However, we note that, in accordance with section 1886(d)(4)(C) of the Act, we adjust the DRG classifications and relative weights at least annually. The FY 2016 ICD–10 MS–DRGs Version 33 were subject to review and comment by the public as part of the FY 2016 IPPS/LTCH PPS proposed and final rulemaking process. We encouraged the public to submit any comments on areas where they believed the ICD–10 MS–DRGs did not accurately reflect the GROUPER logic found in the ICD–9–CM MS–DRGs (80 FR 49356), and discussed in the FY 2016 rulemaking the requests we received to update the ICD–10 MS–DRGs to better replicate the ICD–9 MS–DRGs. In the FY 2017 IPPS/LTCH PPS proposed rule, we proposed further updates to the MS–DRG GROUPER logic, to be effecive October 1, 2016.

With regard to the ability of private payers to adjust claims affected by replication issues, as noted in the FY 2008 IPPS final rule (72 FR 47152), we have stated many times in the past that we encourage private insurers and other non-Medicare payers to make refinements to Medicare's DRG system to better suit the needs of the patients they serve. Consistent with our general approach for implementing updates to the MS–DRGs, the proposals adopted as final policy in this FY 2017 IPPS/LTCH PPS final rule will apply beginning with the FY 2017 MS–DRGs.

2. Pre-Major Diagnostic Category (Pre-MDC): Total Artificial Heart Replacement

An ICD–10 MS–DRG replication issue regarding the assignment of two ICD–10–PCS procedure codes was identified after the October 1, 2015 implementation of the Version 33 ICD–10 MS–DRGs. ICD–10–PCS procedure codes 02RK0JZ (Replacement of right ventricle with synthetic substitute, open approach) and 02RL0JZ (Replacement of left ventricle with synthetic substitute, open approach), when reported together, describe a biventricular heart replacement (artificial heart). Under the Version 32 ICD–9–CM based MS–DRGs, this procedure was described by ICD–9–CM procedure code 37.52 (Implantation

of total internal biventricular heart replacement system) and grouped to MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC, respectively).

As discussed in section II.F.1.a. of the preamble of the proposed rule and this final rule, to assist in the conversion from the ICD–9–CM based MS–DRGs to ICD–10, beginning in FY 2011, draft versions of the ICD–10 based MS–DRGs were developed and made available for public comment. The two ICD–10–PCS procedure codes (02RK0JZ and 02RL0JZ) were assigned as a ''cluster'' to the draft ICD–10 based MS–DRGs 001 and 002 in prior draft versions of the ICD–10 MS–DRGs. In ICD–10–PCS, a cluster is the term used to describe when a combination of ICD–10–PCS procedure codes are needed to fully satisfy the equivalent meaning of an ICD–9–CM procedure code for it to be considered a plausible translation. Upon review of prior draft versions of the ICD–10 MS–DRGs, it was determined that Version 30 was the last version to include ICD–10–PCS procedure codes 02RK0JZ and 02RL0JZ as a code cluster (from ICD–9–CM procedure code 37.52) that grouped to the draft ICD–10 based MS–DRGs 001 and 002. Subsequent draft versions of the ICD–10 MS–DRGs inadvertently omitted this code cluster from those MS–DRGs.

Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24971 through 24972), for FY 2017, we proposed to assign ICD–10–PCS procedure codes 02RK0JZ and 02RL0JZ as a code cluster to ICD–10 Version 34 MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC, respectively) to accurately replicate the Version 32 ICD–9–CM based MS–DRG logic of procedure code 37.52. We invited public comments on our proposal.

Comment: Commenters supported the proposal to assign ICD–10–PCS procedure codes 02RK0JZ and 02RL0JZ as a code cluster to ICD–10 Version 34 MS–DRGs 001 and 002. The commenters noted that this code cluster assignment is crucial to assure that all consumers who require a heart replacement with a total artificial heart will have access to care, regardless of whether they are a Medicare beneficiary, a Medicaid recipient, or a privately insured individual. Other commenters noted the proposal was reasonable, given the data, the ICD–10–PCS codes, and the information provided.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to assign ICD–10–PCS procedure codes 02RK0JZ (Replacement of right ventricle with synthetic substitute, open approach) and 02RL0JZ (Replacement of left ventricle with synthetic substitute, open approach) as a code cluster to MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC, respectively) effective October 1, 2016 for ICD–10 MS–DRGs Version 34.

3. MDC 1 (Diseases and Disorders of the Nervous System)

a. Endovascular Embolization (Coiling) or Occlusion of Head and Neck Procedures

We received a repeat request to change the MS–DRG assignment for procedure codes describing endovascular embolization (coiling) or occlusion of the head and neck. This topic was discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28005 through 28007); the FY 2015 IPPS/LTCH PPS final rule (79 FR 49883 through 49886); the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24351 through 24356); and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49358 through 49363). For these 2 fiscal years, we did not change the MS–DRG assignment for procedure codes describing endovascular embolization (coiling) or occlusion of the head and neck for the reasons discussed in these proposed and final rules.

For FY 2017, the requestor again asked that CMS change the MS–DRG assignment for procedure codes describing endovascular embolization or occlusion of the head and neck as well as several other codes describing endovascular procedures of the head and neck.

The ICD–10–PCS procedure codes listed in the following table capture endovascular embolization or occlusion of the head and neck procedures that are assigned to the following MS–DRGs in ICD–10 Version 33 MS–DRGs: MS–DRG 020 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with MCC); MS–DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with CC); MS–DRG 022 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage without CC/MCC); MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis with MCC or Chemo Implant); MS–DRG 024 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis without MCC); MS–DRG 025 (Craniotomy and Endovascular Intracranial Procedures with MCC); MS–DRG 026 (Craniotomy and Endovascular Intracranial Procedures with CC); and MS–DRG 027 (Craniotomy and Endovascular Intracranial Procedures without CC/MCC):

ICD–10–PCS Codes for Endovascular Embolization or Occlusion of the Head and Neck Procedures Assigned to MS–DRGs 020 Through 027 in ICD–10 MS–DRGs Version 33

ICD–10–PCS code	Code description
03LG3BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous approach.
03LG3DZ	Occlusion of intracranial artery with intraluminal device, percutaneous approach.
03LG4BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LG4DZ	Occlusion of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03LH3BZ	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03LH3DZ	Occlusion of right common carotid artery with intraluminal device, percutaneous approach.
03LH4BZ	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LH4DZ	Occlusion of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03LJ3BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03LJ3DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous approach.
03LJ4BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LJ4DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03LK3BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LK3DZ	Occlusion of right internal carotid artery with intraluminal device, percutaneous approach.
03LK4BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.

ICD–10–PCS CODES FOR ENDOVASCULAR EMBOLIZATION OR OCCLUSION OF THE HEAD AND NECK PROCEDURES ASSIGNED TO MS–DRGS 020 THROUGH 027 IN ICD–10 MS–DRGS VERSION 33—Continued

ICD–10–PCS code	Code description
03LK4DZ	Occlusion of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LL3BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LL3DZ	Occlusion of left internal carotid artery with intraluminal device, percutaneous approach.
03LL4BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LL4DZ	Occlusion of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LM3BZ	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03LM3DZ	Occlusion of right external carotid artery with intraluminal device, percutaneous approach.
03LM4BZ	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LM4DZ	Occlusion of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LN3BZ	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03LN3DZ	Occlusion of left external carotid artery with intraluminal device, percutaneous approach.
03LN4BZ	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LN4DZ	Occlusion of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LP3BZ	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03LP3DZ	Occlusion of right vertebral artery with intraluminal device, percutaneous approach.
03LP4BZ	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LP4DZ	Occlusion of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03LQ3BZ	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03LQ3DZ	Occlusion of left vertebral artery with intraluminal device, percutaneous approach.
03LQ4BZ	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LQ4DZ	Occlusion of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03LR3DZ	Occlusion of face artery with intraluminal device, percutaneous approach.
03LR4DZ	Occlusion of face artery with intraluminal device, percutaneous endoscopic approach.
03LS3DZ	Occlusion of right temporal artery with intraluminal device, percutaneous approach.
03LS4DZ	Occlusion of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03LT3DZ	Occlusion of left temporal artery with intraluminal device, percutaneous approach.
03LT4DZ	Occlusion of left temporal artery with intraluminal device, percutaneous endoscopic approach.
03VG3BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous approach.
03VG3DZ	Restriction of intracranial artery with intraluminal device, percutaneous approach.
03VG4BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VG4DZ	Restriction of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03VH3BZ	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03VH3DZ	Restriction of right common carotid artery with intraluminal device, percutaneous approach.
03VH4BZ	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VH4DZ	Restriction of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VJ3BZ	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03VJ3DZ	Restriction of left common carotid artery with intraluminal device, percutaneous approach.
03VJ4BZ	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VJ4DZ	Restriction of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VK3BZ	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VK3DZ	Restriction of right internal carotid artery with intraluminal device, percutaneous approach.
03VK4BZ	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VK4DZ	Restriction of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VL3BZ	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VL3DZ	Restriction of left internal carotid artery with intraluminal device, percutaneous approach.
03VL4BZ	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VL4DZ	Restriction of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VM3BZ	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03VM3DZ	Restriction of right external carotid artery with intraluminal device, percutaneous approach.
03VM4BZ	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VM4DZ	Restriction of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VN3BZ	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03VN3DZ	Restriction of left external carotid artery with intraluminal device, percutaneous approach.
03VN4BZ	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VN4DZ	Restriction of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VP3BZ	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03VP3DZ	Restriction of right vertebral artery with intraluminal device, percutaneous approach.
03VP4BZ	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VP4DZ	Restriction of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VQ3BZ	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03VQ3DZ	Restriction of left vertebral artery with intraluminal device, percutaneous approach.
03VQ4BZ	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VQ4DZ	Restriction of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VR3DZ	Restriction of face artery with intraluminal device, percutaneous approach.
03VR4DZ	Restriction of face artery with intraluminal device, percutaneous endoscopic approach.
03VS3DZ	Restriction of right temporal artery with intraluminal device, percutaneous approach.
03VS4DZ	Restriction of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03VT3DZ	Restriction of left temporal artery with intraluminal device, percutaneous approach.
03VT4DZ	Restriction of left temporal artery with intraluminal device, percutaneous endoscopic approach.
03VU3DZ	Restriction of right thyroid artery with intraluminal device, percutaneous approach.

ICD–10–PCS CODES FOR ENDOVASCULAR EMBOLIZATION OR OCCLUSION OF THE HEAD AND NECK PROCEDURES ASSIGNED TO MS–DRGS 020 THROUGH 027 IN ICD–10 MS–DRGS VERSION 33—Continued

ICD–10–PCS code	Code description
03VU4DZ	Restriction of right thyroid artery with intraluminal device, percutaneous endoscopic approach.
03VV3DZ	Restriction of left thyroid artery with intraluminal device, percutaneous approach.
03VV4DZ	Restriction of left thyroid artery with intraluminal device, percutaneous endoscopic approach.

Cases reporting any of the ICD–10–PCS procedures codes listed in the table above that are assigned to MS–DRGs 020, 021, and 022 under MDC 1 require a principal diagnosis of hemorrhage. Cases reporting any of the ICD–10–PCS procedure codes listed in the table above that are assigned to MS–DRGs 023 and 024 require the insertion of a major implant or an acute complex central nervous system (CNS) principal diagnosis. Cases reporting any of the ICD–10–PCS procedure codes listed in the table above that are assigned to MS–DRGs 025, 026, and 027 do not have a principal diagnosis of hemorrhage, an acute complex CNS principal diagnosis, or a major device implant.

The requestor expressed concerns about the appropriateness of the MS–DRG assignment for the endovascular embolization or occlusion of head and neck procedures. The requestor stated that past data demonstrated that the cost of cases involving endovascular coils exceeds the average cost of all cases within each of the MS–DRGs to which these procedures are assigned. The requestor pointed out that these procedures were formerly captured by the following ICD–9–CM codes that were assigned to MS–DRGs 020 through 027:

- 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels);
- 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils); and
- 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils).

The commenter also expressed concern about the appropriateness of the current ICD–10 MS–DRG assignment of the following ICD–9–CM codes that describe other endovascular procedures of head and neck that were previously assigned to MS–DRGs 023 through 027 in the ICD–9–CM MS–DRGs Version 32. The commenter stated that these procedures are more clinically complex than other procedures assigned to these MS–DRGs.

- 00.62 (Percutaneous angioplasty of intracranial vessels(s));
- 39.74 (Endovascular removal of obstruction from head and neck vessel(s)); and
- 39.79 (Other endovascular procedures on other vessels).

As we discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24972 through 24976), we examined claims data from the December 2015 update of the FY 2015 MedPAR file for the endovascular embolization or occlusion of the head and neck procedures or other endovascular procedures reported under ICD–9–CM procedure codes 00.62, 39.72, 39.74, 39.75, 39.76, and 39.79 in MS–DRGs 020 through 027. The table below shows our findings.

ENDOVASCULAR EMBOLIZATION OR OCCLUSION OF THE HEAD AND NECK PROCEDURES AND OTHER ENDOVASCULAR PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 020—All cases	1,213	16.44	$70,716
MS–DRG 020—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79	895	16.15	72,357
MS–DRG 021—All cases	350	13.74	53,289
MS–DRG 021—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79	272	13.21	53,478
MS–DRG 022—All cases	84	7.83	33,598
MS–DRG 022—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79	63	7.27	33,606
MS–DRG 023—All cases	6,360	10.63	38,204
MS–DRG 023—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79	2,183	8.57	38,935
MS–DRG 024—All cases	2,376	5.52	28,270
MS–DRG 024—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79	1,402	5.46	28,543
MS–DRG 025—All cases	17,756	9.19	29,657
MS–DRG 025—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76 or 39.79	671	9.20	47,579
MS–DRG 026—All cases	7,630	5.80	21,441
MS–DRG 026—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79	825	3.11	27,429
MS–DRG 027—All cases	9,628	2.99	17,158
MS–DRG 027—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76 or 39.79	1,847	1.62	22,845

As can be seen from the table, most of the cases of endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures reported with procedure codes 00.62, 39.72, 39.74, 39.75, 39.76, and 39.79 occur in MS–DRGs 023, 024, and 027. There were 2,183 of these procedure cases reported in MS–DRG 023 with an average length of stay of 8.57 days and average costs of $38,935, compared to an average length of stay of 10.63 days and average costs of $38, 204 for all 6,360 cases reported in MS–DRG 023. There were 1,402 of these cases reported in MS–DRG 024 with an average length of stay of 5.46 days and average costs of $28,543, compared to an average length of stay of 5.52 days and average costs of $28,270 for all 2,376 cases reported in MS–DRG 024. There were 1,847 of these cases reported in MS–DRG 027 with an average length of stay of 1.62 days and average costs of $22,845, compared to an average length of stay of 2.99 days and average costs of $17,158 for all

9,628 cases reported in MS–DRG 027. The average costs for endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRGs 023 and 024 are not significantly different from the average costs for all cases reported in MS–DRGs 023 and 024. The average costs for endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRG 027 are higher ($22,845) than the average costs of all cases reported in MS–DRG 027 ($17,158). However, average costs are not significantly different for the endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRG 020 ($72,357) compared to the average costs for all cases ($70,716) reported in MS–DRG 020; for the endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRG 021 ($53,478) compared to the average costs for all cases ($53,289) reported in MS–DRG 021; and for the endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRG 022 ($33,606) compared to the average costs for all cases ($33,598) reported in MS–DRG 022.

Average costs were higher for the 671 endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRG 025 ($47,579) compared to the average costs for all 17,756 cases ($29,657) reported in MS–DRG 025. The average costs also were higher for the 825 endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRG 26 ($27,429) compared to the average costs for all 7,630 cases ($21,441) reported in MS–DRG 26. Given that average costs are similar for most endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRGs 020, 021, 022, 023, 024, 025, 026, and 027, we stated in the proposed rule that we did not believe that all endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures should be reassigned from these eight MS–DRGs.

We also examined the average costs for each specific ICD–9–CM code compared to the average costs of all cases within each of the eight MS–DRGs. The following table shows our findings.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 020—All cases	1,213	16.44	$70,716
MS–DRG 020—Cases with code 00.62	11	16.09	95,422
MS–DRG 020—Cases with code 39.72	422	16.31	74,951
MS–DRG 020—Cases with code 39.74	9	16.78	71,478
MS–DRG 020—Cases with code 39.75	424	15.79	69,081
MS–DRG 020—Cases with code 39.76	39	18.26	71,630
MS–DRG 020—Cases with code 39.79	25	16.64	73,043
MS–DRG 021—All cases	350	13.74	53,289
MS–DRG 021—Cases with code 00.62	1	11.00	75,492
MS–DRG 021—Cases with code 39.72	130	13.12	54,715
MS–DRG 021—Cases with code 39.74	1	11.00	75,492
MS–DRG 021—Cases with code 39.75	133	13.46	52,819
MS–DRG 021—Cases with code 39.76	7	10.57	48,749
MS–DRG 021—Cases with code 39.79	3	12.00	40,458
MS–DRG 022—All cases	84	7.83	33,598
MS–DRG 022—Cases with code 00.62	0	0	0
MS–DRG 022—Cases with code 39.72	40	6.43	32,598
MS–DRG 022—Cases with code 39.74	0	0	0
MS–DRG 022—Cases with code 39.75	21	8.81	32,690
MS–DRG 022—Cases with code 39.76	3	10.00	62,417
MS–DRG 022—Cases with code 39.79	0	0	0
MS–DRG 023—All cases	6,360	10.63	38,204
MS–DRG 023—Cases with code 00.62	67	9.30	43,741
MS–DRG 023—Cases with code 39.72	56	11.14	52,589
MS–DRG 023—Cases with code 39.74	2,016	8.30	38,047
MS–DRG 023—Cases with code 39.75	20	12.65	53,837
MS–DRG 023—Cases with code 39.76	3	23.00	84,947
MS–DRG 023—Cases with code 39.79	71	13.08	50,720
MS–DRG 024—All cases	2,376	5.52	28,270
MS–DRG 024—Cases with code 00.62	76	6.74	32,415
MS–DRG 024—Cases with code 39.72	31	6.35	29,977
MS–DRG 024—Cases with code 39.74	1,284	5.35	28,268
MS–DRG 024—Cases with code 39.75	8	6.50	50,333
MS–DRG 024—Cases with code 39.76	2	1.50	19,567
MS–DRG 024—Cases with code 39.79	27	6.74	28,019
MS–DRG 025—All cases	17,756	9.19	29,657
MS–DRG 025—Cases with code 00.62	17	5.88	29,036
MS–DRG 025—Cases with code 39.72	380	9.46	51,082
MS–DRG 025—Cases with code 39.74	55	9.87	45,895
MS–DRG 025—Cases with code 39.75	139	8.94	52,188
MS–DRG 025—Cases with code 39.76	25	5.84	38,654
MS–DRG 025—Cases with code 39.79	82	11.04	39,839
MS–DRG 026—All cases	7,630	5.80	21,441
MS–DRG 026—Cases with code 00.62	31	3.48	25,611
MS–DRG 026—Cases with code 39.72	481	3.00	27,180
MS–DRG 026—Cases with code 39.74	16	4.69	27,519

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 026—Cases with code 39.75	253	2.77	26,863
MS–DRG 026—Cases with code 39.76	31	3.32	27,891
MS–DRG 026—Cases with code 39.79	45	5.42	37,410
MS–DRG 027—All cases	9,628	2.99	17,158
MS–DRG 027—Cases with code 00.62	61	2.23	21,337
MS–DRG 027—Cases with code 39.72	1,159	1.58	22,893
MS–DRG 027—Cases with code 39.74	13	1.62	69,081
MS–DRG 027—Cases with code 39.75	580	1.63	23,296
MS–DRG 027—Cases with code 39.76	61	1.74	27,403
MS–DRG 027—Cases with code 39.79	30	1.53	17,740

As can be seen from the table above, there were a large number of cases reporting procedure code 39.74 in MS–DRGs 023 and 024. There were 2,016 cases that reported procedure code 39.74 in MS–DRG 023 compared to 6,360 total cases reported in the MS–DRG. The cases that reported procedure code 39.74 in MS–DRG 023 had an average length of stay of 8.30 days and average costs of $38,047, compared to an average length of stay of 10.63 days and average costs of $38,204 for all cases reported in MS–DRG 023. There were 1,284 cases that reported procedure code 39.74 in MS–DRG 024 compared to 2,376 total cases reported in MS–DRG 024. The cases that reported procedure code 39.74 in MS–DRG 024 had an average length of stay of 5.35 days and average costs of $28,268, compared to an average length of stay of 5.52 days and average costs of $28,270 for all cases reported in MS–DRG 024. The average length of stay and average costs for cases that reported procedure code 39.74 are very similar to the average length of stay and average costs for all cases reported in MS–DRGs 023 and 024. The only other group of endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases that exceeded 1,000 in number was reported in MS–DRG 027. There were 1,159 cases that reported procedure code 39.72 in MS–DRG 027, compared to 9,628 total cases reported in MS–DRG 027. The cases that reported procedure code 39.72 in MS–DRG 027 had an average length of stay of 1.58 days and average costs of $22,893, compared to an average length of stay of 2.99 days and average costs of $17,158 for all cases reported in MS–DRG 027. In other words, the cases that reported procedure code 39.72 in MS–DRG 027 had a shorter average length of stay and average costs that were $5,735 higher than the average costs for all cases reported in MS–DRG 027. The cases that reported procedure code 39.72 in MS–DRG 020 had a shorter average length of stay and average costs that were $4,235 higher than the average costs for all cases reported in MS–DRG 020. However, the average costs for the cases that reported procedure code 39.72 in MS–DRGs 021, 022, and 024 were close to the average costs for all cases reported in the three MS–DRGs ($54,715 compared to $53,289 in MS–DRG 021; $32,598 compared to $33,598 in MS–DRG 022; and $29,997 compared to $28,270 in MS–DRG 024).

Our clinical advisors reviewed this issue and advised us that the endovascular embolization or occlusion of head and neck procedures and other endovascular procedures currently are appropriately assigned to MS–DRGs 020 through 027. They did not support reassigning these procedures from MS–DRGs 020 through 027 to another MS–DRG or creating a new MS–DRG for these procedures. Our clinical advisors stated that these procedures are all clinically similar to other procedures in these MS–DRGs. In addition, they stated that the surgical techniques are all designed to correct the same clinical problem and advised us against reassigning the procedures from MS–DRGs 020 through 027.

Based on the findings from our data analyses and the recommendations from our clinical advisors, in the FY 2017 IPPS/LTCH PPS proposed rule, we did not propose to reassign the cited endovascular embolization or occlusion of head and neck procedures and other endovascular procedures from MS–DRGs 020 through 027 to another MS–DRG or to create a new MS–DRG for these procedures for FY 2017. We invited public comments on our proposal to maintain the current MS–DRG assignments of these procedures in MS–DRGs 020 through 027.

Comment: Commenters supported the proposal to maintain the current MS–DRG assignments of endovascular embolization or occlusion of head and neck procedures and other endovascular procedures in MS–DRGs 020 through 027. The commenters did not support reassigning these procedures from MS–DRGs 020 through 027 to another MS–DRG or creating a new MS–DRG for these procedures. The commenters stated that the proposal was reasonable, given the data, the ICD–10–PCS codes, and the information provided. One commenter believed that the cost data and clinical profile of endovascular embolization procedures support MS–DRG refinements. This commenter requested that CMS reexamine the issue when ICD–10 claims data become available.

Response: We appreciate the commenters' support. We will review this and other related MS–DRG assignments once ICD–10 claims data become available.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current MS–DRG assignments for endovascular embolization or occlusion of head and neck procedures and other endovascular procedures in MS–DRGs 020 through 027.

b. Mechanical Complication Codes

We received a request to reassign the following four ICD–10–CM diagnosis codes from MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) under MS–DRGs 919, 920, and 921 (Complications of Treatment with MCC, with CC, and without CC/MCC, respectively) to MDC 1 (Diseases and Disorders of the Nervous System) under MS–DRGs 091, 092, and 093 (Other Disorders of the Nervous System with MCC, with CC, and without CC/MCC, respectively):

- T85.610A (Breakdown (mechanical) of epidural and subdural infusion catheter, initial encounter);
- T85.620A (Displacement of epidural and subdural infusion catheter, initial encounter);
- T85.630A (Leakage of epidural and subdural infusion catheter, initial encounter); and
- T85.690A (Other mechanical complication of epidural and subdural infusion catheter, initial encounter).

The requestor stated that these ICD–10–CM diagnosis code titles clearly describe mechanical complications of nervous system devices, implants, or grafts and are unquestionably nervous system codes. Therefore, the requestor recommended that these diagnosis codes be reassigned to MDC 1 under MS–DRGs 091, 092, and 093.

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24976), we examined ICD–10–CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A that are currently assigned to MDC 21 under MS–DRGs 919, 920, and 921. We noted that the predecessor ICD–9–CM diagnosis code for these four ICD–10–CM diagnosis codes was diagnosis code 996.59 (Mechanical complication due to other implant and internal device, not elsewhere classified), which also was assigned to MDC 21 under MS–DRGs 919, 920, and 921. ICD–9–CM diagnosis code 996.59 did not describe the location of the device. However, ICD–10–CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A provide additional detail that describes the location of the mechanical complication as being within the nervous system.

Based on the results of our examination, we agreed with the requestor that ICD–10–CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A describe conditions occurring within the nervous system. Within the ICD–9–CM MS–DRGs, codes describing nervous system disorders were assigned to MDC 1. The prior ICD–9–CM codes for mechanical complications did not indicate the type of complication and therefore could not be assigned to a specific MDC. Therefore, the nonspecific complication codes were assigned to MDC 21. These new ICD–10–CM diagnosis codes describe concepts not previously captured by the ICD–9–CM codes and capture nervous system conditions. Therefore, ICD–10–CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A should be reassigned from MDC 21 under MS–DRGs 919, 920, and 921 to MDC 1 under MS–DRGs 091, 092, and 093. Our clinical advisors reviewed this issue and also agree that the four ICD–10–CM diagnosis codes describe conditions occurring within the nervous system and therefore should be reassigned from MDC 21 to MDC 1. Based on the results of our analysis and the recommendations of our clinical advisors, in the FY 2017 IPPS/LTCH PPS proposed rule, we proposed to reassign ICD–10–CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A from MDC 21 under MS–DRGs 919, 920, and 921 to MDC 1 under MS–DRGs 091, 092, and 093.

We invited public comments on our proposal.

Comment: Commenters supported the proposal to reassign ICD–10–CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A from MDC 21 under MS–DRGs 919, 920, and 921 to MDC 1 under MS–DRGs 091, 092, and 093.

One commenter who supported the proposal suggested that the proposed MS–DRG assignment for 18 additional diagnosis codes describing similar conditions affecting the nervous system is inaccurate, both clinically and in terms of MS–DRG grouping principles. Specifically, the commenter requested that the 18 ICD–10–CN diagnosis codes in the following table be reassigned from MDC 21 under DRGs 919, 920 and 921, as currently proposed, to MDC 1 under MS–DRGs 091, 092, and 093.

ICD–10–CM DIAGNOSIS CODES RECOMMENDED BY COMMENTER FOR REASSIGNMENT FROM MDC 21 TO MDC 1

T85.615A (Breakdown (mechanical) of other nervous system device, implant or graft, initial encounter).
T85.625A (Displacement of other nervous system device, implant or graft, initial encounter).
T85.635A (Leakage of other nervous system device, implant or graft, initial encounter).
T85.695A (Other mechanical complication of other nervous system device, implant or graft, initial encounter).
T85.730A (Infection and inflammatory reaction due to ventricular intracranial (communicating) shunt, initial encounter).
T85.731A (Infection and inflammatory reaction due to implanted electronic neurostimulator of brain, electrode (lead), initial encounter).
T85.732A (Infection and inflammatory reaction due to implanted electronic neurostimulator of peripheral nerve, electrode (lead), initial encounter).
T85.733A (Infection and inflammatory reaction due to implanted electronic neurostimulator of spinal cord, electrode (lead), initial encounter).
T85.734A (Infection and inflammatory reaction due to implanted electronic neurostimulator, generator, initial encounter).
T85.735A (Infection and inflammatory reaction due to cranial or spinal infusion catheter, initial encounter).
T85.738A (Infection and inflammatory reaction due to other nervous system device, implant or graft, initial encounter).
T85.810A (Embolism due to nervous system prosthetic devices, implants and grafts, initial encounter).
T85.820A (Fibrosis due to nervous system prosthetic devices, implants and grafts, initial encounter).
T85.830A (Hemorrhage due to nervous system prosthetic devices, implants and grafts, initial encounter).
T85.840A (Pain due to nervous system prosthetic devices, implants and grafts, initial encounter).
T85.850A (Stenosis due to nervous system prosthetic devices, implants and grafts, initial encounter).
T85.860A (Thrombosis due to nervous system prosthetic devices, implants and grafts, initial encounter).
T85.890A (Other specified complication of nervous system prosthetic devices, implants and grafts, initial encounter).

Response: We appreciate the commenters' support of our proposal. We also appreciate the commenter's recommendation to reassign the additional 18 ICD–10–CM diagnosis codes describing procedures performed on the nervous system from MDC 21 under MS–DRGs 919, 920, and 921 to MDC 1 under MS DRGs 091, 092, and 093. Our clinical advisors agree that these 18 diagnosis codes also should be reassigned from MDC 21 under MS–DRGs 919, 920 and 921 to MDC1 under MS–DRGs 091, 092 and 093.

After consideration of the public comments we received, we are finalizing our proposal to reassign ICD–10–CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A from MDC 21 under MS–DRGs 919, 920, and 921 to MDC 1 under MS–DRGs 091, 092, and 093. The official code titles for these four codes were revised after publication of the proposed rule. Effective October 1, 2016, the revised code titles are as follows (and are reflected in Table 6E associated with this final rule, which is available via the Internet on the CMS Web site):

- T85.610A (Breakdown (mechanical) of cranial or spinal infusion catheter, initial encounter);
- T85.620A (Displacement of cranial or spinal infusion catheter, initial encounter);
- T85.630A (Leakage of cranial or spinal infusion catheter, initial encounter); and
- T85.690A (Other mechanical complication of cranial or spinal infusion catheter, initial encounter).

We also are reassigning the 18 ICD–10–CM diagnosis codes listed in the table above that were recommended by the commenter from MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) under MS–DRGs 919, 920, and 921 (Complications of Treatment with MCC, with CC, and without CC/MCC, respectively) to MDC 1 (Diseases and Disorders of the Nervous System) under MS–DRGs 091, 092, and 093 (Other Disorders of the Nervous System with MCC, with CC, and without CC/MCC, respectively) effective October 1, 2016. These 18 codes also are reflected in Table 6E associated with this final rule, which is available via the Internet on the CMS Web site.

4. MDC 4 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)

a. Reassignment of Diagnosis Code R22.2 (Localized Swelling, Mass and Lump, Trunk)

We received a request to reassign ICD–10–CM diagnosis code R22.2 (Localized swelling, mass and lump, trunk) from MDC 4 (Diseases and Disorders of the Respiratory System) to MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast). The requestor stated that this code is used to capture a buttock mass. The requestor pointed out that the ICD–10–CM index for localized swelling and localized mass directs the coder to diagnosis code R22.2 for both the chest and the trunk as sites.

We reviewed this issue and note that diagnosis code R22.2 is included in a category of ICD–10–CM codes describing symptoms and signs involving the skin and subcutaneous tissue (categories R20 through R23). Diagnosis code R22.2 is clearly designated within the ICD–10 coding system as a code that describes a condition of the skin and subcutaneous tissue. Therefore, we agree with the requester that ICD–10–CM diagnosis code R22.2 should be reassigned from MDC 4 to MDC 9. One of the predecessor ICD–9–CM codes for ICD–10–CM diagnosis code R22.2 was diagnosis code 782.2 (Localized superficial swelling, mass, or lump), which is assigned to MS–DRG 606 and 607 (Minor Skin Disorders with and without MCC, respectively). Our clinical advisors reviewed this issue and agree that ICD–10–CM diagnosis code R22.2 captures a skin diagnosis. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24976), for FY 2017, we proposed to reassign ICD–10–CM diagnosis code R22.2 from MDC 4 to MDC 9 under MS–DRGs 606 and 607 (Minor Skin Disorders with and without MCC, respectively).

We invited public comments on our proposal to reassign ICD–10–CM diagnosis code R22.2 from MDC 4 to MDC 9 under MS–DRGs 606 and 607.

Comment: Commenters supported the proposal to reassign ICD–10–CM diagnosis code R22.2 from MDC 4 to MDC 9 under MS–DRGs 606 and 607.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to reassign ICD–10–CM diagnosis code R22.2 from MDC 4 to MDC 9 under MS–DRGs 606 and 607 (Minor Skin Disorders with and without MCC, respectively).

b. Pulmonary Embolism With tPA or Other Thrombolytic Therapy

We received a request to create a new MS–DRG or to reassign cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy was administered from MS–DRGs 175 and 176 (Pulmonary Embolism with and without MCC, respectively) to a higher paying MS–DRG. The requestor suggested that CMS review cases reporting the following ICD–9–CM diagnosis codes describing pulmonary embolism: 415.11 (Iatrogenic pulmonary embolism and infarction), 415.12 (Septic pulmonary embolism), 415.13 (Saddle embolus of pulmonary artery), and 415.19 (Other pulmonary embolism and infarction), when reported in combination with ICD–9–CM procedure code 99.10 (Injection or infusion of thrombolytic agent), to identify that thrombolytic therapy was administered.

The comparable ICD–10–CM diagnosis code translations for the ICD–9–CM pulmonary embolism diagnosis codes to which the requestor cited consist of the following:

ICD–10–CM diagnosis code	Description
I26.01	Septic pulmonary embolism with acute cor pulmonale.
I26.02	Saddle embolus of pulmonary artery with acute cor pulmonale.
I26.09	Other pulmonary embolism with acute cor pulmonale.
I26.90	Septic pulmonary embolism without acute cor pulmonale.
I26.92	Saddle embolus of pulmonary artery without acute cor pulmonale.
I26.99	Other pulmonary embolism without acute cor pulmonale.

Thrombolytic therapy is identified with the following ICD–10–PCS procedure codes:

ICD–10–PCS procedure code	Description
3E03017	Introduction of other thrombolytic into peripheral vein, open approach.
3E03317	Introduction of other thrombolytic into peripheral vein, percutaneous approach.
3E04017	Introduction of other thrombolytic into central vein, open approach.
3E04317	Introduction of other thrombolytic into central vein, percutaneous approach.
3E05017	Introduction of other thrombolytic into peripheral artery, open approach.
3E05317	Introduction of other thrombolytic into peripheral artery, percutaneous approach.
3E06017	Introduction of other thrombolytic into central artery, open approach.
3E06317	Introduction of other thrombolytic into central artery, percutaneous approach.

A pulmonary embolism is an obstruction of pulmonary vasculature most commonly caused by a venous thrombus, and less commonly by fat or tumor tissue or air bubbles or both. Risk factors for a pulmonary embolism include prolonged immobilization from any cause, obesity, cancer, fractured hip or leg, use of certain medications such as oral contraceptives, presence of certain medical conditions such as heart failure, sickle cell anemia, or certain congenital heart defects. Common symptoms of pulmonary embolism include shortness of breath with or without chest pain, tachycardia, hemoptysis, low grade fever, pleural effusion, and depending on the etiology of the embolus, might include lower extremity pain or swelling, syncope, jugular venous distention, and finally a pulmonary embolus could be asymptomatic.

As we discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24977 through 24979), we examined the claims data from the December 2015 update of the FY 2015 MedPAR file for ICD–9–CM MS–DRGs 175 and 176 for cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy (procedure code 99.10) was administered and cases of a principal diagnosis of pulmonary embolism where no tPA or other thrombolytic therapy was administered. Our findings are shown in the table below.

PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH AND WITHOUT tPA OR OTHER THROMBOLYTIC THERAPY ADMINISTERED

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 175—All MCC cases	19,274	5.76	$10,479
MS–DRG 175—MCC cases with principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy administered	630	6.31	19,419
MS–DRG 175—MCC cases with principal diagnosis of pulmonary embolism without tPA or other thrombolytic therapy administered	18,529	5.74	10,181
MS–DRG 176—All Without MCC cases	33,565	3.81	6,645
MS–DRG 176—Without MCC cases with principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy administered	544	5.07	16,345
MS–DRG 176—Without MCC cases with principal diagnosis of pulmonary embolism without tPA or other thrombolytic therapy administered	32,789	3.79	6,483

As shown in the table above, for MS–DRG 175, there were a total of 19,274 cases with an average length of stay of 5.76 days and average costs of $10,479. Of the 19,274 cases in MS–DRG 175, there were 630 cases that reported a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy was also reported with an average length of stay of 6.31 days and average costs of $19,419. For MS–DRG 176, there were a total of 33,565 cases with an average length of stay of 3.81 days and average costs of $6,645. Of the 33,565 cases reported in MS–DRG 176, there were 544 cases that reported a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy also was reported with an average length of stay of 5.07 days and average costs of $16,345.

To address the request we received to create a new MS–DRG, we reviewed the data for the 1,174 total cases (630 and 544, respectively) that reported a principal diagnosis of pulmonary embolism that received tPA or other thrombolytic therapy in MS–DRGs 175 and 176. As shown in the table above, our data analysis demonstrates the average costs for these cases are higher ($19,419 compared to $10,479 for MS–DRG 175, and $16,345 compared to $6,645 for MS–DRG 176) and the length of stay is slightly longer (6.31 days compared to 5.76 days for MS–DRG 175, and 5.07 days compared to 3.81 days for MS–DRG 176) compared to all cases reported in MS–DRGs 175 and 176. Out of a total of 52,492 cases (630 + 18,529 +544 + 32,789) in MS–DRGs 175 and 176 reporting a principal diagnosis of pulmonary embolism, 1,174 (2.24 percent) of these cases also received tPA or other thrombolytic therapy. While we recognize the differences in average costs and length of stay for these cases, the volume of these cases as well as the potential creation of a new MS–DRG for this subset of patients raised some concerns with our clinical advisors. We present our clinical advisors' concerns following the additional data analysis discussions below.

We then conducted additional data analyses to determine if reassignment of cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy was administered to a higher paying MS–DRG was supported. As displayed in the data findings in the tables below, we explored reassigning cases with a principal diagnosis of pulmonary embolism that received tPA or other thrombolytic therapy from MS–DRG 176 to the higher severity level MS–DRG 175. The data do not adequately support this reassignment, as the cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy is administered would continue to be underpaid.

As shown in the data findings in the table below, the initial data analysis for MS–DRG 175 found the average costs for cases that reported a principal diagnosis of pulmonary embolism that received tPA or other thrombolytic therapy were $19,419, and for MS–DRG 176, the average costs for these cases were $16,345.

PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH tPA OR OTHER THROMBOLYTIC THERAPY ADMINISTERED

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 175—All MCC cases	19,274	5.76	$10,479

PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH tPA OR OTHER THROMBOLYTIC THERAPY ADMINISTERED—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 175—MCC cases with principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy administered	630	6.31	19,419
MS–DRG 176—All without MCC cases	33,565	3.81	6,645
MS–DRG 176—Without MCC cases with principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy administered	544	5.07	16,345

As displayed in the table below, if we reassigned the 544 cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy is administered from the ''without MCC'' level, MS–DRG 176, to the ''with MCC'' severity level, MS–DRG 175, the average costs for all cases in MS–DRG 175 would be approximately $10,640. This figure continues to result in a difference of approximately $9,000 for the MCC cases and $6,000 for the without MCC cases when compared to findings for the average costs of these cases from the initial data analysis ($19,419 − $10,640 = $8,779 and $16,345 − $10,640 = $5,705, respectively). In addition, our clinical advisors had concerns about the prospect of moving the subset of 544 patients from the ''without MCC'' level to the ''with MCC'' level. We present these concerns following the additional data analysis discussion below.

OPTION OF REASSIGNMENT OF CASES OF PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH AND WITHOUT tPA

MS–DRG 175—Cases with pulmonary embolism with MCC or tPA or other thrombolytic therapy	19,818	5.74	$10,640
MS–DRG 176—Cases with pulmonary embolism without MCC	33,021	3.79	6,486

We also reviewed claims data in considering the option of adding another severity level to the current structure of MS–DRGs 175 and 176 and assigning the cases with a principal diagnosis of pulmonary embolism that receive tPA or other thrombolytic therapy to the highest level. This option would involve modifying the current 2-way severity level split of ''with MCC'' and ''without MCC'' to a 3-way severity level split of ''with MCC or tPA, with CC, and without CC/MCC.'' Therefore, it would include proposing new MS–DRGs if the data and our clinical advisors supported creation of new MS–DRGs. However, as displayed in the data findings in the table below, the data did not support this option. In addition to similar results from the previous option's discussion regarding continued differences in average costs for these cases, the data failed to meet the criterion that there be at least a $2,000 difference between the ''with CC'' and ''without CC/MCC'' subgroups. Our data analysis shows the average costs in the hypothetical ''with CC'' subgroup of $6,932 and the average costs in the hypothetical ''without CC/MCC'' subgroup of $5,309. The difference only amounts to $1,623 ($6,932 minus $5,309 = $1,623).

PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH AND WITHOUT tPA OR OTHER THROMBOLYTIC THERAPY

Optional new MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG XXX—Pulmonary embolism with MCC or tPA or other thrombolytic therapy	19,819	5.74	$10,641
MS–DRG XXX—Pulmonary embolism with CC	23,929	4.04	6,932
MS–DRG XXX—Pulmonary embolism without CC/MCC	9,091	3.13	5,309

Lastly, we explored reassigning cases with a principal diagnosis of pulmonary embolism that receive tPA or other thrombolytic therapy to other MS–DRGs within MDC 4. However, our review did not support reassignment of these cases to any other medical MS–DRGs as these cases would not be clinically coherent with the cases assigned to those other MS–DRGs.

In addition to the results of the various data analyses we performed for creating a new MS–DRG or for reassignment of cases of pulmonary embolism with tPA or other thrombolytic therapy to another higher paying MS–DRG, our clinical advisors also expressed a number of concerns. They pointed out that all patients with a diagnosis of pulmonary embolism are considered high risk and the small subset of patients receiving thrombolytic therapy does not necessarily warrant a separate MS–DRG or reassignment at this time. Our clinical advisors noted that it is unclear if: (1) The higher costs associated with receiving tPA or other thrombolytic therapy are due to a different subset of patients or complications; (2) if those patients treated with tPA or other thrombolytic therapy for pulmonary embolism are indeed sicker patients; (3) if the cost of tPA or other thrombolytic therapy for patients with pulmonary embolism is the reason for the higher costs seen with these cases; or (4) if the increased average costs for cases of pulmonary embolism with tPA or other thrombolytic therapy is a combination of numbers (1) through (3). They recommended maintaining the current structure of MS–DRGs 175 and 176.

As a result of the data analysis and the concerns expressed by our clinical advisors, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24977 through 24979), we did not propose to create a new MS–DRG or to reassign cases with a principal diagnosis of pulmonary embolism with tPA or other

thrombolytic therapy for FY 2017. We invited public comment on our proposal.

Comment: Commenters supported the proposal to not create a new MS–DRG or to reassign cases with a principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy. The commenters stated that the proposal was reasonable, given the data, the ICD–10–CM/PCS codes, and information provided.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to not create a new MS–DRG or to reassign cases with a principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy for FY 2017. The current structure of MS–DRGs 175 and 176 (Pulmonary Embolism with and without MCC, respectively) is maintained in the ICD–10 MS–DRGs Version 34 effective October 1, 2016.

5. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Implant of Loop Recorder

We received a request to examine a potential ICD–9 to ICD–10 replication issue for procedures describing implantation or revision of loop recorder that were reported using ICD–9–CM procedure code 37.79 (Revision or relocation of cardiac device pocket). A loop recorder is also known as an implantable cardiac monitor. It is indicated for patients who experience episodes of unexplained syncope (fainting), heart palpitations, or patients at risk for various types of cardiac arrhythmias, such as atrial fibrillation or ventricular tachyarrhythmia. Loop recorders function by detecting and monitoring potential episodes of these kinds of conditions. The requestor acknowledged that these implantation procedures are frequently performed in the outpatient setting. However, the requestor also noted that the implantation procedures are often performed in the inpatient setting and suggested that they be recognized under the ICD–10 MS–DRGs as they had been under the ICD–9–CM based MS–DRG logic.

The requestor stated that, under the ICD–9–CM based MS–DRGs, procedure code 37.79 was designated as an operating room (O.R.) procedure in the Definitions Manual under Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index and grouped to MS–DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or peripheral neurostimulator, and without CC/MCC, respectively); MS–DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively); MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC and without CC/MCC, respectively); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively); and MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively).

Under the current Version 33 ICD–10 MS–DRGs, there are two comparable ICD–10–PCS code translations for ICD–9–CM code 37.79. They are procedure codes 0JWT0PZ (Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, open approach) and 0JWT3PZ (Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, percutaneous approach), which are designated as O.R. procedures and group to the above listed MS–DRGs.

According to the requestor, the following six ICD–10–PCS procedure codes identify the implantation or revision of a loop recorder and were not replicated appropriately because they are currently designated as nonoperating room (non-O.R.) procedures under the ICD–10 MS–DRGs. The requestor suggested that these codes be designated as O.R. procedures and assigned to the same MS–DRGs as the former ICD–9–CM procedure code 37.79:

ICD–10–PCS procedure code	Description
0JH602Z	Insertion of monitoring device into chest subcutaneous tissue and fascia, open approach.
0JH632Z	Insertion of monitoring device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH802Z	Insertion of monitoring device into abdomen subcutaneous tissue and fascia, open approach.
0JH832Z	Insertion of monitoring device into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JWT02Z	Revision of monitoring device in trunk subcutaneous tissue and fascia, open approach.
0JWT32Z	Revision of monitoring device in trunk subcutaneous tissue and fascia, percutaneous approach.

We examined the six ICD–10–PCS procedure codes that the commenter recommended be designated as O.R. procedures and assigned to the same MS–DRGs as ICD–9–CM procedure code 37.79. As discussed in section II.F.1.b. of the preamble of the proposed rule and this final rule, in evaluating requested MS–DRG changes, we determined if they could be replicated in the ICD–9–CM MS–DRGs so as not to affect the FY 2017 relative payment weights. If the answer was ''no,'' we examined whether the change in the ICD–10 MS–DRGs was likely to cause a significant number of patient cases to change or ''shift'' ICD–10 MS–DRGs. If relatively few patient cases would be impacted, we evaluated if it would be feasible to propose the change even though it could not be replicated by the ICD–9 MS–DRGs logic because it would not cause a material payment redistribution.

Under our review, we recognized that the six ICD–10–PCS procedure codes are currently identified as comparable translations of ICD–9–CM procedure code 86.09 (Other incision of skin and subcutaneous tissue), which was designated as a non-O.R. procedure code under the ICD–9–CM based MS–DRGs. Therefore, changing the designation of the six ICD–10–PCS procedure codes from non-O.R. to O.R. for the ICD–10 MS–DRGs cannot be replicated in the ICD–9–CM based MS–DRGs. In other words, we cannot designate ICD–9–CM procedure code 86.09 as an O.R. code. However, we stated in the proposed rule that we believe that if we limit the change in designation to four of the six identified ICD–10–PCS procedure codes from non-O.R. to O.R., the change would not have any impact. We did not include the two ICD–10–PCS procedure codes that describe the insertion of a monitoring device into the abdomen in our proposal because a loop recorder is not inserted into that location and it would not be clinically appropriate.

Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24979 through 24980), for FY 2017, we proposed to designate the following four ICD–10–PCS codes as O.R. procedures

within Appendix E of the Version 34 ICD–10 MS–DRG Definitions Manual:

- 0JH602Z (Insertion of monitoring device into chest subcutaneous tissue and fascia, open approach);
- 0JH632Z (Insertion of monitoring device into chest subcutaneous tissue and fascia, percutaneous approach);
- 0JWT02Z (Revision of monitoring device in trunk subcutaneous tissue and fascia, open approach); and
- 0JWT32Z (Revision of monitoring device in trunk subcutaneous tissue and fascia, percutaneous approach).

We also proposed that the ICD–10 MS–DRG assignment for these four ICD–10–PCS codes replicate the ICD–9–CM based MS–DRG assignment for procedure code 37.79; that is, MS–DRGs 040, 041, 042, 260, 261, 262, 579, 580, 581, 907, 908, 909, 957, 958, and 959 as cited earlier in this section.

We invited public comments on our proposals.

Comment: Commenters supported the proposal to designate the four ICD–10–PCS procedure codes listed in this section that describe the insertion or revision of a monitoring device from non-O.R. to O.R. to better reflect the resources involved with these procedures. The commenters also agreed with the proposed MS–DRG assignments for these procedure codes under the ICD–10 MS–DRGs, stating that the proposal was reasonable, given the data, the ICD–10–PCS codes and information provided. One commenter specifically expressed appreciation with CMS' review of this replication issue and agreed that the codes that were proposed to be changed from non-O.R. to O.R. are accurate and that this change will result in better data on claims. This commenter also commended CMS for the proposed MS–DRG assignments under the ICD–10 MS–DRGs.

Alternatively, another commenter noted that while it agreed with the proposal to change the designation of the four ICD–10–PCS procedure codes from non-O.R. to O.R. and supported the proposed MS–DRG assignments, the commenter believed that the two other ICD–10–PCS procedure codes describing insertion of a monitoring device into the abdomen subcutaneous tissue and fascia (ICD–10–PCS procedure codes 0JH802Z and 0JH832Z) also merit redesignation from non-O.R. to O.R. and assignment to the same corresponding surgical MS–DRGs in order to fully address the ICD–9 to ICD–10 replication issue. According to the commenter, the anatomical location of implants involving loop recorders does not affect the level of effort involved in performing such procedures. The commenter recommended that CMS consider ICD–9–CM procedure code 37.79 (Revision or relocation of cardiac device pocket) and its attributes versus ICD–9–CM procedure code 86.09 (Other incision of skin and subcutaneous tissue) as more appropriate for examining all the comparable ICD–10 code translations and MS–DRG assignments.

Response: We appreciate the commenters' support of our proposals. We agree with the commenters that this modification will better address the resources involved with these procedures.

With regard to the commenter who recommended that we include the two ICD–10–PCS codes describing insertion of a monitoring device into the abdomen subcutaneous tissue and fascia, we are not clear with respect to the commenter's statement that the anatomical location of implants involving loop recorders does not affect the level of effort involved in performing such procedures because loop recorders are not inserted in that area of the abdomen. As we noted in the FY 2017 IPPS/LTCH PPS proposed rule, when we were unable to fully replicate the ICD–9 to ICD–10 MS–DRG logic for a specific request, we sought and proposed an alternative option that would not cause MS–DRG shifts or a material payment distribution. For this particular issue, the request was to change the designation of the six ICD–10–PCS procedure codes from non-O.R. to O.R. and, as described above, we were not able to finalize that specific request. Rather, we finalized an alternative option, which was to change the designation for four of the six codes requested. We also point out that, currently, under the ICD–10 MS–DRGs Version 33, all six ICD–10–PCS procedure codes that were the subject of our specific proposal are designated as non-O.R. procedures affecting the MS–DRG assignment for MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC and without CC/MCC, respectively). Therefore, while we are not finalizing the proposal to change the two ICD–10–PCS procedure codes describing the insertion of a monitoring device into the abdomen (0JH802Z and 0JH832Z) from non-OR to O.R., we note that these two procedure codes will continue to be recognized as non-O.R. procedures affecting MS–DRGs 579, 580, and 581 under the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

After consideration of the public comments we received, we are finalizing our proposal to designate the following four ICD–10–PCS codes as O.R. procedures within Appendix E of the Version 34 ICD–10 MS–DRG Definitions Manual:

- 0JH602Z (Insertion of monitoring device into chest subcutaneous tissue and fascia, open approach);
- 0JH632Z (Insertion of monitoring device into chest subcutaneous tissue and fascia, percutaneous approach);
- 0JWT02Z (Revision of monitoring device in trunk subcutaneous tissue and fascia, open approach); and
- 0JWT32Z (Revision of monitoring device in trunk subcutaneous tissue and fascia, percutaneous approach).

We also are finalizing our proposal that the ICD–10 MS–DRG assignment for the above four ICD–10–PCS procedure codes replicate the ICD–9–CM based MS–DRG assignment for procedure code 37.79; that is, MS–DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or peripheral neurostimulator, and without CC/MCC, respectively); MS–DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively); MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC and without CC/MCC, respectively); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively); and MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively), effective October 1, 2016.

b. Endovascular Thrombectomy of the Lower Limbs

We received a comment stating that the logic for ICD–10 MS–DRGs Version 33 is not compatible with the ICD–9–CM MS–DRGs Version 32 for the assignment of procedures describing endovascular thrombectomy of the lower limbs. The commenter asked CMS to reconfigure the MS–DRG structure within the ICD–10 MS–DRGs for endovascular thrombectomy of the lower limbs, specifically MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively)). (We note that in the FY 2017 IPPS/LTCH PPS proposed rule, we incorrectly cited the titles for MS–DRGs 270, 271, and 272 as ''(Endovascular Thrombectomy of the Lower Limbs with MCC, with CC, and without CC/MCC, respectively)''. The commenter believed that this requested restructuring would be consistent with the MS–DRG assignments for the other procedures describing lower extremity

thrombectomy, and would accurately replicate the logic of the ICD–9–CM MS–DRGs Version 32. Under the ICD–9–CM, endovascular thrombectomy of the lower limbs is described by procedure code 39.79 (Other endovascular procedures on other vessels). The commenter stated that, with deep vein thrombosis (DVT) or any other circulatory system disorders as the principal diagnosis, cases involving procedures described by procedure code 39.79 grouped to ICD–9–CM MS–DRGs 237 and 238 (Major Cardiovascular Procedures with and without MCC, respectively). However, the commenter pointed out that, for FY 2016, ICD–9–CM MS–DRGs 237 and 238 were deleted and replaced with ICD–10 Version 33 MS–DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with and without MCC, respectively), for the higher complexity procedures, and MS–DRGs 270, 271, and 272 for the lower complexity procedures (80 FR 49389). The commenter stated that ICD–9–CM procedure code 39.79 describes the lower complexity procedures assigned to ICD–10–PCS MS–DRGs 270, 271, and 272. The commenter believed that the comparable ICD–10–PCS procedure codes also should have been assigned to MS–DRGs 270, 271, and 272.

We agreed with the requestor that procedures describing endovascular thrombectomy of the lower limbs should be assigned to ICD–10 MS–DRGs 270, 271, and 272. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24980 through 24981), for implementation October 1, 2016, we proposed to restructure the ICD–10–PCS MS–DRG configuration and add the ICD–10–PCS code translations listed in the following chart (which would capture procedures describing endovascular thrombectomy of the lower limbs) to ICD–10 Version 34 MS–DRGs 270, 271, and 272.

ICD–10–PCS Endovascular Thrombectomy Procedure Codes Proposed To Be Assigned to MS–DRGs 270, 271, and 272 for FY 2017

03C53ZZ	Extirpation of matter from right axillary artery, percutaneous approach.
03C63ZZ	Extirpation of matter from left axillary artery, percutaneous approach.
03C73ZZ	Extirpation of matter from right brachial artery, percutaneous approach.
03C83ZZ	Extirpation of matter from left brachial artery, percutaneous approach.
03C93ZZ	Extirpation of matter from right ulnar artery, percutaneous approach.
03CA3ZZ	Extirpation of matter from left ulnar artery, percutaneous approach.
03CB3ZZ	Extirpation of matter from right radial artery, percutaneous approach.
03CC3ZZ	Extirpation of matter from left radial artery, percutaneous approach.
03CD3ZZ	Extirpation of matter from right hand artery, percutaneous approach.
03CF3ZZ	Extirpation of matter from left hand artery, percutaneous approach.
03CY3ZZ	Extirpation of matter from upper artery, percutaneous approach.
04CK3ZZ	Extirpation of matter from right femoral artery, percutaneous approach.
04CL3ZZ	Extirpation of matter from left femoral artery, percutaneous approach.
04CM3ZZ	Extirpation of matter from right popliteal artery, percutaneous approach.
04CN3ZZ	Extirpation of matter from left popliteal artery, percutaneous approach.
04CP3ZZ	Extirpation of matter from right anterior tibial artery, percutaneous approach.
04CQ3ZZ	Extirpation of matter from left anterior tibial artery, percutaneous approach.
04CR3ZZ	Extirpation of matter from right posterior tibial artery, percutaneous approach.
04CS3ZZ	Extirpation of matter from left posterior tibial artery, percutaneous approach.
04CT3ZZ	Extirpation of matter from right peroneal artery, percutaneous approach.
04CU3ZZ	Extirpation of matter from left peroneal artery, percutaneous approach.
04CV3ZZ	Extirpation of matter from right foot artery, percutaneous approach.
04CW3ZZ	Extirpation of matter from left foot artery, percutaneous approach.
04CY3ZZ	Extirpation of matter from lower artery, percutaneous approach.
05C73ZZ	Extirpation of matter from right axillary vein, percutaneous approach.
05C83ZZ	Extirpation of matter from left axillary vein, percutaneous approach.
05C93ZZ	Extirpation of matter from right brachial vein, percutaneous approach.
05CA3ZZ	Extirpation of matter from left brachial vein, percutaneous approach.
05CB3ZZ	Extirpation of matter from right basilic vein, percutaneous approach.
05CC3ZZ	Extirpation of matter from left basilic vein, percutaneous approach.
05CD3ZZ	Extirpation of matter from right cephalic vein, percutaneous approach.
05CF3ZZ	Extirpation of matter from left cephalic vein, percutaneous approach.
05CG3ZZ	Extirpation of matter from right hand vein, percutaneous approach.
05CH3ZZ	Extirpation of matter from left hand vein, percutaneous approach.
05CL3ZZ	Extirpation of matter from intracranial vein, percutaneous approach.
05CM3ZZ	Extirpation of matter from right internal jugular vein, percutaneous approach.
05CN3ZZ	Extirpation of matter from left internal jugular vein, percutaneous approach.
05CP3ZZ	Extirpation of matter from right external jugular vein, percutaneous approach.
05CQ3ZZ	Extirpation of matter from left external jugular vein, percutaneous approach.
05CR3ZZ	Extirpation of matter from right vertebral vein, percutaneous approach.
05CS3ZZ	Extirpation of matter from left vertebral vein, percutaneous approach.
05CT3ZZ	Extirpation of matter from right face vein, percutaneous approach.
05CV3ZZ	Extirpation of matter from left face vein, percutaneous approach.
05CY3ZZ	Extirpation of matter from upper vein, percutaneous approach.
06C33ZZ	Extirpation of matter from esophageal vein, percutaneous approach.
06CM3ZZ	Extirpation of matter from right femoral vein, percutaneous approach.
06CN3ZZ	Extirpation of matter from left femoral vein, percutaneous approach.
06CP3ZZ	Extirpation of matter from right greater saphenous vein, percutaneous approach.
06CQ3ZZ	Extirpation of matter from left greater saphenous vein, percutaneous approach.
06CR3ZZ	Extirpation of matter from right lesser saphenous vein, percutaneous approach.
06CS3ZZ	Extirpation of matter from left lesser saphenous vein, percutaneous approach.
06CT3ZZ	Extirpation of matter from right foot vein, percutaneous approach.

We invited public comments on our proposal to assign the ICD–10–PCS procedures describing the endovascular thrombectomy of the lower limbs listed in the table above to ICD–10 Version 34 MS–DRGs 270, 271, and 272 for FY 2017.

Comment: Several commenters supported the proposal to assign the ICD–10–PCS procedures describing the endovascular thrombectomy of the lower limbs listed in the table in the proposed rule to ICD–10 Version 34 MS–DRGs 270, 271 and 272 for FY 2017. The commenters noted it is important that endovascular thrombectomy procedures be assigned to the same MS–DRGs as other procedures describing lower extremity thrombectomy. However, some commenters also noted that a subset of the codes listed in the table in the proposed rule describe non-lower limb procedures. The commenters were concerned that moving the 34 non-lower limb procedure codes displayed in the following table would not support clinical and resource use homogeneity in the MS–DRG.

ICD–10–PCS Endovascular Thrombectomy Non-Lower Limb Procedure Codes Identified by Commenters

03C53ZZ	Extirpation of matter from right axillary artery, percutaneous approach.
03C63ZZ	Extirpation of matter from left axillary artery, percutaneous approach.
03C73ZZ	Extirpation of matter from right brachial artery, percutaneous approach.
03C83ZZ	Extirpation of matter from left brachial artery, percutaneous approach.
03C93ZZ	Extirpation of matter from right ulnar artery, percutaneous approach.
03CA3ZZ	Extirpation of matter from left ulnar artery, percutaneous approach.
03CB3ZZ	Extirpation of matter from right radial artery, percutaneous approach.
03CC3ZZ	Extirpation of matter from left radial artery, percutaneous approach.
03CD3ZZ	Extirpation of matter from right hand artery, percutaneous approach.
03CF3ZZ	Extirpation of matter from left hand artery, percutaneous approach.
03CY3ZZ	Extirpation of matter from upper artery, percutaneous approach.
04CT3ZZ	Extirpation of matter from right peroneal artery, percutaneous approach.
04CU3ZZ	Extirpation of matter from left peroneal artery, percutaneous approach.
05C73ZZ	Extirpation of matter from right axillary vein, percutaneous approach.
05C83ZZ	Extirpation of matter from left axillary vein, percutaneous approach.
05C93ZZ	Extirpation of matter from right brachial vein, percutaneous approach.
05CA3ZZ	Extirpation of matter from left brachial vein, percutaneous approach.
05CB3ZZ	Extirpation of matter from right basilic vein, percutaneous approach.
05CC3ZZ	Extirpation of matter from left basilic vein, percutaneous approach.
05CD3ZZ	Extirpation of matter from right cephalic vein, percutaneous approach.
05CF3ZZ	Extirpation of matter from left cephalic vein, percutaneous approach.
05CG3ZZ	Extirpation of matter from right hand vein, percutaneous approach.
05CH3ZZ	Extirpation of matter from left hand vein, percutaneous approach.
05CL3ZZ	Extirpation of matter from intracranial vein, percutaneous approach.
05CM3ZZ	Extirpation of matter from right internal jugular vein, percutaneous approach.
05CN3ZZ	Extirpation of matter from left internal jugular vein, percutaneous approach.
05CP3ZZ	Extirpation of matter from right external jugular vein, percutaneous approach.
05CQ3ZZ	Extirpation of matter from left external jugular vein, percutaneous approach.
05CR3ZZ	Extirpation of matter from right vertebral vein, percutaneous approach.
05CS3ZZ	Extirpation of matter from left vertebral vein, percutaneous approach.
05CT3ZZ	Extirpation of matter from right face vein, percutaneous approach.
05CV3ZZ	Extirpation of matter from left face vein, percutaneous approach.
05CY3ZZ	Extirpation of matter from upper vein, percutaneous approach.
06C33ZZ	Extirpation of matter from esophageal vein, percutaneous approach.

One commenter suggested adding two additional procedure codes describing thrombectomy of the lower limbs (ICD–10–PCS codes 06CV3Z (Extirpation of matter from left foot vein, percutaneous approach) and 06CY3Z (Extirpation of matter from lower vein, percutaneous approach)) to the list of procedure codes to be moved to MS–DRGs 270, 271 and 272.

Response: We appreciate the commenters' support for the assignment of ICD–10–PCS procedure codes describing endovascular thrombectomy of the lower limbs to ICD–10 Version 34 MS–DRGs 270, 271 and 272 for FY 2017. We agree with removing the 34 codes that the commenters identified as not describing endovascular thrombectomy of the lower limbs from the list of codes that were proposed to be reassigned to MS–DRGs 270, 271 and 272. Our clinical advisors reviewed and also agree with removing these 34 non-lower limb procedure codes from the proposed list of codes to be reassigned to MS–DRGs 270, 271 and 272. These 34 non-lower limb procedure codes will remain assigned to MS–DRGs 252, 253, and 254 (Other vascular procedures with MCC, with CC, and without CC/MCC, respectively) for FY 2017.

In addition, our clinical advisors agree with the commenter's recommendation to add procedure codes 06CV3Z and 06CY3Z to the list of lower limb procedure codes to be reassigned to MS–DRGs 270, 271, and 272. Therefore, we are reassigning these two procedure codes from MS–DRG 263 (Vein ligation and stripping) and MS–DRGs 252, 253, and 254 to MS–DRGs 270, 271, and 272 for FY 2017.

After consideration of the public comments we received, we are finalizing our proposal with these modifications. We are finalizing the assignment of the ICD–10–PCS procedure codes describing endovascular thrombectomy of the lower limbs listed in the following table to ICD–10 Version 34 MS–DRGs 270, 271 and 272 for FY 2017 (which reflects the removal of the 34 proposed procedure codes and the addition of the 2 procedure codes discussed in our response above).

ICD–10–PCS ENDOVASCULAR THROMBECTOMY PROCEDURE CODES REASSIGNED TO MS–DRGS 270, 271, AND 272 FOR FY 2017

04CK3ZZ	Extirpation of matter from right femoral artery, percutaneous approach.
04CL3ZZ	Extirpation of matter from left femoral artery, percutaneous approach.
04CM3ZZ	Extirpation of matter from right popliteal artery, percutaneous approach.
04CN3ZZ	Extirpation of matter from left popliteal artery, percutaneous approach.
04CP3ZZ	Extirpation of matter from right anterior tibial artery, percutaneous approach.
04CQ3ZZ	Extirpation of matter from left anterior tibial artery, percutaneous approach.
04CR3ZZ	Extirpation of matter from right posterior tibial artery, percutaneous approach.
04CS3ZZ	Extirpation of matter from left posterior tibial artery, percutaneous approach.
04CV3ZZ	Extirpation of matter from right foot artery, percutaneous approach.
04CW3ZZ	Extirpation of matter from left foot artery, percutaneous approach.
04CY3ZZ	Extirpation of matter from lower artery, percutaneous approach.
06CM3ZZ	Extirpation of matter from right femoral vein, percutaneous approach.
06CN3ZZ	Extirpation of matter from left femoral vein, percutaneous approach.
06CP3ZZ	Extirpation of matter from right greater saphenous vein, percutaneous approach.
06CQ3ZZ	Extirpation of matter from left greater saphenous vein, percutaneous approach.
06CR3ZZ	Extirpation of matter from right lesser saphenous vein, percutaneous approach.
06CS3ZZ	Extirpation of matter from left lesser saphenous vein, percutaneous approach.
06CT3ZZ	Extirpation of matter from right foot vein, percutaneous approach.
06CV3ZZ	Extirpation of matter from left foot vein, percutaneous approach.
06CY3ZZ	Extirpation of matter from lower vein, percutaneous approach.

c. Pacemaker Procedures Code Combinations

We received a request that CMS examine the list of ICD–10–PCS procedure code combinations that describe procedures involving pacemakers to determine if some procedure code combinations were excluded from the ICD–10 MS–DRG assignments for MS–DRGs 242, 243, and 244 (Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC). The requestor believed that some ICD–10–PCS procedure code combinations describing procedures involving pacemaker devices and leads are not included in the current list.

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24981 through 24984), we reviewed the list of ICD–10–PCS procedure code combinations describing procedures involving pacemakers assigned to ICD–10 MS–DRGs 242, 243, and 244, and determined that our initial approach of using specified procedure code combinations to identify procedures involving pacemakers and leads was overly complex and may have led to inadvertent omissions of qualifying procedure code combinations. Under our initial approach, we developed a list of possible ICD–10–PCS procedure code combinations that describe procedures involving pacemaker devices and leads as well as ICD–10–PCS procedure code combinations for procedures describing the removal and replacement of pacemaker devices. We stated that we now believe that a more appropriate approach would be to compile a list of all procedure codes describing procedures involving pacemaker devices and a list of all procedure codes describing procedures involving pacemaker leads. If a procedure code from the list of procedure codes describing procedures involving pacemaker devices and a procedure code from the list of procedure codes describing procedures involving pacemaker leads are reported in combination with one another, the case would be assigned to ICD–10 MS–DRGs 242, 243, and 244. We stated that we believe that this more generic approach would capture a wider range of possible reported procedure codes describing procedures involving pacemaker devices and leads. Therefore, we proposed to modify the ICD–10 MS–DRG logic so that if one of the ICD–10–PCS procedure codes describing procedures involving pacemaker devices listed in column 1 of the table below is reported in combination with one of the ICD–10–PCS procedure codes describing procedures involving leads listed in column 3 of the table below, the case would be assigned to MS–DRGs 242, 243, and 244. We stated that we believe that this proposed simplified approach would capture all possible cases reporting procedure code combinations describing procedures involving pacemaker devices and leads to ensure that these cases would be assigned to MS–DRGs 242, 243, and 244.

ICD–10–PCS procedure codes describing procedures involving cardiac pacemaker devices (any one code reported from this column list) (1)		in combination with (2)	ICD–10–PCS procedure codes describing procedures involving cardiac pacemaker leads (any one code reported from this column list) (3)	
Procedure code	Code description		Procedure code	Code description
0JH604Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach.		02H40JZ	Insertion of pacemaker lead into coronary vein, open approach.
0JH605Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach.		02H40MZ	Insertion of cardiac lead into coronary vein, open approach.
0JH606Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach.		02H43JZ	Insertion of pacemaker lead into coronary vein, percutaneous approach.

ICD–10–PCS procedure codes describing procedures involving cardiac pacemaker devices (any one code reported from this column list) (1)		in combination with (2)	ICD–10–PCS procedure codes describing procedures involving cardiac pacemaker leads (any one code reported from this column list) (3)	
Procedure code	Code description		Procedure code	Code description
0JH607Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach.		02H43MZ	Insertion of cardiac lead into coronary vein, percutaneous approach.
0JH60PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach.		02H44JZ	Insertion of pacemaker lead into coronary vein, percutaneous endoscopic approach.
0JH634Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach.		02H44MZ	Insertion of cardiac lead into coronary vein, percutaneous endoscopic approach.
0JH635Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach.		02H60JZ	Insertion of pacemaker lead into right atrium, open approach.
0JH636Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach.		02H60MZ	Insertion of cardiac lead into right atrium, open approach.
0JH637Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach.		02H63JZ	Insertion of pacemaker lead into right atrium, percutaneous approach.
0JH63PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach.		02H63MZ	Insertion of cardiac lead into right atrium, percutaneous approach.
0JH804Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach.		02H64JZ	Insertion of pacemaker lead into right atrium, percutaneous endoscopic approach.
0JH805Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach.		02H64MZ	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach.
0JH806Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach.		02H70JZ	Insertion of pacemaker lead into left atrium, open approach.
0JH807Z	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, open approach.		02H70MZ	Insertion of cardiac lead into left atrium, open approach.
0JH80PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach.		02H73JZ	Insertion of pacemaker lead into left atrium, percutaneous approach.
0JH834Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.		02H73MZ	Insertion of cardiac lead into left atrium, percutaneous approach.
0JH835Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, percutaneous approach.		02H74JZ	Insertion of pacemaker lead into left atrium, percutaneous endoscopic approach.
0JH836Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.		02H74MZ	Insertion of cardiac lead into left atrium, percutaneous endoscopic approach.
0JH837Z	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, percutaneous approach.		02HK0JZ	Insertion of pacemaker lead into right ventricle, open approach.
0JH83PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach.		02HK0MZ	Insertion of cardiac lead into right ventricle, open approach.
			02HK3JZ	Insertion of pacemaker lead into right ventricle, percutaneous approach.
			02HK3MZ	Insertion of cardiac lead into right ventricle, percutaneous approach.
			02HK4JZ	Insertion of pacemaker lead into right ventricle, percutaneous endoscopic approach.
			02HK4MZ	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach.
			02HL0JZ	Insertion of pacemaker lead into left ventricle, open approach.
			02HL0MZ	Insertion of cardiac lead into left ventricle, open approach.

ICD–10–PCS procedure codes describing procedures involving cardiac pacemaker devices (any one code reported from this column list) (1)		in combination with (2)	ICD–10–PCS procedure codes describing procedures involving cardiac pacemaker leads (any one code reported from this column list) (3)	
Procedure code	Code description		Procedure code	Code description
			02HL3JZ	Insertion of pacemaker lead into left ventricle, percutaneous approach.
			02HL3MZ	Insertion of cardiac lead into left ventricle, percutaneous approach.
			02HL4JZ	Insertion of pacemaker lead into left ventricle, percutaneous endoscopic approach.
			02HL4MZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach.
			02HN0JZ	Insertion of pacemaker lead into pericardium, open approach.
			02HN0MZ	Insertion of cardiac lead into pericardium, open approach.
			02HN3JZ	Insertion of pacemaker lead into pericardium, percutaneous approach.
			02HN3MZ	Insertion of cardiac lead into pericardium, percutaneous approach.
			02HN4JZ	Insertion of pacemaker lead into pericardium, percutaneous endoscopic approach.
			02HN4MZ	Insertion of cardiac lead into pericardium, percutaneous endoscopic approach.

We invited public comments on our proposal to modify the MS–DRG logic for MS–DRGs 242, 243, and 244 to establish that cases reporting one ICD–10–PCS code from the list of procedure codes describing procedures involving pacemaker devices and one ICD–10–PCS code from the list of procedure codes describing procedures involving pacemaker leads in combination with one another would qualify the case for assignment to MS–DRGs 242, 243, and 244.

Comment: Commenters supported the proposed updates for MS–DRGs 242, 243, and 244. The commenters stated that the proposed logic is simpler than the prior logic. One commenter stated that the proposal was logical and less complicated and appeared to be able to correctly capture procedures involving pacemaker devices. Several commenters recommended that CMS continue to monitor the impact of this change in future years to determine whether further modifications will be necessary.

Response: We appreciate the commenters' support for our proposed updates to MS–DRGs 242, 243, and 244. We agree that this is a simpler approach to the MS–DRG GROUPER logic. We will continue to monitor this and other related MS–DRGs as we receive ICD–10 claims data.

After consideration of the public comments we received, we are finalizing our proposal to modify the MS–DRG logic for MS–DRGs 242, 243, and 244 to establish that cases reporting one ICD–10–PCS code from the list of procedure codes describing procedures involving pacemaker devices and one ICD–10–PCS code from the list of procedure codes describing procedures involving pacemaker leads in combination with one another will qualify the case for assignment to MS–DRGs 242, 243, and 244.

We also examined our GROUPER logic for MS–DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with and without MCC, respectively). Assignments of cases to these MS–DRGs also include qualifying ICD–10–PCS procedure code combinations describing procedures that involve the removal of pacemaker devices and the insertion of new devices. We believe that this logic may also be overly complex. Moreover, we believe that a more simplified approach would be to compile a list of all ICD–10–PCS procedure codes describing procedures involving cardiac pacemaker device insertions. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24983 through 24984), we proposed this approach for FY 2017. Under the proposed approach, if one of the procedure codes describing procedures involving pacemaker device insertions is reported, and there are no other procedure codes describing procedures involving the insertion of a pacemaker lead reported in combination with one of these procedures, the case would be assigned to MS–DRG 258 and 259. We included in the proposed rule the following listing of ICD–10–PCS procedure codes describing procedures involving pacemaker device insertions that would be assigned to MS–DRG 258 and 259.

PROCEDURE CODES DESCRIBING PROCEDURES INVOLVING CARDIAC PACEMAKER DEVICE INSERTIONS REPORTED WITHOUT ANY OTHER PACEMAKER DEVICE PROCEDURE CODE PROPOSED TO BE ASSIGNED TO ICD–10 MS–DRGS 258 AND 259 FOR FY 2017

Procedure code	Description
0JH604Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach.
0JH605Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach.
0JH606Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach.
0JH607Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach.
0JH60PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach.

PROCEDURE CODES DESCRIBING PROCEDURES INVOLVING CARDIAC PACEMAKER DEVICE INSERTIONS REPORTED WITHOUT ANY OTHER PACEMAKER DEVICE PROCEDURE CODE PROPOSED TO BE ASSIGNED TO ICD–10 MS–DRGS 258 AND 259 FOR FY 2017—Continued

Procedure code	Description
0JH634Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach.
0JH635Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach.
0JH636Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach.
0JH637Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach.
0JH63PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH804Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach.
0JH805Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach.
0JH806Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach.
0JH807Z	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, open approach.
0JH80PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach.
0JH834Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH835Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH836Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH837Z	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH83PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach.

We invited public comments on our proposal to modify the GROUPER logic for MS–DRGs 258 and 259 to establish that a case reporting one procedure code from the proposed rule list of ICD–10–PCS procedure codes describing procedures involving pacemaker device insertions without any other procedure codes describing procedures involving pacemaker leads reported would be assigned to MS–DRGs 258 and 259.

Comment: Commenters supported the proposed updates to MS–DRGs 258 and 259. The commenters stated that the proposed updates appeared to be logical and less complicated and appeared to be able to correctly capture these circumstances.

Response: We appreciate the commenters' support for our proposed updates to MS–DRGs 258 and 259. We agree this approach is logical and less complicated.

After consideration of the public comments we received, we are finalizing our proposal to modify the MS–DRG logic for MS–DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with and without MCC, respectively) to establish that a case reporting one ICD–10–PCS procedure code describing procedures involving pacemaker device insertions without any other procedure codes describing procedures involving pacemaker leads reported is assigned to MS–DRGs 258 and 259 for FY 2017. We are finalizing the table above (which was included in the proposed rule) that lists the ICD–10–PCS procedure codes describing procedures involving pacemaker device insertions without any other procedure codes describing procedures involving pacemaker leads reported that are assigned to MS–DRGs 258 and 259 for FY 2017.

We also point out that the ICD–10–PCS pacemaker codes listed in the following table are classified as non-operating room (non-O.R.) codes within the MS–DRGs. The GROUPER logic will continue to classify these codes as non-O.R. codes. However, a case reporting one of these non-O.R. procedure codes describing procedures involving pacemaker device insertions without any other procedure codes describing procedures involving pacemaker leads reported is assigned to MS–DRGs 258 and 259 within MDC 5 in our final policy.

ICD–10–PCS code (non–O.R.)	Description
0JH604Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach.
0JH605Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach.
0JH606Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach.
0JH634Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach.
0JH635Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach.
0JH636Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach.
0JH637Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach.
0JH804Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach.
0JH805Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach.
0JH806Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach.
0JH834Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH835Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH836Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.

We also examined our GROUPER logic for MS–DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device with MCC, with CC, and without CC/MCC, respectively). Cases assigned to MS–DRGs 260, 261, and 262 also include lists of procedure code combinations describing procedures involving the removal of pacemaker leads and the insertion of new leads, in addition to lists of single procedure codes describing procedures involving the insertion of pacemaker leads, removal of devices, and revision of devices. We stated in the proposed rule that we believe that this logic may also be overly complex. Moreover, we believe that a more simplified approach would be to provide a single list of procedure codes describing procedures involving cardiac pacemaker lead insertions and other related procedures involving device insertions that would be assigned to MS–DRGs 260, 261, and 262. If one of these procedure codes describing procedures involving the insertion of pacemaker leads is reported, and there are no other procedure codes describing procedures involving the insertion of a device reported, the case would be assigned to MS–DRGs 260, 261, and 262. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24984 through 24985), we proposed that the list of ICD–10–PCS procedure codes describing procedures involving pacemaker lead insertion, removal, or revisions and insertion of hemodynamic devices in a table included in the proposed rule (81 FR 24984 through 24985) would be assigned to MS–DRGs 260, 261, and 262. We simply proposed to use a single list of ICD–10–PCS procedure codes to determine the MS–DRG assignment.

We invited public comments on our proposal to modify the GROUPER logic for MS–DRGs 260, 261, and 262 so that cases reporting any one of the ICD–10–PCS procedure codes describing procedures involving pacemakers and related procedures and associated devices listed in the table in the proposed rule would be assigned to MS–DRGs 260, 261, and 262.

Comment: Commenters supported the proposal to modify the GROUPER logic for MS–DRGs 260, 261, and 262 so that cases reporting any one of the ICD–10–PCS procedure codes describing procedures involving pacemakers and related procedures and associated devices listed in the table in the proposed rule would be assigned to MS DRGs 260, 261, and 262. The commenters stated that the proposed updates were logical and less complicated and appeared to be able to correctly capture cardiac pacemaker revisions. However, several of the commenters supporting the proposal pointed out that there were errors in the code titles for codes included in the table labeled ''List of Procedure Codes Proposed to be Assigned to MS–DRGs 260, 261, and 262'' in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24984 through 24985). The commenters stated that the table included errors such as referring to a ''pacemaker'' lead instead of a ''cardiac'' lead in code 02H60MZ (Insertion of Cardiac Lead into Right Atrium, Open Approach) and referring to a ''cardiac'' lead instead of a ''pacemaker'' lead in code 02H63JZ (Insertion of Pacemaker Lead into Right Atrium, Percutaneous Approach). The commenters recommended that CMS correct the code titles to align with the official ICD–10–PCS code titles.

Response: We appreciate the commenter's support for our proposal. In addition, we reviewed the list of codes in the table included in the proposed rule and agree that there were errors in some of the code titles (ICD–10–PCS codes 02H60MZ through 02HN4MZ) in that table. We have corrected these title errors and are finalizing a corrected table below.

After consideration of the public comments we received, we are finalizing our proposal to modify the GROUPER logic for MS–DRGs 260, 261, and 262 so that cases reporting any one of the ICD–10–PCS procedure codes describing procedures involving pacemakers and related procedures and associated devices listed in the corrected table below are assigned to MS DRGs 260, 261, and 262.

LIST OF PROCEDURE CODES ASSIGNED TO MS–DRGS 260, 261, AND 262

Procedure code	Description
02H40JZ	Insertion of pacemaker lead into coronary vein, open approach.
02H40MZ	Insertion of cardiac lead into coronary vein, open approach.
02H43JZ	Insertion of pacemaker lead into coronary vein, percutaneous approach.
02H43MZ	Insertion of cardiac lead into coronary vein, percutaneous approach.
02H44JZ	Insertion of pacemaker lead into coronary vein, percutaneous endoscopic approach.
02H44MZ	Insertion of cardiac lead into coronary vein, percutaneous endoscopic approach.
02H60MZ	Insertion of Cardiac Lead into Right Atrium, Open Approach.
02H63JZ	Insertion of Pacemaker Lead into Right Atrium, Percutaneous Approach.
02H63MZ	Insertion of Cardiac Lead into Right Atrium, Percutaneous Approach.
02H64JZ	Insertion of Pacemaker Lead into Right Atrium, Percutaneous Endoscopic Approach.
02H64MZ	Insertion of Cardiac Lead into Right Atrium, Percutaneous Endoscopic Approach.
02H70JZ	Insertion of Pacemaker Lead into Left Atrium, Open Approach.
02H70MZ	Insertion of Cardiac Lead into Left Atrium, Open Approach.
02H73JZ	Insertion of Pacemaker Lead into Left Atrium, Percutaneous Approach.
02H73MZ	Insertion of Cardiac Lead into Left Atrium, Percutaneous Approach.
02H74JZ	Insertion of Pacemaker Lead into Left Atrium, Percutaneous Endoscopic Approach.
02H74MZ	Insertion of Cardiac Lead into Left Atrium, Percutaneous Endoscopic Approach.
02HK00Z	Insertion of Pressure Sensor Monitoring Device into Right Ventricle, Open Approach.
02HK02Z	Insertion of Monitoring Device into Right Ventricle, Open Approach.
02HK0JZ	Insertion of Pacemaker Lead into Right Ventricle, Open Approach.
02HK0MZ	Insertion of Cardiac Lead into Right Ventricle, Open Approach.
02HK30Z	Insertion of Pressure Sensor Monitoring Device into Right Ventricle, Percutaneous Approach.
02HK32Z	Insertion of Monitoring Device into Right Ventricle, Percutaneous Approach.
02HK3JZ	Insertion of Pacemaker Lead into Right Ventricle, Percutaneous Approach.
02HK3MZ	Insertion of Cardiac Lead into Right Ventricle, Percutaneous Approach.
02HK40Z	Insertion of Pressure Sensor Monitoring Device into Right Ventricle, Percutaneous Endoscopic Approach.
02HK42Z	Insertion of Monitoring Device into Right Ventricle, Percutaneous Endoscopic Approach.
02HK4JZ	Insertion of Pacemaker Lead into Right Ventricle, Percutaneous Endoscopic Approach.
02HK4MZ	Insertion of Cardiac Lead into Right Ventricle, Percutaneous Endoscopic Approach.
02HL0JZ	Insertion of Pacemaker Lead into Left Ventricle, Open Approach.

LIST OF PROCEDURE CODES ASSIGNED TO MS–DRGS 260, 261, AND 262—Continued

Procedure code	Description
02HL0MZ	Insertion of Cardiac Lead into Left Ventricle, Open Approach.
02HL3JZ	Insertion of Pacemaker Lead into Left Ventricle, Percutaneous Approach.
02HL3MZ	Insertion of Cardiac Lead into Left Ventricle, Percutaneous Approach.
02HL4JZ	Insertion of Pacemaker Lead into Left Ventricle, Percutaneous Endoscopic Approach.
02HL4MZ	Insertion of Cardiac Lead into Left Ventricle, Percutaneous Endoscopic Approach.
02HN0JZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach.
02HN0MZ	Insertion of pacemaker lead into pericardium, open approach.
02HN3JZ	Insertion of cardiac lead into pericardium, open approach.
02HN3MZ	Insertion of pacemaker lead into pericardium, percutaneous approach.
02HN4JZ	Insertion of cardiac lead into pericardium, percutaneous approach.
02HN4MZ	Insertion of pacemaker lead into pericardium, percutaneous endoscopic approach.
02PA0MZ	Insertion of cardiac lead into pericardium, percutaneous endoscopic approach.
02PA3MZ	Removal of cardiac lead from heart, open approach.
02PA4MZ	Removal of cardiac lead from heart, percutaneous approach.
02PAXMZ	Removal of cardiac lead from heart, percutaneous endoscopic approach.
02WA0MZ	Revision of cardiac lead in heart, open approach.
02WA3MZ	Revision of cardiac lead in heart, percutaneous approach.
02WA4MZ	Revision of cardiac lead in heart, percutaneous endoscopic approach.
0JH600Z	Insertion of hemodynamic monitoring device into chest subcutaneous tissue and fascia, open approach.
0JH630Z	Insertion of hemodynamic monitoring device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH800Z	Insertion of hemodynamic monitoring device into abdomen subcutaneous tissue and fascia, open approach.
0JH830Z	Insertion of hemodynamic monitoring device into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JPT0PZ	Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, open approach.
0JPT3PZ	Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, percutaneous approach.
0JWT0PZ	Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, open approach.
0JWT3PZ	Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, percutaneous approach.

d. Transcatheter Mitral Valve Repair With Implant

As we did for the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28008 through 28010), for FY 2017, we received a request to modify the MS–DRG assignment for transcatheter mitral valve repair with implant procedures. We refer readers to detailed discussions of the MitraClip® System (hereafter referred to as MitraClip®) for transcatheter mitral valve repair in previous rulemakings, including the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25822) and final rule (76 FR 51528 through 51529) and the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27902 through 27903) and final rule (77 FR 53308 through 53310), in response to requests for MS–DRG reclassification, as well as the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27547 through 27552), under the new technology add-on payment policy. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50575), the application for a new technology add-on payment for MitraClip® was unable to be considered further due to lack of FDA approval by the July 1, 2013 deadline.

In the FY 2015 IPPS/LTCH PPS final rule, we finalized our proposal to not create a new MS–DRG or to reassign cases reporting procedures involving the MitraClip® to another MS–DRG (79 FR 49890 through 49892). Under a separate process, the request for a new technology add-on payment for the MitraClip® System was approved (79 FR 49941 through 49946). As discussed in section II.I.4.e. of the preamble of the proposed rule and this final rule, we proposed to discontinue the new technology add-on payment for MitraClip® for FY 2017 and are finalizing our proposal in this final rule.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49371), we finalized a modification to the MS–DRGs to which the procedure involving the MitraClip® System was assigned. For the ICD–10 based MS–DRGs to fully replicate the ICD–9–CM based MS–DRGs, ICD–10–PCS code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach), which identifies the use of the MitraClip® technology and is the ICD–10–PCS code translation for ICD–9–CM procedure code 35.97 (Percutaneous mitral valve repair with implant), was assigned to new MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectively) and continued to be assigned to MS–DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively). According to the requestor, there are substantial clinical and resource differences between the transcatheter mitral valve repair procedure and other procedures currently grouping to MS–DRGs 273 and 274, which are the focus of the request.

The requestor submitted three options for CMS to consider for FY 2017. The first option was to create a new MS–DRG for endovascular cardiac valve repair with implant; the second option was to reassign cases for the MitraClip® implant from MS–DRGs 273 and 274 to MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with and without MCC, respectively); and the third option was to reassign cases involving the MitraClip® system to another higher paying MS–DRG.

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule, we analyzed claims data from the December 2015 update of the FY 2015 MedPAR file on reported cases of percutaneous mitral valve repair with implant (ICD–9–CM procedure code 35.97) in MS–DRGs 273 and 274. Our findings are shown in the table below.

PERCUTANEOUS MITRAL VALVE REPAIR WITH IMPLANT

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 273—All cases	6,620	8.01	$27,625
MS–DRG 273—Cases with procedure code 35.97	457	7.57	50,560
MS–DRG 274—All cases	14,220	3.46	19,316
MS–DRG 274—Cases with procedure code 35.97	693	2.67	37,686

As shown in the table, the total number of cases reported in MS–DRG 273 was 6,620 and had an average length of stay of 8.01 days and average costs of $27,625. The number of cases reporting the ICD–9–CM procedure code 35.97 in MS–DRG 273 totaled 457 and had an average length of stay of 7.57 days and average costs of $50,560. For MS–DRG 274, there were a total of 14,220 cases with an average length of stay of 3.46 days and average costs of $19,316. There were a total of 693 cases in MS–DRG 274 that reported procedure code 35.97; these cases had an average length of stay of 2.67 days and average costs of $37,686. We recognize that the cases reporting procedure code 35.97 had a shorter length of stay and higher average costs in comparison to all the cases within MS–DRGs 273 and 274.

As stated above, the first option of the requestor was that we create a new MS–DRG for endovascular cardiac valve repair with implant procedures for all cardiac valve repairs. We reviewed the following list of ICD–10–PCS procedure codes that the requestor submitted to comprise this proposed new MS–DRG.

ICD–10–PCS code	Description
02UF37Z	Supplement aortic valve with autologous tissue substitute, percutaneous approach.
02UF38Z	Supplement aortic valve with zooplastic tissue, percutaneous approach.
02UF3JZ	Supplement aortic valve with synthetic substitute, percutaneous approach.
02UF3KZ	Supplement aortic valve with nonautologous tissue substitute, percutaneous approach.
02UG37Z	Supplement mitral valve with autologous tissue substitute, percutaneous approach.
02UG38Z	Supplement mitral valve with zooplastic tissue, percutaneous approach.
02UG3JZ	Supplement mitral valve with synthetic substitute, percutaneous approach.
02UG3KZ	Supplement mitral valve with nonautologous tissue substitute, percutaneous approach.
02UH37Z	Supplement pulmonary valve with autologous tissue substitute, percutaneous approach.
02UH38Z	Supplement pulmonary valve with zooplastic tissue, percutaneous approach.
02UH3JZ	Supplement pulmonary valve with synthetic substitute, percutaneous approach.
02UH3KZ	Supplement pulmonary valve with nonautologous tissue substitute, percutaneous approach.
02UJ37Z	Supplement tricuspid valve with autologous tissue substitute, percutaneous approach.
02UJ38Z	Supplement tricuspid valve with zooplastic tissue, percutaneous approach.
02UJ3JZ	Supplement tricuspid valve with synthetic substitute, percutaneous approach.
02UJ3KZ	Supplement tricuspid valve with nonautologous tissue substitute, percutaneous approach.

The above list of ICD–10–PCS procedure codes are currently assigned to MS–DRGs 216 through 221 (Cardiac Valve and Other Major Cardiovascular Procedures with and without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively), with the exception of procedure code 02UG3JZ, which is assigned to MS–DRGs 273 and 274, as noted earlier in this section.

All 16 of the ICD–10–PCS procedure codes submitted by the requester are comparable translations of ICD–9–CM procedure code 35.33 (Annuloplasty), which also grouped to MS–DRGs 216 through 221. However, ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) is the comparable translation for both ICD–9–CM procedure code 35.33 and ICD–9–CM procedure code 35.97 (Percutaneous mitral valve repair with implant), which group to MS–DRGs 273 and 274 as mentioned previously.

Upon review of the 16 ICD–10–PCS procedure codes submitted for consideration by the requestor, we stated in the proposed rule that we determined that we could not propose the suggestion of a new MS–DRG because the resulting ICD–10 MS–DRG logic would not be an accurate replication of the ICD–9–CM based MS–DRG logic. Specifically, it is not possible to replicate reassigning the percutaneous annuloplasty codes from ICD–9–CM based MS–DRGs 216 through 221 to a new MS–DRG because we cannot isolate those cases from procedure code 35.33. Under ICD–9–CM, procedure code 35.33 does not differentiate the specific type of approach used to perform the procedure. This is in contrast to the 60 comparable ICD–10 code translations that do differentiate among various approaches (open, percutaneous, and percutaneous endoscopic).

As stated previously, if the ICD–9–CM and ICD–10 versions of the MS–DRGs cease to be replications of each other, the relative payment weights (computed using the ICD–9–CM based MS–DRGs) would be inconsistent with the ICD–10 MS–DRG assignment, which may cause unintended payment redistribution. Therefore, we did not propose to create a new MS–DRG for transcatheter mitral valve repair with implant procedures for FY 2017.

The second option in the request was to evaluate reassigning cases involving the MitraClip® to MS–DRGs 266 and 267. This option is not supported for the same reasons provided in previous rulemaking regarding differences between valve replacements and valve repairs. Our clinical advisors did not believe that these procedures are clinically coherent or similar in terms of resource consumption because the MitraClip® technology is utilized for a percutaneous mitral valve *repair,* while the other technologies assigned to MS–DRGs 266 and 267 are utilized for transcatheter/endovascular cardiac valve *replacements.* In addition, if cases involving the MitraClip® were

reassigned to MS–DRGs 266 and 267, they would be overpaid by approximately $10,000 as shown in the table below. Our clinical advisors agreed that we should not propose to reassign endovascular cardiac valve repair procedures to the endovascular cardiac valve replacement MS–DRGs.

ENDOVASCULAR CARDIAC VALVE REPLACEMENT WITH AND WITHOUT MCC

MS–DRG 266—All cases	7,436	8.54	$59,675
MS–DRG 267—All cases	8,480	4.45	47,013

Next, for the proposed rule, we analyzed claims data from the December 2015 update of the FY 2015 MedPAR file relating to the possible reassignment of cases involving the MitraClip® (identified by ICD–9–CM procedure code 35.97) to MS–DRGs 228, 229, and 230 (Other Cardiothoracic Procedures with MCC, with CC, and without CC/MCC, respectively). However, as shown in the findings in the table below, the claims data did not support this option under the current 3-way severity level split. That is, the data findings based on reassignment of MitraClip® cases (ICD–9–CM procedure code 35.97) to MS–DRGs 228, 229, and 230 did not support the required criterion that there be at least a $2,000 difference between subgroups. A reassignment would not meet the requirement for the ''with CC'' and ''without CC/MCC'' subgroups ($34,461 minus $33,216 = $1,245).

OTHER CARDIOTHORACIC PROCEDURES (WITH PROCEDURE CODE 35.97)

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 228—with MCC	1,966	11.53	$51,634
MS–DRG 229—with CC	2,318	6.28	34,461
MS–DRG 230—without CC/MCC	709	3.76	33,216

We then performed additional analysis consisting of the base DRG report for MS–DRGs 228, 229 and 230. As shown in the table below, the average costs between the ''with CC'' and the ''without CC/MCC'' subgroups no longer meet the criterion that there be at least a 20-percent difference in average costs between subgroups. These data findings support collapsing MS–DRGs 228, 229, and 230 from a 3-way severity level split into a 2-way severity level split (with MCC and without MCC) based on 2 years (FY 2014 and FY 2015) of MedPAR data. This option would involve the deletion of an MS–DRG.

OTHER CARDIOTHORACIC PROCEDURES

MS–DRG	Number of cases FY 2015	Average length of stay FY 2015	Average costs FY 2015	Number of cases FY 2014	Average length of stay FY 2014	Average costs FY 2014
MS–DRG 228—with MCC	1,509	12.73	$51,960	1,486	12.75	$50,688
MS–DRG 229—with CC	1,835	7.16	33,786	1,900	7.46	33,277
MS–DRG 230—without CC/MCC	499	4.52	30,697	443	4.84	31,053

In the additional analysis, we evaluated if reassignment of cases reporting ICD–9–CM procedure code 35.97 to this proposed 2-way severity split was supported. We confirmed that the reassignment of ICD–9–CM procedure code 35.97 could be replicated under the ICD–9 MS–DRGs. We believe that deleting MS–DRG 230, revising MS–DRG 229, and reassigning cases with procedure code 35.97 from MS–DRGs 273 and 274 to this new structure would reflect these procedures more accurately in the ICD–10 MS–DRGs. Our clinical advisors agreed with a proposal to delete MS–DRG 230 and reassign cases involving percutaneous mitral valve repair with implant (MitraClip®) to MS–DRG 228 and revised MS–DRG 229. We believe that this approach would maintain clinical coherence for these MS–DRGs and reflect more appropriate payment for procedures involving percutaneous mitral valve repair. The proposed revisions to the MS–DRGs, which include the MitraClip® cases, are shown in the table below.

OTHER CARDIOTHORACIC PROCEDURES

Proposed revised MS–DRGs	Number of cases	Average length of stay	Average costs
MS–DRG 228—with MCC	1,966	11.53	$51,634
MS–DRG 229—without MCC	3, 027	5.69	34,169

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24987 through 24988), for FY 2017, we proposed to collapse MS–DRGs 228, 229, and 230 from three severity levels to two severity levels by deleting MS–DRG 230 and revising MS–DRG 229. We also proposed to reassign ICD–9–CM procedure code 35.97 and the cases

reporting ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) from MS–DRGs 273 and 274 to MS–DRG 228 and proposed revised MS–DRG 229. The title of MS–DRG 229 would be modified as follows to reflect the ''without MCC'' designation. The title of proposed revised MS–DRG 229 would be ''Other Cardiothoracic Procedures without MCC''. The title for MS–DRG 228 would remain the same: MS–DRG 228 (Other Cardiothoracic Procedures with MCC). We invited public comments on our proposals.

We also note that, as discussed earlier in this section of the proposed rule and this final rule, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49371), ICD–10–PCS code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) was assigned to MS–DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively), in addition to new MS–DRGs 273 and 274, to fully replicate the ICD–9–CM based MS–DRG logic for ICD–9–CM procedure code 35.97. We stated that if our proposal in the FY 2017 proposed rule to reassign ICD–10–PCS code 02UG3JZ to MS–DRG 228 and proposed revised MS–DRG 229 was finalized in this FY 2017 IPPS/LTCH PPS final rule, it would eliminate the need to continue having ICD–10–PCS code 02UG3JZ and ICD–9–CM code 35.97 group to MS–DRGs 231 and 232. This is due to the fact that, currently, MS–DRGs 228, 229, and 230 are listed higher than MS–DRGs 231 through 236 in the surgical hierarchy, as shown in the ICD–9 and ICD–10 MS–DRGs Definitions Manual Files in Appendix D—MS–DRG Surgical Hierarchy by MDC and MS–DRG, which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*. Therefore, we stated in the proposed rule that if the proposal is finalized for FY 2017, cases reporting ICD–10–PCS procedure code 02UG3JZ will group to MS–DRG 228 and revised MS–DRG 229 versus MS–DRGs 231 and 232 because of the surgical hierarchy GROUPER logic.

As a result, in the FY 2017 IPPS/LTCH PPS proposed rule, we proposed to remove ICD–10–PCS procedure code 02UG3JZ and ICD–9–CM procedure code 35.97 from the PTCA list in MS–DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively) for FY 2017 if the proposal to reassign ICD–9–CM procedure code 35.97 and the cases reporting ICD–10–PCS procedure codes 02UG3JZ from MS–DRGs 273 and 274 to MS–DRG 228 and proposed revised MS–DRG 229 is finalized. We invited public comments on our proposals.

Comment: A large number of commenters supported the proposal to reassign ICD–9–CM procedure code 35.97 and ICD–10–PCS procedure code 02UG3JZ, which describe a mitral valve repair procedure involving the MitraClip®, from MS–DRGs 273 and 274 to MS–DRG 228 and proposed revised MS–DRG 229. Commenters stated that patient access to the procedure has been very restricted at their institutions due to the financial hardship that results from the current payment inadequacies. Several commenters noted that mitral valve interventions are an integral part of their organizations structural heart disease programs and stated that, with the expiration of the new technology add-on payment effective September 30, 2016, the insufficient payment amount and issues with patient access would only increase.

Other commenters reported that these high-risk degenerative mitral valve patients have no alternative options, are not surgical candidates for open procedures, are generally older, more complex to treat and require greater resources by a multidisciplinary heart team; therefore, the commenters urged CMS to finalize the proposal. According to the commenters, the procedure is labor and time intensive with a higher complexity than traditional percutaneous procedures. Commenters also stated the proposed modifications to the MS–DRG structure will enable more patients to have an improved quality of life. These commenters stated that, for the patients who actually receive a mitral valve repair procedure with the MitraClip®, they have witnessed improved clinical outcomes, such as improvements in their NYHA class designation and walk distances. Other commenters described how patients' families shared the impact of what it meant for their family member to have a new outlook on life after having undergone the procedure. A number of commenters also pointed out the cost savings to Medicare with the procedure, which they stated were evidenced by reduced lengths of stay and decreased heart failure readmissions.

Conversely, a few commenters opposed the proposal to modify the structure of MS–DRGs 228, 229, and 230. These commenters recommended that the only changes made should be for replication of the ICD–9–CM MS–DRG logic. These commenters suggested that, because FY 2016 is the first year of implementation in which CMS will have ICD–10 claims data, CMS allow the data to stabilize prior to evaluating for any proposed changes. The commenters stated that replication is important because both the logic for the proposed MS–DRGs and the data source used to calculate and develop the proposed relative payment weights are based on the same ICD–9–CM MedPAR claims data.

Response: We appreciate the commenters' support of our proposal. With regard to the commenters who opposed the proposal to modify the structure of MS–DRGs 228, 229, and 230 and recommended that the only changes made should be for replication of the ICD–9–CM MS–DRG logic as noted and illustrated in the tables above, the proposal to revise the structure of MS–DRGs 228, 229, and 230 was based on the analysis of claims data from the December 2015 update of the FY 2015 MedPAR file on reported cases of percutaneous mitral valve repair with implant (ICD–9–CM procedure code 35.97) in the ICD–9 based MS–DRGs 273 and 274. The ICD–9–CM data and our clinical advisors supported the reassignment of ICD–9–CM procedure code 35.97 from ICD–9–CM MS–DRGs 273 and 274 to restructured ICD–9–CM MS–DRGs 228 and 229. Therefore, the proposal for restructuring the ICD–10 MS–DRGs is in fact replicating the ICD–9–CM MS–DRG logic that was finalized.

Consistent with how the current FY 2016 relative payment weights are based on the ICD–9–CM diagnosis and procedure codes from the FY 2014 MedPAR claims data that were grouped through the ICD–9–CM version of the FY 2016 GROUPER Version 33, the FY 2017 relative payment weights are based on the ICD–9–CM diagnosis and procedure codes from the FY 2015 MedPAR claims data that were grouped through the ICD–9–CM version of the FY 2017 GROUPER Version 34. We note that we have made the MS–DRG GROUPER and MCE ICD–9–CM Software Version 34 available to the public for use in analyzing ICD–9–CM data to create relative payment weights using ICD–9–CM data on our CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html?DLSort=0&DLEntries=10&DLPage=1&DLSortDir=ascending*.

After consideration of the public comments we received, we are finalizing our proposal to collapse MS–DRGs 228, 229, and 230 from three severity levels to two severity levels by

deleting MS–DRG 230 and revising MS–DRG 229. We also are finalizing our proposal to reassign ICD–9–CM procedure code 35.97 and the cases reporting ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) from MS–DRGs 273 and 274 to MS–DRG 228 and revised MS–DRG 229. The title of revised MS–DRG 229 is finalized as follows to reflect the ''without MCC'' designation, ''Other Cardiothoracic Procedures without MCC''. The title for MS–DRG 228 is finalized as ''MS–DRG 228 (Other Cardiothoracic Procedures with MCC)''. In addition, we are finalizing our proposal to remove ICD–10–PCS procedure code 02UG3JZ and ICD–9–CM procedure code 35.97 from the PTCA list in MS–DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively) for FY 2017. All of these finalized modifications are effective October 1, 2016.

e. MS–DRG 245 (AICD Generator Procedures)

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49369), we stated that we would continue to monitor MS–DRG 245 (AICD Generator Procedures) to determine if the data supported subdividing this base MS–DRG into severity levels. As displayed in the table below, the results of the FY 2015 data analysis showed there were a total of 1,464 cases, with an average length of stay of 5.5 days and average costs of $34,564 for MS–DRG 245.

AICD Generator Procedures

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 245	1,464	5.5	$34,564

We applied the five criteria established in the FY 2008 IPPS final rule (72 FR 47169), as described in section II.F.1.b. of the preamble of the proposed rule and this final rule to determine if it was appropriate to subdivide MS–DRG 245 into severity levels. The table below illustrates our findings.

AICD Generator Procedures

MS–DRG by suggested severity level	Number of cases	Average length of stay	Average costs
MS–DRG 245—with MCC	449	8.37	$40,175
MS–DRG 245—with CC	861	4.59	32,518
MS–DRG 245—without CC/MCC	154	2.86	29,646

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24988 through 24989), based on our analysis of claims data from the December 2015 update of the FY 2015 MedPAR file, the data findings did not support creating new severity levels. The findings showed that the data do not meet the criteria for a 3-way severity level split as the criterion that there be at least a 20-percent difference in average costs between subgroups is not met for the ''with CC'' and ''without CC/MCC'' severity levels. We also looked at the prospect of a 2-way severity level split.

AICD Generator Procedures

MS–DRG by suggested severity level	Number of cases	Average length of stay	Average costs
MS–DRG 245—with MCC	449	8.37	$40,175
MS–DRG 245—without MCC	1,015	4.33	32,081

The findings did show that the data are close to meeting the criteria for a 2-way severity level split of ''with MCC and without MCC.'' However, the required criterion that there must be at least 500 cases in the MCC group is not met.

Therefore, for FY 2017, we did not propose to subdivide MS–DRG 245 into severity levels. We invited public comments on our proposal to maintain the current structure for MS–DRG 245.

Comment: Commenters supported the proposal not to subdivide MS–DRG 245 into severity levels. One commenter agreed that volumes were not sufficient to justify a three-way split in the AICD generator procedures, but neared meeting the levels required for a two-way split (with MCC and without MCC). The commenter requested that we examine the issue for a two-way split again next year.

Response: We appreciate the commenters' support. We agree that the criteria were not met to support the subdivision of MS–DRG 245 into severity levels for FY 2017. We will continue to monitor MS–DRG 245 claim data as we analyze issues for the FY 2018 IPPS/LTCH PPS proposed rule.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current structure of MS–DRG 245 (AICD Generator Procedures) for FY 2017.

6. MDC 6 (Diseases and Disorders of the Digestive System): Excision of Ileum

We received a request to analyze an MS–DRG replication issue from the ICD–9–CM based MS–DRGs to the ICD–10 based MS–DRGs for excision procedures performed on the ileum. Under ICD–9–CM, procedure code 45.62 (Other partial resection of small intestine) was assigned to MS–DRGs 329, 330 and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively). Under the current ICD–10 MS–DRGs

Version 33, ICD–10–PCS procedure code 0DBB0ZZ (Excision of ileum, open approach) is assigned to MS–DRGs 347, 348, and 349 (Anal and Stomal Procedures with MCC, with CC, and without CC/MCC, respectively). The requestor indicated that, despite the variation in terms for ''excision'' and ''resection'' between the two code sets, the surgical procedure to remove a portion of the small intestine, whether it is the ileum, duodenum, or jejunum, has not changed and should not result in different MS–DRG assignments when translated from ICD–9–CM to ICD–10.

We agree that this is a replication error. In addition to ICD–10–PCS code 0DBB0ZZ, we also reviewed the MS–DRG assignments for ICD–10–PCS code 0DBA0ZZ (Excision of jejunum, open approach) and determined the MS–DRG assignment for this code resulted in the same replication error. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24989), we proposed to reassign ICD–10–PCS codes 0DBB0ZZ and 0DBA0ZZ from MS–DRGs 347, 348, and 349 to MS–DRGs 329, 330, and 331, effective with the ICD–10 MS–DRGs Version 34 on October 1, 2016.

We invited public comments on our proposal.

Comment: Many commenters supported our proposal to reassign two ICD–10–PCS procedure codes that identify excision procedures performed on the ileum and jejunum. The commenters believed that the proposal was reasonable, given the data, the ICD–10–PCS codes, and the information provided. One commenter recommended that CMS reassign ICD–10–PCS procedure code 0DB90ZZ (Excision of duodenum, open approach) to ICD–10 MS–DRGs 329, 330, and 331, noting that, as stated in the proposed rule, the requester indicated the surgical procedure to remove a portion of the small intestine, whether it is the ileum, duodenum, or jejunum, has not changed and should not result in different MS–DRG assignments when translated from ICD–9–CM to ICD–10.

Response: We appreciate the commenters' support of our proposal. In response to the commenter's recommendation that we also reassign ICD–10–PCS procedure code 0DB90ZZ to ICD–10 MS–DRGs 329, 330, and 331, we note that, under ICD–9–CM, procedure code 45.31 (Other local excision of lesion of duodenum) is the comparable translation and was assigned to ICD–9 based MS–DRGs 326, 327, and 328 (Stomach, Esophageal and Duodenal Procedures with MCC, with CC and without CC/MCC, respectively). We did not include ICD–10–PCS procedure code 0DB90ZZ in our proposal because, upon review, we determined that this code is currently assigned to ICD–10 MS–DRGs 326, 327, and 328 (Stomach, Esophageal and Duodenal Procedures with MCC, with CC and without CC/MCC, respectively), and therefore, is accurately replicating the ICD–9 based MS–DRG logic.

After consideration of the public comments we received, we are finalizing our proposal to reassign ICD–10–PCS procedure codes 0DBB0ZZ (Excision of ileum, open approach) and 0DBA0ZZ (Excision of jejunum, open approach) from MS–DRGs 347, 348, and 349 (Anal and Stomal Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively) effective with the ICD–10 MS–DRGs Version 34 on October 1, 2016.

7. MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas): Bypass Procedures of the Veins

We received a request to assign ICD–10–PCS code 06183DY (Bypass portal vein to lower vein with intraluminal device, percutaneous approach) to MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas) under MS–DRGs 405, 406, and 407 (Pancreas Liver and Shunt Procedures with MCC, with CC, and without CC/MCC, respectively). The requestor described this code as capturing a transjugular intrahepatic portosystem shunt procedure. The requestor stated that, under ICD–9–CM, when a procedure for cirrhosis of the liver was performed, the procedure was assigned to ICD–9–CM code 39.1 (Intra-abdominal venous shunt). The requestor noted that when ICD–9–CM procedure code 39.1 is reported with a principal diagnosis of cirrhosis of the liver, the procedure was assigned to MS–DRG 405, 406, or 407 in the ICD–9–CM MS–DRGs.

Currently, ICD–10–PCS procedure code 06183DY is assigned to only MDC 5 (Diseases and Disorders of the Circulatory System) and MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively) under ICD–10 MS–DRGs Version 33. The requestor stated that ICD–10–PCS procedure code 06183DY should also be assigned to MDC 7 and MS–DRGs 405, 406, and 407 to be consistent with the ICD–9–CM MS–DRGs Version 32.

We analyzed this issue and agreed that the ICD–10 MS–DRGs do not fully replicate the ICD–9–CM MS–DRGs. We agree that ICD–10–PCS procedure code 06183DY should be assigned to MDC 7 and MS–DRGs 405, 406, and 407 to replicate the ICD–9–CM MS–DRGs. Our clinical advisors reviewed this issue and also agreed that ICD–10–PCS procedure code 06183DY should be assigned to MDC 7 and MS–DRGs 405, 406, and 407. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24989), we proposed to assign ICD–10–PCS procedure code 06183DY to MDC 7 and MS–DRGs 405, 406, and 407 for FY 2017.

We invited public comments on our proposal.

Comment: Commenters supported the proposal to assign ICD–10–PCS procedure code 06183DY to MDC 7 under MS–DRGs 405, 406, and 407. One commenter stated that the proposed change to MDC 7 and MS–DRGs 405, 406, and 407 is a more appropriate fit for ICD–10–PCS procedure code 06183DY.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to assign ICD–10–PCS code 06183DY (Bypass portal vein to lower vein with intraluminal device, percutaneous approach) to MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas) under MS–DRGs 405, 406, and 407 (Pancreas Liver and Shunt Procedures with MCC, with CC, and without CC/MCC, respectively).

8. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Updates to MS–DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity With and Without MCC, Respectively)

(1) Total Ankle Replacement (TAR) Procedures

We received a request to create a new MS–DRG for total ankle replacement (TAR) procedures, which are currently assigned to MS–DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with and without MCC, respectively). We previously discussed requested changes to the MS–DRG assignment for TAR procedures in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28013 through 28015) and in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49896 through 49899). For FY 2015, we did not change the MS–DRG assignment for total ankle replacements. The requestor stated that reassigning total ankle replacement procedures from MS–DRGs 469 and 470 to a new MS–DRG would have an important benefit for the new

Medicare Comprehensive Care for Joint Replacement (CJR) model. The commenter noted that because total ankle replacement cases currently are assigned to MS–DRGs 469 and 470, they are included in the model.

Ankle replacement procedures were captured by ICD–9–CM code 81.56 (Total ankle replacement). As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24989 through 24990), we examined claims data for total ankle procedures using the December 2015 update of the FY 2015 MedPAR file. Our findings are displayed in the table below.

TOTAL ANKLE REPLACEMENT CASES REPORTED IN MS–DRGS 469 AND 470

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 469—All cases	25,729	6.92	$22,358
MS–DRG 469—Total ankle replacement cases	30	5.40	34,889
MS–DRG 470—All cases	421,149	2.92	14,834
MS–DRG 470—Total ankle replacement cases	1,626	1.94	20,019

As the total ankle replacement claims data analysis showed, these procedures represent a small fraction of the total number of cases reported in MS–DRGs 469 and 470. There were 30 total ankle replacement cases reported in MS–DRG 469 and 1,626 total ankle replacement cases in MS–DRG 470, compared to 25,729 total cases reported in MS–DRG 469 and 421,149 total cases reported in MS–DRG 470. The average length of stay for total ankle replacement cases was 5.40 days and average costs for total ankle replacement cases were $34,889 reported in MS–DRG 469, compared to average length of stay of 6.92 days and average costs of $22,358 for all cases reported in MS–DRG 469. The average length of stay for total ankle replacement cases was 1.94 days and average costs of total ankle replacement cases were $20,019 reported in MS–DRG 470, compared to an average length of stay of 2.92 days and average costs of $14,834 for all cases reported in MS–DRG 470.

Given the low volume of cases, we stated in the proposed rule that we believe these cost data may not be a complete measure of actual differences in inpatient resource utilization for beneficiaries receiving total ankle replacements. In addition, these total ankle replacement cases may have been impacted by other factors such as complication or comorbidities. Several expensive cases could impact the average costs for a very small number of patients. The average cost of total ankle replacement cases reported in MS–DRG 469 was $12,531 higher than all cases reported in MS–DRG 469 ($34,889 compared to $22,358 for all reported cases), but there were only 30 cases compared to a total of 25,729 cases reported in MS–DRG 469. The average cost of total ankle replacement cases reported in MS–DRG 470 was $5,185 higher than all cases reported in MS–DRG 470. There were 1,626 total ankle replacement cases out of a total of 421,149 cases reported in MS–DRG 470. The average costs of the total ankle replacement cases were higher than those for all cases reported in MS–DRG 469 and 470. However, some cases have higher and some cases have lower average costs within any MS–DRG. MS–DRGs are groups of clinically similar cases that have similar overall costs. Within a group of cases, one would expect that some cases have costs that are higher than the overall average and some cases have costs that are lower than the overall average.

The data did not support creating a new total ankle replacement MS–DRG for this small number of cases. Also, our clinical advisors pointed out that creating a new MS–DRG for total ankle replacements would result in combining cases reporting an MCC with an average length of stay of 5.40 days and cases not reporting an MCC with an average length of stay of 1.94 days. Our clinical advisors did not recommend the creation of a new MS–DRG for this single procedure with such a small number of cases. They also stated that patients undergoing total ankle replacement have similar clinical features compared to other patients undergoing procedures included in MS–DRGs 469 and 470. Furthermore, we believe that the volume of total ankle replacement procedures performed relative to hip and knee replacement procedures minimizes the benefit that a new MS–DRG would have on the Medicare CJR model. Our clinical advisors determined that the cases involving total ankle replacements are more appropriately assigned to MS–DRGs 469 and 470 with the two severity levels.

Based on the findings from our data analysis and the recommendations from our clinical advisors, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24989 through 24990), we did not propose to create a new MS–DRG for total ankle replacement procedures. We proposed to maintain the current MS–DRG structure for MS–DRGs 469 and 470.

We invited public comments on this proposal.

Comment: Some commenters supported the proposal to maintain the current MS–DRG structure for revision of total ankle replacement procedures within MS–DRGs 469 and 470 and not create a new MS–DRG for total ankle replacements. Several of the commenters stated that the proposal was reasonable, given the data, the ICD–10–PCS codes, and the information provided.

Response: We appreciate the commenters' support for our proposal.

Comment: Several commenters disagreed with the proposal not to create a new MS–DRG for total ankle replacement procedures and to maintain the current MS–DRG structure for MS–DRGs 469 and 470 for total ankle replacement procedures. The commenters stated that the current MS–DRG assignment for TAR procedures was inadequate to reflect the actual cost and complexity of these procedures. The commenters stated that the combined total ankle replacement cases in MS–DRGs 469 and 470 exceeds the minimum number of cases (500) in the criterion which CMS established for consideration of a distinct MS–DRG group. Therefore, the commenters believed that CMS should create a new MS–DRG for total ankle replacements.

The commenters stated that the MS–DRG assignment was impacting Medicare beneficiary access to total ankle replacement as an alternative to an arthrodesis (fusion) of the ankle joint. The commenters further stated that there were significant dissimilarities in the inpatient hospital costs and length of stay, and different postoperative and postdischarge care and rehabilitation protocols for total ankle replacement procedures.

One commenter objected to CMS' comparison of the volume of total ankle replacement cases to total hip and knee cases within MS–DRG 469 and 470 and the statement that, within the inpatient prospective payment system framework, some cases have higher and some cases have lower average costs within any MS–DRG. The commenter stated that CMS' statements about possible explanations for the higher costs of total ankle replacement cases within MS–DRGs 469 and 470 does not change the fact that the total ankle replacement cases have higher costs than all cases within MS–DRGs 469 and 470. The commenter stated that total ankle replacement cases have a greater clinical complexity compared to other procedures within MS–DRGs 469 and 470. The commenter stated that a total ankle replacement procedure was a complicated surgery that involved the replacement of the damaged parts of the three bones that make up the ankle joint, as compared to two bones in hip and knee replacement procedures. Furthermore, as the smallest weight-bearing large joint in the body, the commenter stated that total ankle replacement demanded a complexity of implant device design, engineering, and manufacture to exacting functional specifications that is vastly different from that of total hip and total knee replacement devices. In addition, the commenter stated that the unique anatomical characteristics and function of the ankle joint requires a specialized surgical skill set, operative technique, and level of operating room resource utilization that is vastly dissimilar from that of total hip and total ankle replacement procedures.

Another commenter stated that accurate representation of patients within each MS–DRG is an important step for fair payment and analysis. The commenter believed that reassigning fractures and ankle procedures from MS–DRGs 469 and 470 would help to accomplish that purpose. Another commenter asked that CMS reexamine the appropriate MS–DRG assignment for total ankle replacement procedures once ICD–10 claims data are available.

Response: We disagree with the commenters' statement that the number of total ankle replacement cases in MS–DRGs 469 and 470 justifies the creation of a new MS–DRG based on the criterion of there being more than 500 cases. The criterion the commenters mentioned is part of criteria established in FY 2008 (72 FR 47169) to determine if the creation of a new CC or MCC subgroup within a base MS–DRG was warranted (which was discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24971)), but is not determinative of whether a new MS–DRG should be created.

As stated earlier, the data showed that the average costs of total ankle replacement cases were higher than the average costs for all cases reported in MS–DRG 469 and 470. We found that the average costs of total ankle replacement procedures were higher in MS–DRG 469 ($34,889 compared to $22,358 for all cases) and in MS–DRG 470 ($20,019 compared to $14,834 for all cases). However, there were only 30 total ankle replacement cases in MS–DRG 469 out of 25,729 total cases. There were only 1,626 cases in MS–DRG 470 out of 421,149 cases.

As we explained in the proposed rule, given the low volume of cases, we believe that these cost data may not be a complete measure of actual differences in inpatient resource utilization for beneficiaries receiving total ankle replacements. Several expensive cases could impact the average costs for a very small number of patients. MS–DRGs are groups of clinically similar cases that have similar overall costs. Within a group of cases, one would expect that some cases have costs that are higher than the overall average and some cases have costs that are lower than the overall average. While the commenters disagreed with this approach to classifying similar procedures within a set of MS–DRGs, our clinical advisors reviewed the procedures assigned within MS–DRGs 469 and 470 and determined that patients undergoing total ankle replacement have similar clinical features compared to other patients undergoing procedures included in MS–DRGs 469 and 470. The clinical differences are not great enough to justify the creation of a new MS–DRG. While the ankle may be the smallest weight-bearing joint in the body and the devices used may be more costly, the joint repairs of the lower extremity are clinically similar. The clinical expertise used by surgeons performing ankle procedures versus the clinical expertise required to perform other lower joint procedures does not justify creating a new MS–DRG. Our clinical advisors determined that the cases involving total ankle replacements are appropriately assigned to MS–DRGs 469 and 470 with the two severity levels.

In response to the commenter's request that CMS reexamine the appropriate MS–DRG assignment for total ankle replacement procedures once ICD–10 claims data are available, we encourage requests for MS–DRG updates to be submitted by December 7 of each year via the new CMS MS–DRG Classification Change Requests Mailbox located at: *MSDRGClassification Change@cms.hhs.gov.* Once ICD–10 claims dara are received, we will use these data to evaluate MS–DRG assignments.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current MS–DRG assignment for total ankle replacements in MS–DRGs 469 and 470 and not create a new MS–DRG for total ankle replacements.

(2) Hip Replacement Procedures With Principal Diagnosis of Hip Fracture

We received several requests to remove hip replacement procedures with a principal diagnosis of hip fracture from MS–DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with and without MCC, respectively) and to create a new MS–DRG for assignment of these hip replacement procedures. One requestor suggested that if such a new MS–DRG could not be created, CMS consider reassigning all hip replacement procedures with a principal diagnosis of hip fracture only to MS–DRG 469, even if there were no reported MCC.

The requestors stated that hip replacement procedures performed on patients with hip fractures involve a more fragile population of patients than the typical patient population who undergo elective hip or knee replacement and that these more fragile patient cases also are assigned to MS–DRGs 469 and 470. The requestors stated that cases of patients who have hip replacements with hip fractures may have significant comorbidities not present in patients who undergo elective hip replacements. One requestor stated that the absolute number of hospitalizations for hip fractures in the United States is currently more than 350,000 and the number is rising. The requestor stated that 90 percent of hip fractures result from a simple fall, and that hip fracture rates increase with age. According to the requestor, the 1-year mortality rate for patients who undergo hip replacement procedures after a hip fracture was approximately 20 percent, and the 3-year mortality rate was up to 50 percent. The requestor also stated that one out of three adults who lived independently before their hip fracture remains in a nursing home for at least a year after the hip fracture. In contrast, the requestor noted that patients under elective hip replacement procedures for arthritis have fewer comorbidities, improved health after the procedure, low rates of readmission, and less postacute needs. The requestor believed that there are

many factors that impact the outcome of hip replacements for hip fractures, including patient factors, fracture type, surgeon and hospital factors, treatment decisions, complication rates, and rehabilitation factors/access. The requestor added that, despite the commitment to standardization, the use of protocol-driven care, early surgery (< 24 hours) after surgical optimization, prevention of recurrent fractures, and comanagement with medical/surgical teams, many patients who undergo hip replacement procedures for hip fractures have serious renal, cardiovascular, and liver disease, as well as multiple medical comorbidities. The rates of postoperative infections, readmissions, and postacute care for the patients who undergo hip replacements for hip fractures are higher than for patients who undergo elective hip replacement. Some requestors referenced the Bundled Payments for Care Improvement Initiative (BPCI) and believed that their requested changes to MS–DRGs 469 and 470 would support this effort. The requestors stated that the MS–DRG assignment for the hip replacement procedures with hip fractures has tremendous implications for successful participation in the BPCI because the BPCI's clinical episodes track to MS–DRG assignment, and the Major Joint Replacement of the Lower Extremity Clinical Episode encompasses procedures assigned to MS–DRGs 469 and 470. Alternatively, the requestors suggested that CMS reassign all cases of hip replacement procedures with a principal diagnosis of hip fracture to MS–DRG 469 to recognize the more significant adverse health profile of these types of cases.

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24990 through 24992), we examined claims data for cases reporting hip replacement procedures for patients admitted with hip fractures under MS–DRGs 469 and 470 in the December 2015 update of the FY 2015 MedPAR file. We used the following list of ICD–9–CM diagnosis codes to identify cases representing hip replacements for hip fractures:

ICD–9–CM Diagnosis Codes Reviewed for Cases Representing Hip Replacement for Hip Fractures

ICD–9–CM diagnosis code	Descriptions
733.14	Pathological fracture of neck of femur.
733.15	Pathological fracture of other specified part of femur.
733.81	Malunion of fracture.
733.82	Nonunion of fracture.
733.96	Stress fracture of femoral neck.
808.0	Closed fracture of acetabulum.
808.1	Open fracture of acetabulum.
820.8	Fracture of unspecified part of neck of femur closed.
820.9	Fracture of unspecified part of neck of femur open.
820.00	Fracture of unspecified intracapsular section of neck of femur closed.
820.01	Fracture of epiphysis (separation) (upper) of neck of femur closed.
820.02	Fracture of midcervical section of femur closed.
820.03	Fracture of base of neck of femur closed.
820.09	Other transcervical fracture of femur closed.
820.10	Fracture of unspecified intracapsular section of neck of femur open.
820.11	Fracture of epiphysis (separation) (upper) of neck of femur open.
820.12	Fracture of midcervical section of femur open.
820.13	Fracture of base of neck of femur open.
820.19	Other transcervical fracture of femur open.
820.20	Fracture of unspecified trochanteric section of femur closed.
820.21	Fracture of intertrochanteric section of femur closed.
820.22	Fracture of subtrochanteric section of femur closed.
820.30	Fracture of unspecified trochanteric section of femur open.
820.31	Fracture of intertrochanteric section of femur open.
820.32	Fracture of subtrochanteric section of femur open.

Our findings from our examination of the data are shown in the table below.

Cases of Hip Replacements With and without Principal Diagnosis of Hip Fracture

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 469—All cases	25,729	6.9	$22,358
MS–DRG 469—Hip replacement cases with hip fractures	14,459	7.9	22,852
MS–DRG 469—Hip replacement cases without hip fractures	4,714	5.7	22,430
MS–DRG 470—All cases	421,149	2.9	14,834
MS–DRG 470—Hip replacement cases with hip fractures	49,703	4.7	15,795
MS–DRG 470—Hip replacement cases without hip fractures	125,607	2.6	14,870

For MS–DRG 469, the average costs of all 25,729 reported cases were $22,358 and the average length of stay was 6.9 days. Within MS–DRG 469, there were 14,459 cases of hip replacements with hip fractures reported, with average costs of $22,852 and an average length of stay of 7.9 days. Within MS–DRG 469, there were 4,714 cases of hip replacements without hip fractures reported, with average costs of $22,430 and an average length of stay of 5.7

days. The average costs of reported cases of hip replacements with hip fractures are similar to the average costs of all cases reported within MS–DRG 469 ($22,852 compared to $22,358), and to the average costs of reported cases of hip replacements without hip fractures ($22,852 compared to $22,430). However, the average length of stay for cases of hip replacements with hip fractures reported in MS–DRG 469 is higher than the average length of stay for all cases reported in MS–DRG 469 and for cases of hip replacements without hip fractures reported in MS–DRG 469 (7.9 days compared to 6.9 days and 5.7 days, respectively.)

For MS–DRG 470, the average costs of all 421,149 cases reported were $14,834 and the average length of stay was 2.9 days. Within MS–DRG 470, there were 49,703 reported cases of hip replacements with hip fractures, with average costs $15,795 and an average length of stay of 4.7 days. Within MS–DRG 470, there were 125,607 cases of hip replacements without hip fractures reported, with average costs of $14,870 and an average length of stay of 2.6 days. However, the average length of stay for cases of hip replacements with hip fractures reported in MS–DRG 470 was higher than the average length of stay for all cases and for cases of hip replacements without hip fractures reported in MS–DRG 470 (4.7 days compared to 2.9 days and 2.6 days, respectively). Therefore, the average costs of cases of hip replacements with hip fractures were similar for both MS–DRG 469 and MS–DRG 470 ($22,852 compared to $22,358 and $15,795 compared to $14,834, respectively). However, the average lengths of stay are longer for cases of hip replacements with hip fractures compared to all cases reported in both MS–DRGs 469 and 470 (7.9 days compared to 6.9 days and 4.7 days compared to 2.9 days, respectively).

The claims data did not support creating a new MS–DRG for the assignment of cases of hip replacements with hip fractures. As discussed earlier, the average costs for cases of hip replacements with hip fractures reported in MS–DRG 469 and MS–DRG 470 are similar to the average costs for all cases reported in MS–DRG 469 and MS–DRG 470. While the average length of stay is longer for cases of hip replacements with hip fractures than for cases of hip replacements without hip fractures reported within MS–DRGs 469 and 470, the increased length of stay did not impact the average costs of reported cases in either MS–DRG 469 or 470. The data showed that cases of hip replacement procedures are clearly influenced by the presence of an MCC. The average costs of all cases reported in MS–DRG 469, which identifies an MCC, were $22,358, compared to average costs of $14,834 for all cases reported in MS–DRG 470, which did not identify an MCC. The data showed that the presence of a principal diagnosis of a hip fracture did not impact the average costs of cases reported in either MS–DRG 469 or MS–DRG 470.

We also examined the data in relation to the request to reassign all procedures of hip replacement with hip fractures from MS–DRG 470 to MS–DRG 469, even if there is no MCC present. The data showed that the 49,703 cases of hip replacements with hip fractures reported in MS–DRG 470 have average costs of $15,795 and an average length of stay of 4.7 days. The 25,729 total cases of hip replacements reported in MS–DRG 469 have average costs of $22,358 and an average length of stays of 6.9 days. Therefore, the data for average costs and average length of stay for all cases involving hip replacement procedures with hip fractures reported in MS–DRG 470 do not support reassigning all cases of hip replacement procedures with hip fractures to MS–DRG 469, even if there is no MCC present.

Our clinical advisors reviewed this issue and agreed that the hip replacement procedures performed for patients with hip fractures are appropriately assigned to MS–DRGs 469 and 470. They did not support reassigning these procedures from MS–DRGs 469 and 470 to a new MS–DRG or reassigning all cases of hip replacement procedures with hip fractures to MS–DRG 469, even if the case does not have an MCC. Our clinical advisors stated that the surgical techniques used for hip replacements are similar for all patients. They advised that the fact that some patients also had a hip fracture would not justify creating a new MS–DRG or reassigning all cases of hip replacement procedures with hip fractures to MS–DRG 469. Our clinical advisors noted that the costs of cases of hip replacements are more directly impacted by the presence or absence of an MCC than the presence or absence of a hip fracture.

Based on the findings from our data analyses and the recommendations from our clinical advisors, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24990 through 24992), we did not propose to create a new MS–DRG for the assignment of procedures involving hip replacement in patients who have hip fractures or to reassign all procedures involving hip replacements with hip fractures to MS–DRG 469 even if there is no MCC present. We proposed to maintain the current MS–DRG structure for MS–DRGs 469 and 470.

We invited public comments on our proposals.

Comment: Several commenters supported the proposal to maintain the current MS–DRG structure for hip replacement procedures with a principal diagnosis of hip fractures within MS–DRGs 469 and 470. They did not support the creation of a new MS–DRG for hip replacement procedures with a principal diagnosis of hip fractures. The commenters stated that the proposal was reasonable, given the data, the ICD–10–CM and ICD–10–PCS codes, and the information provided.

Response: We appreciate the commenters' support for the proposal.

Comment: Several commenters expressed concern with the current MS–DRG assignment for hip replacement procedures with a principal diagnosis of hip fractures. One commenter recommended that CMS consider creating an MS–DRG or reassigning all hip replacement procedures with a principal diagnosis of hip fracture only to MS–DRG 469, even if there were no reported MCC. The commenter recognized that the claims data presented in the proposed rule did not show significantly different average costs for hip replacement procedures with a principal diagnosis of hip fractures. However, the commenter stated that the average length of stay and the patient profile are different for hip replacement procedures with a principal diagnosis of hip fractures.

Response: We agree with the commenter that the claims data do not show significant differences between the average costs for hip replacement procedures with a principal diagnosis of hip fractures and those without a hip fracture. For this reason and the reasons stated in the proposed rule, the claims data did not support creating a new MS–DRG for the assignment of cases of hip replacements with hip fractures. As discussed in the proposed rule and earlier in this final rule, the average costs for cases of hip replacements with hip fractures reported in MS–DRG 469 and MS–DRG 470 are similar to the average costs for all cases reported in MS–DRG 469 and MS–DRG 470. While the average length of stay is longer for cases of hip replacements with hip fractures than for cases of hip replacements without hip fractures reported within MS–DRGs 469 and 470, the increased length of stay did not impact the average costs of reported cases in either MS–DRG 469 or 470. In response to the commenter's recommendation that CMS consider

reassigning all hip replacement procedures with a principal diagnosis of hip fracture only to MS–DRG 469, even if there is no reported MCC, we also examined the data in relation to the request to reassign all procedures of hip replacement with hip fracture to MS–DRG 469, even if there is no reported MCC. As discussed in the proposed rule and earlier in this final rule, the data for average costs and average length of stay for all cases involving hip replacement procedures with hip fractures reported in MS–DRG 470 do not support reassigning all cases of hip replacement procedures with hip fractures to MS–DRG 469, even if there is no MCC present.

After consideration of the public comments we received, we are finalizing our proposal to maintain the MS–DRG assignment for hip replacements with a principal diagnosis of hip fractures in MS–DRGs 469 and 470 and not create a new MS–DRG for hip replacements with a principal diagnosis of hip fractures.

b. Revision of Total Ankle Replacement Procedures

(1) Revision of Total Ankle Replacement Procedures

We received a request to modify the MS–DRG assignment for revision of total ankle replacement procedures. Currently, these procedures are assigned to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC and without CC/MCC, respectively). This topic was discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28013 through 28015) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49896 through 49899). However, at that time, we did not change the MS–DRG assignment for revisions of total ankle replacement procedures.

The requestor presented two options for consideration for modifying the MS–DRG assignment for the revisions of total ankle replacement procedures. The requestor's first option was to create a new MS–DRG for the assignment of revision of total ankle replacement procedures. The requestor believed that a new MS–DRG would be justified based on the distinct costs, resources, and utilization associated with ankle joint revision cases. The requestor's second option was to reassign revision of total ankle replacement procedures to MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively) and rename MS–DRGs 466, 467, and 468 as ''Revision of Hip, Knee, or Ankle with MCC, with CC, and without CC/MCC'', respectively. The requestor believed that this second option would be justified because it is a reasonable, temporary approach until CMS has sufficient utilization and cost data for revision of total ankle replacement procedures based on the reporting of the new and more specific ICD–10–PCS procedure codes. The requestor pointed out that the following more specific ICD–10–PCS procedure codes were implemented effective October 1, 2015, with the implementation of ICD–10. The requestor stated that these new codes will provide improved data on these procedures that can be analyzed for future MS–DRG updates.

ICD–10–PCS procedure code	Description
0SWF0JZ	Revision of synthetic substitute in right ankle joint, open approach.
0SWF3JZ	Revision of synthetic substitute in right ankle joint, percutaneous. approach.
0SWF4JZ	Revision of synthetic substitute in right ankle joint, percutaneous endoscopic approach.
0SWFXJZ	Revision of synthetic substitute in right ankle joint, external approach.
0SWG0JZ	Revision of synthetic substitute in left ankle joint, open approach.
0SWG3JZ	Revision of synthetic substitute in left ankle joint, percutaneous approach.
0SWG4JZ	Revision of synthetic substitute in left ankle joint, percutaneous endoscopic approach.
0SWGXJZ	Revision of synthetic substitute in left ankle joint, external approach.

We agree with the requestor that the previous code used to identify revisions of total ankle replacement procedures, ICD–9–CM procedure code 81.59 (Revision of joint replacement of lower extremity, not elsewhere classified), is not as precise as the new ICD–10–PCS procedure codes that were implemented on October 1, 2015. As discussed in the FY 2015 IPPS/LTCH PPS proposed rule and final rule, ICD–9–CM procedure code 81.59 included procedures involving revisions of joint replacements of a variety of lower extremity joints, including the ankle, foot, and toe. Therefore, the ICD–9–CM procedure code does not provide precise information on the number of revisions of total ankle replacement procedures as do the ICD–10–PCS procedure codes listed above. We also agree that the ICD–10–PCS procedure codes will provide more precise data on revisions of ankle replacements.

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24992 through 24993), we examined claims data from the December 2015 update of the FY 2015 MedPAR file on cases reporting procedure code 81.59 in MS–DRGs 515, 516, and 517. The table below shows our findings.

REVISIONS OF JOINT REPLACEMENTS PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 515—All cases	3,852	8.54	$21,900
MS–DRG 515—Cases reporting procedure code 81.59	2	7.00	36,983
MS–DRG 516—All cases	8,567	5.24	14,839
MS–DRG 516—Cases reporting procedure code 81.59	19	3.74	14,957
MS–DRG 517—All cases	5,664	3.20	12,979
MS–DRG 517—Cases reporting procedure code 81.59	47	1.89	16,524

As can be seen from the data in the above table, there were only 68 total cases reported with procedure code 81.59 among MS–DRGs 515, 516, and 517: 2 cases in MS–DRG 515; 19 cases in MS–DRG 516; and 47 in MS–DRG 517. We point out that while there were 68 total cases reported with procedure code 81.59 in MS–DRGs 515, 516, and 517, we are unable to determine how many of these cases were actually revisions of ankle replacements versus other revisions of joint replacement of lower extremities such as those of the foot or toe. This small number of cases does not justify creating a new MS–DRG as suggested by the requestor in its first option.

While the average costs of cases reporting procedure code 81.59 in MS–DRG 515 were $36,983, compared to $21,900 for all cases reported in MS–DRG 515, there were only 2 cases reporting procedure code 81.59 in MS–DRG 515, of the 3,852 total cases reported in MS–DRG 515. In MS–DRG 516, the average costs of the 19 cases reporting procedure code 81.59 were $14,957, which is very close to the average costs of $14,839 for all 8,567 cases reported in MS–DRG 516. The average costs for cases reporting procedure code 81.59 in MS–DRG 517 were higher than the average costs for all cases reported in MS–DRG 517 ($16,524 for cases reporting procedure code 81.59 compared to $12,979 for all cases reported in MS–DRG 517). While the average costs for cases reporting procedure code 81.59 were $3,545 higher than all cases reported in MS–DRG 517, we point out that there were only 47 cases that reported procedure code 81.59 out of the 5,664 total cases reported in MS–DRG 517. The relatively small number of cases may have been impacted by other factors. Several expensive cases could impact the average costs for a very small number of patients.

As stated by the requestor, we do not yet have data using the more precise ICD–10–PCS revisions of total ankle replacement procedure codes that were implemented on October 1, 2015. These new codes will more precisely identify the number of patients who had a revision of total ankle replacement procedure and the number of patients who had revisions of other lower joint replacement procedures such as the foot or toe. The available clinical data from the December 2015 update of the FY 2015 MedPAR file do not support the creation of a new MS–DRG for the assignment of revisions of total ankle replacement procedures or the reassignment of these cases to other MS–DRGs, such as MS–DRGs 466, 467, and 468, because there were so few cases and because we could not determine how many of these cases were revisions of ankle replacements. Claims data on the ICD–10–PCS codes will not be available until 2 years after the implementation of the codes, which was October 1, 2015.

Our clinical advisors reviewed this issue and determined that the revision of total ankle replacement procedures are appropriately classified within MS–DRGs 515, 516, and 517 along with other orthopedic procedures captured by nonspecific codes. They did not support reassignment of the procedures to MS–DRGs 466, 467, and 468 until such time as detailed data for ICD–10–PCS claims are available to evaluate revision of total ankle replacement procedures. Therefore, based on the findings of our analysis of claims data and the advice of our clinical advisors, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24992 through 24993), we proposed to maintain the current MS–DRG assignment for revision of total ankle replacement procedures for FY 2017.

We invited public comments on our proposal.

Comment: Commenters supported the proposal to maintain the current MS–DRG structure for revision of total ankle replacement procedures within MS–DRGs 515, 516, and 517. The commenters stated that the proposal was reasonable, given the data, the ICD–10–PCS codes, and the information provided.

Response: We appreciate the commenters' support for the proposal.

Comment: One commenter expressed appreciation for CMS' analysis of the MS–DRG assignment for revision of total ankle replacement procedures within MS–DRGs 515, 516, and 517. The commenter agreed that these procedures were previously assigned to code 81.59 (Revision of joint replacement of lower extremity, not elsewhere classified), which includes toe and foot joint revision procedures as well as revisions of total ankle replacements. The commenter agreed that this nonspecific ICD–9–CM code did not allow CMS to determine how many cases were actually revisions of total ankle replacements. The commenter also agreed that ICD–10–PCS provides greater detail and will provide information on revisions of total ankle replacement. The commenter acknowledged that CMS does not yet have ICD–10 claims data to analyze this issue.

The commenter urged CMS to accelerate the incorporation of ICD–10 claims data to examine the issue of revision of total ankle replacements. The commenter urged CMS to consider the following three options when these data become available:

- Map the new ICD–10–PCS ankle revision procedure codes to MS–DRGs 466, 467, and 468 and rename these MS–DRGs Revision of Hip, Knee or Ankle with MCC, with CC, and without CC/MCC, respectively;
- Map the new ICD–10–PCS ankle revision procedure codes to MS–DRG 469 to more appropriately recognize higher hospital procedure costs associated with revision of TAR; or
- Establish a new MS–DRG for the new ICD–10–PCS ankle revision codes and ankle joint revision cases.

The commenter requested that CMS consider one of these three options in FY 2017 if these data were available, but if these data are not available, the commenter requested that CMS use ICD–10 claims data to revise the MS–DRG assignment for revision of total ankle replacement procedures in FY 2018.

Another commenter also recommended that CMS review this MS–DRG assignment again once ICD–10 claims data are available.

Response: We agree with the commenter that ICD–10–PCS claims data will provide more detail to evaluate the MS–DRG assignment for revision of total ankle replacement procedures. Once ICD–10 claims data become available, we will use these claims data to evaluate this and other MS–DRG updates.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current MS–DRG assignment for revision of total ankle replacement procedures.

(2) Combination Codes for Removal and Replacement of Knee Joints

We received several requests asking CMS to examine whether additional combinations of procedure codes for the removal and replacements of knee joints should be added to MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively). This topic was discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24379 through 24395) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49390 through 49406). One requestor stated that the procedure codes in the following table were not included in the code pairs that group to MS–DRGs 466, 467, and 468 in the ICD–10 MS–DRGs Version 33.

ICD–10–PCS procedure code	Description
0SPD08Z	Removal of spacer from left knee joint, open approach.
0SPD38Z	Removal of spacer from left knee joint, percutaneous approach.
0SPD48Z	Removal of spacer from left knee joint, percutaneous endoscopic approach.
0SPC08Z	Removal of spacer from right knee joint, open approach.
0SPC38Z	Removal of spacer from right knee joint, percutaneous approach.
0SPC48Z	Removal of spacer from right knee joint, percutaneous approach.

Other requestors stated that the procedure codes in the following table are not included in the list of combinations that group to MS–DRGs 466, 467, and 468 when reported in conjunction with an ICD–10–PCS code for the removal of synthetic substitute from the joint in the ICD–10 MS–DRGs Version 33.

ICD–10–PCS Procedure code	Description
0SRC0J9	Replacement of right knee joint with synthetic substitute, cemented, open approach.
0SRC0JA	Replacement of right knee joint with synthetic substitute, uncemented, open approach.
0SRC0JZ	Replacement of right knee joint with synthetic substitute, open approach.
0SRC07Z	Replacement of right knee joint with autologous tissue substitute, open approach.
0SRC0KZ	Replacement of right knee joint with nonautologous tissue substitute, open approach.

We agree that the joint revision cases involving the removal of a spacer and subsequent insertion of a new knee joint prosthesis should be assigned to MS–DRGs 466, 467, and 468. We examined knee joint revision combination codes that are not currently assigned to MS–DRGs 466, 467, and 468 in ICD–10 MS–DRGs Version 33 and identified 58 additional combinations that also should be included so that the same logic is used in the ICD–10 version of the MS–DRGs as is used in the ICD–9–CM version. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24993 through 24996), we proposed to add the following 58 new code combinations that capture the joint revisions to the Version 34 MS DRG structure for MS–DRGs 466, 467, and 468, effective October 1, 2016.

ICD–10–PCS Code Pairs Proposed To Be Added to Version 34 ICD–10 MS–DRGs 466, 467, and 468: Proposed New Knee Revision ICD–10–PCS Combinations

Code	Code description		Code	Code description
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRC0J9	Replacement of Right Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRC0JA	Replacement of Right Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRC0JZ	Replacement of Right Knee Joint with Synthetic Substitute, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRT0J9	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRT0JA	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRT0JZ	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRV0J9	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRV0JA	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRV0JZ	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRC0J9	Replacement of Right Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRC0JA	Replacement of Right Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRC0JZ	Replacement of Right Knee Joint with Synthetic Substitute, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRT0J9	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.

ICD–10–PCS CODE PAIRS PROPOSED TO BE ADDED TO VERSION 34 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW KNEE REVISION ICD–10–PCS COMBINATIONS—Continued

Code	Code description		Code	Code description
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRT0JA	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRT0JZ	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRV0J9	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRV0JA	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRV0JZ	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRC0J9	Replacement of Right Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRC0JA	Replacement of Right Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRC0JZ	Replacement of Right Knee Joint with Synthetic Substitute, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRT0J9	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRT0JA	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRT0JZ	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRV0J9	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRV0JA	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRV0JZ	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPC4JZ	Removal of Synthetic Substitute from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRT0JZ	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPC4JZ	Removal of Synthetic Substitute from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRV0JZ	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRD0J9	Replacement of Left Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRD0JA	Replacement of Left Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRD0JZ	Replacement of Left Knee Joint with Synthetic Substitute, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRU0JA	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRU0JA	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRU0JZ	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRW0J9	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRW0JA	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRW0JZ	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRD0J9	Replacement of Left Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRD0JA	Replacement of Left Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRD0JZ	Replacement of Left Knee Joint with Synthetic Substitute, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRU0JA	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.

ICD–10–PCS CODE PAIRS PROPOSED TO BE ADDED TO VERSION 34 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW KNEE REVISION ICD–10–PCS COMBINATIONS—Continued

Code	Code description		Code	Code description
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRU0JA	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRU0JZ	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRW0J9	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRW0JA	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRW0JZ	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRD0J9	Replacement of Left Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRD0JA	Replacement of Left Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRD0JZ	Replacement of Left Knee Joint with Synthetic Substitute, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRU0JA	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRU0JA	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRU0JZ	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRW0J9	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRW0JA	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRW0JZ	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPD4JZ	Removal of Synthetic Substitute from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRU0JZ	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.

We invited public comments on our proposal to add the joint revision code combinations listed above to the ICD–10 Version 34 MS–DRGs 466, 467, and 468.

Comment: A number of commenters supported the proposal to add the joint revision code combinations listed in the table in the proposed rule to the ICD–10 Version 34 MS–DRGs 466, 467, and 468. Several commenters stated that these proposed updates better replicate the logic of the prior ICD–9–CM version of the MS–DRGs. Another commenter stated that adding the 58 new combinations of procedure codes for the removal and replacement of knee joints to MS–DRGs 466, 467, and 468 improves the alignment of these cases under the ICD–10 MS–DRGs. One commenter stated that it appreciated CMS' proposed updates to MS–DRGs 466, 467, and 468. Several of the commenters requested that the update be made retroactive to FY 2016 because this was a replication error of the ICD–9–CM MS–DRGs.

Response: We appreciate the commenters' support for our proposal. We agree that this addition better replicates the prior ICD–9–CM MS–DRGs. The FY 2016 MS–DRGs were subject to review and comment by the public as part of the FY 2016 IPPS/LTCH PPS rulemaking. As stated earlier, this topic was discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24379 through 24395) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49390 through 49406). We proposed to add the 58 new combinations of procedure codes for the removal and replacement of knee joints to MS–DRGs 466, 467, and 468 in the FY 2017 IPPS/LTCH PPS proposed rule for the FY 2017 MS–DRGs, effective October 1, 2016. Therefore, consistent with our general approach for implementing updates to the MS–DRGs, these updates apply beginning with the FY 2017 MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to add the 58 new code combinations listed above that capture the joint revisions to the Version 34 MS DRG structure for MS–DRGs 466, 467, and 468, effective October 1, 2016.

c. Decompression Laminectomy

Currently, under ICD–10–PCS, the procedure describing a decompression laminectomy is coded for the ''release'' of a specified area of the spinal cord. These decompression codes are assigned to MS–DRGs 028, 029, and 030 (Spinal Procedures with MCC, with CC or Spinal Neurostimulators, or without CC/MCC, respectively) and to MS–DRGs 518, 519, and 520 (Back and Neck Procedures Except Spinal Fusion with MCC or Disc Device or Neurostimulator, with CC, or without CC/MCC, respectively) in the ICD–10 MS–DRGs Version 33. A commenter brought to our attention that codes describing release of specific peripheral nerve are assigned to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). The commenter suggested that a subset of these codes also be assigned to MS–DRGs 028 through 030 and MS–DRGs 518 through 520 for clinical coherence purposes. The commenter stated, for example, that ICD–10–PCS procedure code 00NY0ZZ (Release lumbar spinal

cord, open approach) is assigned to MS–DRGs 028 through 030 and MS–DRGs 518 through 520. However, ICD–10–PCS procedure code 01NB0ZZ (Release lumbar nerve, open approach) is assigned to MS–DRGs 515 through 517.

We stated in the FY 2017 IPPS/LTCH PPS proposed rule that we agreed with the commenter's suggestion. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24996), for FY 2017, we proposed to reassign the ICD–10–PCS procedure codes listed in the following table from MS–DRGs 515 through 517 to MS–DRGs 028 through 030 and MS–DRGs 518 through 520 under the ICD–10 MS–DRGs Version 34.

ICD–10–PCS procedure code	Description
01N00ZZ	Release cervical plexus, open approach.
01N03ZZ	Release cervical plexus, percutaneous approach.
01N04ZZ	Release cervical plexus, percutaneous endoscopic approach.
01N10ZZ	Release cervical nerve, open approach.
01N13ZZ	Release cervical nerve, percutaneous approach.
01N14ZZ	Release cervical nerve, percutaneous endoscopic approach.
01N80ZZ	Release thoracic nerve, open approach.
01N83ZZ	Release thoracic nerve, percutaneous approach.
01N84ZZ	Release thoracic nerve, percutaneous endoscopic approach.
01N90ZZ	Release lumbar plexus, open approach.
01N93ZZ	Release lumbar plexus, percutaneous approach.
01N94ZZ	Release lumbar plexus, percutaneous endoscopic approach.
01NA0ZZ	Release lumbosacral plexus, open approach.
01NA3ZZ	Release lumbosacral plexus, percutaneous approach.
01NA4ZZ	Release lumbosacral plexus, percutaneous approach.
01NB0ZZ	Release lumbar nerve, open approach.
01NB3ZZ	Release lumbar nerve, percutaneous approach.
01NB4ZZ	Release lumbar nerve, percutaneous endoscopic approach.

We invited public comments on our proposal.

Comment: Several commenters supported the proposal to reassign the ICD–10–PCS procedure codes listed in the table in the proposed rule from MS–DRGs 515, 516 and 517 to MS–DRGs 028, 029, 030 and MS–DRGs 518, 519 and 520 under the ICD–10 MS–DRGs Version 34.

One commenter recommended that CMS delay reassigning the codes listed in the table in the proposed rule from MS–DRGs 515, 516 and 517 to MS–DRGs 028, 029, 030 and MS–DRGs 518, 519 and 520 until the FY 2016 MedPAR data are available, which would include ICD–10 coded claims. According to the commenter, it was difficult to assess the impact of the proposal in the absence of ICD–10 claims data. The commenter conducted its own data analysis of ICD–9–CM procedure code 04.49 (Other peripheral nerve or ganglion decompression or lysis of adhesions), which is a comparable translation of the ICD–10–PCS codes listed in the table in the proposed rule. The commenter stated that under Version 32 of the ICD–9–CM MS–DRGs, procedure code 04.49 grouped to MS–DRGs 515, 516, and 517. Based on its analysis, the commenter suggested that *if* CMS were to proceed with this proposal without ICD–10 claims data, CMS consider reassigning the entire list of ICD–10–PCS codes in the 01N (Release/Peripheral Nervous System) category to ICD–10 MS–DRGs 028, 029, and 030 for length of stay and average cost alignment purposes. The commenter did not make any recommendation for reassignment of the listed ICD–10–PCS procedure codes to MS–DRGs 518, 519, and 520.

Response: We appreciate the commenters' support of our proposal. With regard to the commenter who did not support the proposal and recommended we not finalize it in the absence of ICD–10 claims data, we acknowledge that it can be somewhat challenging to fully assess the impact of a proposal without the coded data to analyze. We note that the proposal was based on clinical coherence of the listed ICD–10–PCS codes with other codes describing procedures on the neck and spine currently assigned to MS–DRGs 028, 029, 030 in MDC 1 (Diseases and Disorders of the Nervous System) and MS–DRGs 518, 519, and 520 in MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue). We also note that the ICD–9–CM code 04.49 lacks the detail and specificity of the corresponding ICD–10–PCS codes proposed for reassignment. For example, the ICD–9–CM code does not specify which peripheral nerve is being treated or what approach was utilized. Therefore, we cannot fully evaluate and rely upon the commenter's analysis results for the ICD–9–CM data to accurately determine the impact of reassigning all the cited ICD–10–PCS codes, which do specify the nerve being treated, and the approach that was used to MS–DRGs 028, 029, and 030. In addition, it is not clear which list of ICD–10–PCS codes the commenter was requesting us to consider for reassignment to MS–DRGs 028, 029, and 030 based on its submitted comment. It is unclear if the commenter was suggesting that we reassign the entire list of ICD–10–PCS codes that appeared in the proposed rule or if the commenter was suggesting that we reassign the entire list of available code options in Table 01N (Release/Peripheral Nervous System) of the ICD–10–PCS classification because the commenter's languge referred to the 01N ''category'' and that is not a standard term used in ICD–10–PCS.

Therefore, we agree that we should delay this proposed change until the ICD–10 claims data are available, because we will have the ability to better analyze the impact of reassigning the specified codes according to their anatomic location, as well as receive clarification regarding which specific codes should be taken under consideration for reassignment. Our clinical advisors reviewed this issue and recommended maintaining the current structure of MS–DRGs 515, 516, and 517 for FY 2017. They agreed that we should not finalize our proposal to reassign the ICD–10–PCS codes discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24996 through 24997) to MS–DRGs 028, 029, and 030 and MS–DRGs 518, 519, and 520 until ICD–10–PCS data are available for analysis because we will have the opportunity to examine the detailed ICD–10–PCS codes and assess their impact on MS–DRGs 028, 029, and 030 and determine the specific codes

that were suggested for reassignment (the list of ICD–10–PCS codes displayed in the proposed rule and this final rule above or the entire list of codes available from Table 01N of the ICD–10–PCS classification). We also will have the coded claims data to assess the impact for MS–DRGs 518, 519, and 520 to better evaluate if that reassignment is supported.

After consideration of the public comments we received and based on the recommendations from our clinical advisors, we are not finalizing our proposal to reassign the ICD–10–PCS procedure codes listed in the table in the proposed rule and above from MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC and without CC/MCC) to MS–DRGs 028, 029, 030 (Spinal Procedures with MCC, with CC or Spinal Neurostimulators and without CC/MCC, respectively) and MS–DRGs 518, 519, and 520 (Back and Neck Procedures Except Spinal Fusion with MCC or Disc Device or Neurostimulator, with CC and without CC/MCC, respectively) under the ICD–10 MS–DRGs Version 34. The ICD–10–PCS codes that were listed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24996 through 24997) will remain in their current assignment to MS–DRGs 515, 516, and 517.

d. Lordosis

An ICD–10 replication issue involving four diagnosis codes related to lordosis (excessive curvature of the lower spine) was discovered in MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC, with CC, and without CC/MCC). These MS–DRGs contain specific logic that requires a principal diagnosis describing a spinal curvature, a malignancy, or infection or a secondary diagnosis that describes a spinal curvature disorder related to another condition.

Under the ICD–10 MS–DRGs Version 33, the following diagnosis codes were listed on the principal diagnosis list and the secondary diagnosis list for MS–DRGs 456, 457, and 458:

- M40.50 (Lordosis, unspecified, site unspecified);
- M40.55 (Lordosis, unspecified, thoracolumbar region);
- M40.56 (Lordosis, unspecified, lumbar region); and
- M40.57 (Lordosis, unspecified, lumbosacral region).

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24997), we proposed to remove the above four diagnosis codes from the secondary diagnosis list. We also proposed to maintain these same four codes in the logic for the principal diagnosis list. We proposed that this proposed change for MS–DRGs 456, 457, and 458 would be effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

We invited public comments on our proposals.

Comment: Commenters supported the proposal to remove diagnoses codes M40.50, M40.55, M40.56, and M40.57 from the secondary diagnosis list for MS DRGs 456, 457, and 458. Commenters also supported the proposal to maintain these same four codes in the logic for the principal diagnosis list for MS–DRGs 456, 457, and 458.

Response: We appreciate the commenters' support of our proposal to remove the above four diagnosis codes from the secondary diagnosis list and to maintain these same four codes in the logic for the principal diagnosis list for MS DRGs 456, 457, and 458.

After consideration of the public comments we received, we are finalizing our proposal to remove diagnoses codes M40.50 (Lordosis, unspecified, site unspecified); M40.55 (Lordosis, unspecified, thoracolumbar region); M40.56 (Lordosis, unspecified, lumbar region); and M40.57 (Lordosis, unspecified, lumbosacral region) from the secondary diagnosis list for MS DRGs 456, 457, and 458. These four codes are retained in the logic for the principal diagnosis list. This change for MS–DRGs 456, 457, and 458 (Spinal fusion except cervical with spinal curvature or malignancy or infection or extensive fusions with MCC, with CC and without CC/MCC) is effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

9. MDC 13 (Diseases and Disorders of the Female Reproductive System): Pelvic Evisceration

In the ICD–10 MS–DRG Definitions Manual Version 33, the GROUPER logic for ICD–10 MS–DRGs 332, 333, and 334 (Rectal Resection with MCC, with CC and without CC/MCC, respectively) under MDC 6 (Diseases and Disorders of the Digestive System) and the GROUPER logic for MS–DRGs 734 and 735 (Pelvic Evisceration, Radical Hysterectomy and Radical Vulvectomy with CC/MCC and without CC/MCC, respectively) under MDC 13 (Diseases and Disorders of the Female Reproductive System) include a ''cluster'' of ICD–10–PCS procedure codes that describe pelvic evisceration. A ''cluster'' is the term used to describe a circumstance when a combination of ICD–10–PCS procedure codes is needed to fully satisfy the equivalent meaning of an ICD–9–CM procedure code for it to be considered a plausible code translation. The code cluster in MS–DRGs 332, 333, and 334 and MS–DRGs 734 and 735 is shown in the table below.

ICD–10–PCS procedure code in cluster	Description
0TTB0ZZ	Resection of bladder, open approach.
0TTD0ZZ	Resection of urethra, open approach.
0UT20ZZ	Resection of bilateral ovaries, open approach.
0UT70ZZ	Resection of bilateral fallopian tubes, open approach.
0UT90ZZ	Resection of uterus, open approach.
0UTC0ZZ	Resection of cervix, open approach.
0UTG0ZZ	Resection of vagina, open approach.

Pelvic evisceration (or exenteration) is a procedure performed to treat gynecologic cancers (cervical, uterine, vulvar, and vaginal, among others) and involves resection of pelvic structures such as the procedures described by the cluster of procedure codes listed above.

Under the ICD–9–CM MS–DRGs Version 32, procedure code 68.8 (Pelvic evisceration) was used to report pelvic evisceration. ICD–9–CM procedure code 68.8 also was assigned to ICD–9–CM MS–DRGs 332, 333, and 334 and MS–DRGs 734 and 735 in MDCs 6 and 13, respectively. The inclusion term in the ICD–9–CM Tabular List of Diseases for pelvic evisceration (procedure code 68.8) was ''Removal of ovaries, tubes, uterus, vagina, bladder, and urethra (with removal of sigmoid colon and rectum).'' In the ICD–9–CM Tabular List, the terms shown in parentheses are called a ''non-essential modifier''. A ''non-essential modifier'' is used in the classification to identify a supplementary word that may, or may not, be present in the statement of a disease or procedure. In other words, the terms in parentheses do not have to be documented to report the code.

Because the removal of sigmoid colon and the removal of rectum were classified as non-essential modifiers under ICD–9–CM, documentation that identified that removal of those body sites occurred was not required to report the procedure code describing pelvic evisceration (procedure code 68.8). In other words, when a pelvic evisceration procedure was performed and included removal of other body sites (ovaries and tubes, among others) listed in the inclusion term, *absent* the terms in parentheses, procedure code 68.8 could

be reported and grouped appropriately to MDC 13 under MS–DRGs 734 and 735. When a pelvic evisceration procedure was performed and removal of the body sites listed in the inclusion term occurred, *including* the terms in parentheses, procedure code 68.8 could be reported and grouped appropriately to MDC 6 under MS–DRGs 332 through 334.

Under ICD–10–PCS, users are instructed to code separately the organs or structures that are actually removed and for which there is a distinctly defined body part. Therefore, the case of a patient who undergoes a pelvic evisceration (exenteration) that involves the removal of the sigmoid colon and rectum would have each of those procedure sites (sigmoid colon and rectum) coded and reported separately (in addition to the procedure codes displayed in the cluster). In this scenario, if the principal diagnosis is a condition from the MDC 6 diagnosis list, the case would group to MS–DRGs 332, 333, and 334, regardless of the code cluster. In other words, it would not be necessary to retain the code cluster describing procedures performed on female pelvic organs in MDC 6.

Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24997 through 24998), for FY 2017, we proposed to remove the procedure code cluster for pelvic evisceration procedures from MDC 6 under the ICD–10 MS–DRGs Version 34. The cluster would remain in ICD–10 MDC 13 under MS–DRGs 734 and 735 only. We invited public comments on our proposal.

Comment: Commenters supported the proposal to remove the procedure code cluster for pelvic evisceration procedures currently under MDC 6 in ICD–10 MS–DRGs 332, 333, and 334 for the ICD–10 MS–DRGs Version 34. The commenters stated the proposal was reasonable, given the data, the ICD–10–PCS codes, and the information provided.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to remove the following procedure codes currently listed as a ''cluster'' in MDC 6 under MS–DRGs 332, 333, and 334 effective October 1, 2016 under the ICD–10 MS–DRGs Version 34. The codes will remain as a cluster in MDC 13 under MS–DRGs 734 and 735 (Pelvic Evisceration, Radical Hysterectomy and Radical Vulvectomy with CC/MCC and without CC/MCC, respectively)

ICD–10–PCS procedure code in cluster	Description
0TTB0ZZ	Resection of bladder, open approach.
0TTD0ZZ	Resection of urethra, open approach.
0UT20ZZ	Resection of bilateral ovaries, open approach.
0UT70ZZ	Resection of bilateral fallopian tubes, open approach.
0UT90ZZ	Resection of uterus, open approach.
0UTC0ZZ	Resection of cervix, open approach.
0UTG0ZZ	Resection of vagina, open approach.

10. MDC 19 (Mental Diseases and Disorders): Proposed Modification of Title of MS–DRG 884 (Organic Disturbances and Mental Retardation)

We received a request to change the title of MS–DRG 884 (Organic Disturbances and Mental Retardation) under MDC 19 (Mental Diseases and Disorders) to ''MS–DRG 884 (Organic Disturbances and Intellectual Disability)'' to reflect more recent terminology used to appropriately describe the latter medical condition in the MDC.

We agree with the requestor that the reference to the phrase ''Mental Retardation'' should be changed to ''Intellectual Disability'', to reflect the current terminology used to describe the condition. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24988), we proposed to change the title of MS–DRG 884 as requested by the requestor.

We invited public comments on our proposal to change the title of MS–DRG 884 from ''Organic Disturbances and Mental Retardation'' to ''Organic Disturbances and Intellectual Disability'', effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

Comment: Commenters supported the proposal to modify the title for ICD–10 MS–DRG 884. The commenters stated that the proposal was reasonable, given the data and information provided.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to modify the title for ICD–10 MS–DRG 884. The finalized title for MS–DRG 884 for the FY 2017 ICD–10 MS–DRGs Version 34 is ''MS–DRG 884 (Organic Disturbances and Intellectual Disability),'' effective October 1, 2016.

11. MDC 23 (Factors Influencing Health Status and Other Contacts With Health Services): Logic of MS–DRGs 945 and 946 (Rehabilitation With and Without CC/MCC, Respectively)

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24998 through 25000), we received several requests to examine the MS–DRG logic for MS–DRGs 945 and 946 (Rehabilitation with CC/MCC and without CC/MCC, respectively). The requestors were concerned that ICD–9–CM codes that clearly identify an encounter for rehabilitation services such as diagnosis codes V57.89 (Care involving other specified rehabilitation procedure) and V57.9 (Care involving unspecified rehabilitation procedure) were not included in ICD–10–CM Version 33. In addition, the requestors pointed out that ICD–10–CM has significantly changed the guidelines for coding of admissions/encounters for rehabilitation. The requestors pointed out that under ICD–9–CM, Section I.B.15. of the Official Guidelines for Coding and Reporting indicates that ''when the purpose for the admission/encounter is rehabilitation, sequence the appropriate V code from category V57, Care involving use of rehabilitation procedures, as the principal/first listed diagnosis.'' The requestors stated that the concept of the ICD–9–CM category V57 codes is no longer valid in ICD–10–CM and the guidelines have been revised to provide greater specificity. Instead, the requestors added, the ICD–10–CM guidelines state in Section II.K., ''When the purpose for the admission/encounter is rehabilitation, sequence first the code for the condition for which the service is being performed. For example, for an admission/encounter for rehabilitation for right-sided dominant hemiplegia following a cerebrovascular infarction, report code I69.351, Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side, as the first-listed or principal diagnosis.''

Given this lack of ICD–10–CM codes to indicate that the reason for the encounter was for rehabilitation, some requesters asked that CMS review ICD–10–CM codes for conditions requiring rehabilitation (such as codes from category I69) and add them to MS–DRGs 945 and 946 when rehabilitation services are provided in order to replicate the logic found in the ICD–9–CM MS–DRG GROUPER. The requestors did not suggest any specific ICD–10–CM codes to add to MS–DRGs 945 and 946.

One requestor made a specific recommendation for updating MS–DRGs 945 and 946. The requestor previously

recommended that CMS review diagnosis codes in ICD–10–CM category I69 for possible addition to MS–DRGs 945 and 946. The requestor stated that, upon further review, it believed that a great number of diagnosis codes beyond sequelae of stroke (ICD–10–CM category I69) would need to be added in order to replicate the logic of the ICD–9–CM MS–DRGs. Therefore, the requestor modified its recommendation as follows:

- Designate MS–DRGs 945 and 946 as pre-major diagnostic categories (Pre-MDC) MS–DRGs so that cases are grouped to these MS–DRGs on the basis of the procedure code rather than the principal diagnosis. The requestor stated that the ICD–10–PCS rehabilitation codes (Section F, Physical Rehabilitation and Diagnostic Audiology, Body system 0, Rehabilitation) should be used to group cases to MS–DRGs 945 and 946 similar to how the MS–DRG GROUPER logic currently treats lung transplants and tracheostomies. This would ensure that the rehabilitation procedure codes drive the MS–DRG assignment.
- Revise ICD–10–PCS Official Guidelines for Coding and Reporting and designate that the ICD–10–PCS rehabilitation codes be used only for admissions for rehabilitation therapy.

We acknowledge that ICD–10–CM does not have clear diagnosis codes that indicate the reason for the encounter was for rehabilitation services. For that reason, CMS had to modify the MS–DRG logic using ICD–10–PCS procedure codes to assign these cases to MS–DRGs 945 and 946. The logic used in MS–DRGs 945 and 946 is shown in the Definitions Manual Version 33, which is posted on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*. We also posted a Frequently Asked Question section to explain how inpatient admissions are assigned to MS–DRGs 945 and 946, which is posted on the CMS Web site at: *https://questions.cms.gov/faq.php?id=5005&faqId=12548*. As indicated in the Frequently Asked Question section, the ICD–10–CM codes required a different approach to make sure the same cases captured with ICD–9–CM codes would be captured with ICD–10–CM codes. As stated earlier, ICD–10–CM does not contain specific codes for encounters for rehabilitation such as ICD–9–CM procedure codes V57.89 and V57.9. In order to replicate the ICD–9–CM MS–DRG logic using ICD–10–CM and ICD–10–PCS codes, CMS developed the new logic included in the MS–DRG Version 33 Definitions Manual.

The Frequently Asked Question section explains that, in order to be assigned to ICD–10 MS–DRG 945 or 946, a case must first have a principal diagnosis from MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services), where MS–DRGs 945 and 946 are assigned. This is currently the logic with the ICD–9–CM MS–DRGs Version 33 where one would first have to have a MDC 23 principal diagnosis. A complete list of ICD–10–CM principal diagnoses for MDC 23 can be found in the ICD–10 MS–DRGs Version 33 Definitions Manual which is posted on the FY 2016 IPPS Final Rule Home Page under the link for the FY 2016 Final Rule Data Files at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html*. Look under the Related Links section and select the ICD–10–CM/PCS MS–DRG v33 Definitions Manual Table of Contents Full Titles HTML Version file. Open this file and the Table of Contents page will appear. Click on the link for MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services). On the next page that opens (MDC 23), click on the link titled ''MDC 23 Assignment of Diagnosis Codes'' on the upper left side of the screen. By using the navigation arrows at the top right hand side of the page, users can review the 24 pages listing all of the principal diagnosis codes assigned to MDC 23, including many injury codes for subsequent encounters.

Under the GROUPER Logic, cases are assigned to MS–DRGs 945 and 946 in one of two ways as described in the Definitions Manual as follows:

- The encounter has a principal diagnosis code Z44.8 (Encounter for fitting and adjustment of other external prosthetic devices) or Z44.9 (Encounter for fitting and adjustment of unspecified external prosthetic device). Both of these codes are included in the list of principal diagnosis codes assigned to MDC 23.
- The encounter has an MDC 23 principal diagnosis code and one of the rehabilitation procedure codes listed under MS–DRGs 945 and 946.

If the case does not have a principal diagnosis code from the MDC 23 list, but does have a procedure code from the list included under the Rehabilitation Procedures for MS–DRGs 945 and 946, the case will not be assigned to MS–DRGs 945 or 946. The case will instead be assigned to a MS–DRG within the MDC where the principal diagnosis code is found.

Example: The encounter has a principal diagnosis code of S02119D (Unspecified fracture of occiput, subsequent encounter for fracture with routine healing). This code is included in MDC 8. Therefore, diagnosis code S02119D and a procedure code from the MS–DRG 945 and 946 Rehabilitation Procedure list, such as procedure code F0706GZ (Therapeutic Exercise Treatment of Neurological System—Head and Neck using Aerobic Endurance and Conditioning Equipment) would not lead to assignment of the case to MS–DRGs 945 and 946 because the principal diagnosis code is not included in MDC 23.

Diagnosis code S02119D is included in MDC 8 as was the ICD–9–CM predecessor code, V54.19 (Aftercare for healing traumatic fracture of other bone). Therefore, these cases would be assigned to MS–DRGs 559, 560, and 561 (Aftercare, Musculoskeletal System and Connective Tissue with MCC, with CC, and without MCC/CC, respectively) within MDC 8.

At the time of development of the proposed rule, we did not have any claims data that indicate how well this MS–DRG logic is working. We stated in the proposed rule that we were hesitant to simply add more codes from category I69 without evaluating the impact of doing so using claims data. We also did not have claims data to indicate whether or not there have been changes in the types or numbers of cases assigned to MS–DRGs 945 and 946. We welcomed specific suggestions of codes to be added to MS–DRGs 945 and 946 based on hospitals' experience in coding these cases. We stated that we would evaluate these suggestions once we have claims data to study the impact. Based on the lack of ICD–10 claims data, we proposed to maintain the current logic of MS–DRGs 945 and 946 and not make updates until these claims data become available.

Comment: A number of commenters supported the proposal to maintain the current structure of MS–DRGs 945 and 946 and reconsider the issue when ICD–10 claims data become available and prior to proposing any updates. Several commenters who agreed with this proposal stated that additional analysis should be undertaken in order to fully understand the industry impact of the current logic of MS–DRGs 945 and 946. The commenters stated that it was not clear to what extent the current logic for these MS–DRGs has created actual payment issues or what the nature of any identified problems might be.

One commenter suggested that if an analysis of ICD–10 claims data indicate that the current logic of MS–DRGs 945 and 946 is creating significant payment issues, CMS consider reclassifying MS–DRGs 945 and 946 as pre-MDC MS–DRGs as a possible solution.

Response: We agree with the commenters that, without ICD–10 claims data, it is not possible to evaluate the impact of the logic using ICD–10 codes within MS–DRGs 945 and 946. We agree that it is appropriate to wait for the claims data prior to proposing any MS–DRG updates.

We stated in the proposed rule that we have major concerns about the recommendation to revise the ICD–10–PCS Official Guidelines for Coding and Reporting and designate that the ICD–10–PCS rehabilitation codes be assigned and reported only for admissions for rehabilitation therapy. This would be a major and new process for developing coding and reporting guidelines based on one specific payer's payment polices, in this case Medicare inpatient acute care prospective payment system policies. Hospitals would need to know who the payer was prior to knowing whether or not they could assign a code for a rehabilitation service that they provided. If those payment policies change, the hospital coder would need to be aware of those changes in order to determine whether or not they could submit a code that captures the fact that a rehabilitation service was provided. CMS has worked with the Centers for Disease Control and Prevention (CDC), the American Hospital Association (AHA), and the American Health Information Management Association (AHIMA) to make ICD–10–PCS guidelines generic and applicable to all types of inpatient facilities and for all payer types. The current ICD–10–PCS Guidelines for Coding and Reporting do not support this recommendation that rehabilitation services could only be coded and reported if the admission was specifically for rehabilitation therapy. The ICD–10–PCS codes were created to accurately capture services provided.

We also have concerns about designating MS–DRGs 945 and 946 as pre-MDCs so that cases are grouped to these MS–DRGs on the basis of a rehabilitation procedure code rather than a principal diagnosis. Pre-MDCs were an addition to Version 8 of the Diagnosis Related Groups. This was the first departure from the use of principal diagnosis as the initial variable in DRG and subsequently MS–DRG assignment. For Pre-MDC DRGs, the initial step in DRG assignment was not the principal diagnosis, but was instead certain surgical procedures with extremely high costs such as heart transplant, liver transplant, bone marrow transplant, and tracheostomies performed on patients on long-term ventilation. These types of services were viewed as being very resource intensive. Recognizing these resource intensive services and assigning them to one of the high-cost MS–DRGs assures appropriate payment even if the patient is admitted for a variety of principal diagnoses. We believe it is inappropriate to consider rehabilitation services in the same group as high-cost procedures such as heart transplants. There is the significant potential of patients being classified out of higher paying surgical MS–DRGs in other MDCs and into the lower paying MS–DRGs 945 and 946 based on the reporting of a rehabilitation procedure code if these MS–DRGs are moved to the Pre-MDCs. We examined claims data for cases reporting a rehabilitation therapy code and found cases assigned to a wide variety of both medical and surgical MS–DRGs. The current coding and reporting of rehabilitation procedure codes for services provided suggest the potential of significant payment problems if MS–DRGs 945 and 946 were assigned to the Pre-MDC section and the reporting of cases with a rehabilitation code led to an inappropriate reassignment to the lower paying medical MS–DRGs 945 and 946.

The following are only a few examples of current claims data that showed the hospital reported a rehabilitation therapy procedure code for services provided which did not impact the MS–DRG assignment. Under the suggested approach of making MS–DRGs 945 and 946 a Pre-MDC, these cases would move from the appropriately assigned MS–DRGs which may have significantly higher average costs, to MS–DRGs 945 and 946, which have much lower average costs. Based on claims data from the December 2015 update of the FY 2015 MedPAR file, the average costs for cases reported in MS–DRGs 945 and 946 were $8,531 and $8,411, respectively.

Examples of cases reporting a rehabilitation therapy code that would move to MS–DRGs 945 and 946 based on the suggested logic change are as follows:

- An MS–DRG 460 (Spinal Fusion Except Cervical with MCC) case with average costs of $42,390;
- An MS–DRG 464 (Wound Debridement and Skin Graft Excluding Hand, for Musculoskeletal Tissue Disease with CC) case with average costs of $55,633;
- An MS–DRG 579 (Other Skin, Subcutaneous Tissue and Breast Procedure with MCC) case with average costs of $63,834;
- An MS–DRG 854 (Infectious and Parasitic Diseases with O.R. procedure with MCC) case with average costs of $62,455; and
- An MS–DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with CC) case with average costs of $90,522.

Our clinical advisors reviewed this issue and agreed that we should wait for ICD–10 claims data to become available prior to proposing updates to MS–DRGs 945 and 946. They did not support adding MS–DRGs 945 and 946 to the Pre-MDCs because the rehabilitation services are not as resource intensive as are the other MS–DRGs in the Pre-MDC section.

Considering these ICD–10–PCS guideline concerns, the structure of the pre-MDC section, and the lack of any ICD–10 claims data for MS–DRGs 945 and 946, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24998 through 25000), we proposed to maintain the current structure of MS–DRGs 945 and 946 and reconsider the issue when ICD–10 claims data become available and prior to proposing any updates.

We invited public comments on our proposal to maintain the current structure of MS–DRGs 945 and 946.

Comment: One commenter agreed with CMS that, given there is no ICD–10–CM code describing encounters for rehabilitation, it was reasonable that identification of admissions for rehabilitation had to rely on ICD–10–PCS procedure codes. One commenter believed that it was not appropriate for the MS–DRG logic to require a principal diagnosis from MDC 23 to be assigned to MS–DRGs 945 and 946 because most admissions for rehabilitation would appropriately have any number of diagnosis codes sequenced as the principal diagnosis rather than a diagnosis code from MDC 23. The commenter did not believe it was feasible to identify all of the ICD–10–CM codes for which rehabilitation services might be provided, due to the range and number of diagnoses that could potentially be involved.

Response: We agree with the commenter that there is no ICD–10–CM code describing encounters for rehabilitation. Given this lack of an ICD–10–CM code describing encounters for rehabilitation, we used ICD–10–PCS procedure codes as a means of identifying these cases. Therefore, the ICD–10 MS–DRG logic cannot be the same as the ICD–9–CM code logic. We also agree with the commenter that it is not feasible to identify all of the ICD–10–CM codes for which rehabilitation

services might be provided, due to the range and number of diagnoses that could potentially be involved. Therefore, it is necessary to wait for ICD–10 claims data in order to evaluate and propose MS–DRG updates.

Comment: One commenter disagreed with CMS' proposal to maintain the current structure of MS–DRGs 945 and 946 and to only reconsider the issue when ICD–10 claims data become available. The commenter stated that further research of claims data was not necessary as there was enough evidence and clinical knowledge to identify the majority of appropriate principal diagnoses that frequently require an inpatient admission for rehabilitation. The commenter advised adding the codes and code categories in the following table to MDC 23.

CODE/CODE CATEGORY AND DESCRIPTION
G20 Parkinson's disease.
G21.0 Malignant neuroleptic syndrome.
G21.11 Neuroleptic induced parkinsonism.
G21.19 Other drug induced secondary parkinsonism.
G21.2 Secondary parkinsonism due to other external agents.
G21.3 Postencephalitic parkinsonism.
G21.4 Vascular parkinsonism.
G21.8 Other secondary parkinsonism.
G21.9 Secondary parkinsonism, unspecified.
G31.84 Mild cognitive impairment, so stated.
G35 Multiple sclerosis.
G37.3 Acute transverse myelitis in demyelinating disease of central nervous system.
G61.0 Guillain-Barre syndrome.
G61.81 Chronic inflammatory demyelinating polyneuritis.
G62.81 Critical illness polyneuropathy.
G62.9 Polyneuropathy, unspecified.
G65.0 Sequelae of Guillain-BarrÃ© syndrome.
G70.00 Myasthenia gravis without (acute) exacerbation.
G70.01 Myasthenia gravis with (acute) exacerbation.
G72.81 Critical illness myopathy.
G91.0 Communicating hydrocephalus.
G91.1 Obstructive hydrocephalus.
G91.2 (Idiopathic) normal pressure hydrocephalus.
G91.3 Post-traumatic hydrocephalus, unspecified.
G91.4 Hydrocephalus in diseases classified elsewhere.
G91.8 Other hydrocephalus.
G91.9 Hydrocephalus, unspecified.
G92 Toxic encephalopathy.
G93.1 Anoxic brain damage, not elsewhere classified.
G93.40 Encephalopathy, unspecified.
G93.41 Metabolic encephalopathy.
G93.49 Other encephalopathy.
I50.22 Chronic systolic (congestive) heart failure.
I50.23 Acute on chronic systolic (congestive) heart failure.
I50.32 Chronic diastolic (congestive) heart failure.
I50.33 Acute on chronic diastolic (congestive) heart failure.
I50.42 Chronic combined systolic (congestive) and diastolic (congestive) heart failure.
I50.43 Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure.
I50.9 Heart failure, unspecified.
M62.81 Muscle weakness (generalized).
M62.82 Rhabdomyolysis.
R26.0 Ataxic gait.
R26.1 Paralytic gait.
R26.2 Difficulty in walking, not elsewhere classified.
R26.81 Unsteadiness on feet.
R26.89 Other abnormalities of gait and mobility.
R26.9 Unspecified abnormalities of gait and mobility.
R27.0 Ataxia, unspecified.
R27.8 Other lack of coordination.
R27.9 Unspecified lack of coordination.
R41.84 Cognitive communication deficit.
R41.842 Visuospatial deficit.
R41.843 Psychomotor deficit.
R41.844 Frontal lobe and executive function deficit.
R41.89 Other symptoms and signs involving cognitive functions and awareness.
Z47.1 Aftercare following joint replacement surgery.
Z47.81 Encounter for orthopedic aftercare following surgical amputation.
Z47.89 Encounter for other orthopedic aftercare.
Z48.21 Encounter for aftercare following heart transplant.
Z48.22 Encounter for aftercare following kidney transplant.
Z48.23 Encounter for aftercare following liver transplant.
Z48.24 Encounter for aftercare following lung transplant.
Z48.280 Encounter for aftercare following heart-lung transplant.
Z48.288 Encounter for aftercare following multiple organ transplant.

CODE/CODE CATEGORY AND DESCRIPTION—Continued

Z48.290 Encounter for aftercare following bone marrow transplant.
Z48.298 Encounter for aftercare following other organ transplant.
Z48.3 Aftercare following surgery for neoplasm.
Code categories G81, G82, and G83.
Code Category I69.
Code Category M84.3–M84.6 with 7th digit ''D''.
Code Categories S32.4–S32.9 with 7th digit ''D''.
Code Categories S72.0–S72.3 with 7th digit ''D'', ''E'', or ''F''.

Response: We disagree with the recommendation to add the list of ICD–10–CM codes shown in the table above to MS–DRGs 945 and 946. As stated previously, we do not have claims data to evaluate how this suggested update would impact MS–DRG assignments. We agree with the other commenters who recommended that CMS wait for claims data in order to evaluate updates to MS–DRGs 945 and 946. While this commenter took the position that further research of claims data was not necessary because there is enough evidence and clinical knowledge to identify the majority of principal diagnoses that frequently require an inpatient admission for rehabilitation, and, as noted, submitted the above list of ICD–10–CM codes and code categories to add to MDC 23, we believe that ICD–10 claims data are necessary to evaluate this recommended change; without claims data, we cannot determine the number of cases that might be reassigned and if this reassignment was appropriate.

Comment: Commenters who agreed with waiting until claims data become available to evaluate MS–DRG updates stated that they understood that the current pre-MDC structure is limited to resource-intensive surgical procedures. However, they believed that there are some similarities between the existing pre-MDCs and MS–DRGs 945 and 946. The commenters stated that, similar to the existing pre-MDCs, the driver for the rehabilitation MS–DRGs is a specific type of service, and this service may be provided for a wide variety of principal diagnoses. Therefore, the commenters suggested the creation of a guideline that limits the use of the ICD–10–PCS rehabilitation codes to rehabilitation admissions would address the potential for patient cases to be reassigned from higher paying surgical MS–DRGs in other MDCs to the lower paying MS–DRGs 945 and 946 based on the reporting of a rehabilitation procedure code if these MS–DRGs were reassigned to the pre-MDCs. One commenter stated that, after the establishment of a new ICD–10–PCS coding guideline, the reporting of ICD–10–PCS rehabilitation codes for nonrehabilitation hospitalizations would be considered coding errors and, as with any coding error, could lead to inappropriate MS–DRG assignment. However, the commenter recommended that edits and reminders would likely be needed to minimize this type of coding error.

Response: We agree with the commenters that the issue of any updates to ICD–10–PCS guidelines should be considered along with any proposed MS–DRG updates because updated guidelines may impact code reporting.

We welcome any suggestions on how to update the ICD–10–PCS guidelines. These suggestions should be sent to *ICDProcedureCodeRequest@cms.hhs.gov*. We plan to take any proposed ICD–10–PCS rehabilitation guideline updates to a future meeting of the ICD–10 Coordination and Maintenance Committee so that the public can provide input on any new rehabilitation guideline. We continue to be concerned about creating a new ICD–10–PCS guideline whose purpose is to restrict assignment to certain MS–DRGs. Over time, the MS–DRGs are updated as part of the annual IPPS rulemaking. To create a guideline on a current MS–DRG structure as opposed to a means of capturing national data for all payers is not consistent with past guideline development. However, we look forward to working with the public on examining the need to improve the ICD–10–PCS guidelines for rehabilitation services reporting.

Comment: Other commenters who agreed with CMS' proposal to maintain the current structure of MS–DRGs 945 and 946 until such time as ICD–10 claims data become available recommended that the ICD–10 Coordination and Maintenance Committee address the creation of a single, new ICD–10–CM diagnosis code in Section Z of ICD–10–CM to replicate the ICD–9–CM code category V57 (Care involving use of rehabilitation procedures). The commenters recommended that if the CDC created this new code, the new ICD–10–CM code be added to MS–DRGs 945 and 946 when reported as a secondary diagnosis. The commenters urged CMS to obtain industry input from experts in rehabilitation on possible coding and MS–DRG updates.

Several commenters recommended that the existing ICD–10–CM Official Guidelines for Coding and Reporting be maintained to allow the sequencing of the diagnosis code for the condition for which the service is being performed as the principal diagnosis when the purpose for the admission/encounter is rehabilitation. Several commenters recommended a revision of the ICD–10–CM Official Guidelines for Coding and Reporting if a new ICD–10–CM code for care involving use of rehabilitation procedures were created. Some of the commenters recommended that the new diagnosis code be reported as a secondary diagnosis when the purpose for the admission/encounter was rehabilitation while others recommended that the new code be reported as the principal diagnosis.

One commenter objected to the development of coding guidelines based on Medicare payment policies. However, the commenter stated that any such guideline should be applied to all payers. The commenter stated that creating such a guideline that would restrict the use of these procedure codes such that they could only be used to identify rehabilitation admissions for the purpose of appropriately assigning MS–DRGs 945 and 946 merited serious consideration.

Response: We have referred the requests for a new ICD–10–CM code for care involving the use of rehabilitation procedures to the CDC for consideration at a future ICD–10 Coordination and Maintenance Committee meeting. Requests for ICD–10–CM code updates should be sent to the CDC at *nchsicd10CM@cdc.gov*. Information on submitting proposals for new diagnosis codes can be found on CDC's Web site at *http://www.cdc.gov/nchs/icd/icd10_maintenance.htm*. Should such a new diagnosis code be created, CMS would examine the possibility of using this new diagnosis code in the MS–DRGs 945 and 946 logic, as was the case in the ICD–9–CM version of the MS–DRGs. The public is also encouraged to send any specific recommendations for

updates to the ICD–10–CM coding guidelines to CDC at: *nchsicd10CM@cdc.gov*. Updates that are made to ICD–10–CM, ICD–10–PCS, and the relevant coding guidelines will be considered along with claims data in evaluating any proposed updates to MS–DRGs 945 and 946.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current structure of MS–DRGs 945 and 946. We look forward to working with the public on updates to the ICD–10–PCS guidelines or updates to ICD–10–CM to better capture these services. Once we receive ICD–10 claims data, we will again examine this issue.

12. Medicare Code Editor (MCE) Changes

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49409 through 49412), we finalized the ICD–10 Definitions of Medicare Code Edits (ICD–10 MCE) Version 33. ICD–10 MCE Version 33 was based on the FY 2015 ICD–9–CM MCE Version 32 and the draft ICD–10 MCE Version 32 that had been made publicly available for comments in November 2014 on the ICD–10 MS–DRG Conversion Project Web site at: *https://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. In August 2015, we posted the finalized FY 2016 ICD–10 MCE Version 33 manual file and an ICD–9–CM MCE Version 33.0A manual file (for analysis purposes only). The links to these MCE manual files, along with the links to purchase the mainframe and computer software for the MCE Version 33 (and ICD–10 MS–DRGs) were posted on the CMS Web site through the FY 2016 IPPS Final Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html?DLSort=0&DLEntries=10&DLPage=1&DLSortDir=ascending*.

After implementation of the ICD–10 MCE Version 33, we received several requests to examine specific code edit lists that the requestors believed were incorrect and that affected claims processing functions. We received requests to review the MCE relating specifically to the Age conflict edit, the Sex conflict edit, the Non-covered procedure edit, and the Unacceptable principal diagnosis code edit. We discuss these code edit issues below. In addition, as a result of new and modified code updates approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting, we routinely make changes to the MCE. In the past, in both the IPPS proposed and final rules, we only provided the list of changes to the MCE that were brought to our attention after the prior year's final rule. We historically have not listed the changes we have made to the MCE as a result of the new and modified codes approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting. These changes are approved too late in the rulemaking schedule for inclusion in the proposed rule. Furthermore, although our MCE policies have been described in our proposed and final rules, we have not provided the detail of each new or modified diagnosis and procedure code edit in the final rule. However, we make available the finalized Definitions of Medicare Code Edits (MCE) file. Therefore, we have made available the FY 2017 ICD–10 MCE Version 34 manual file and an ICD–9–CM MCE Version 34.0A manual file (for analysis purposes only). The links to these MCE manual files, along with the links to purchase the mainframe and computer software for the MCE Version 34 (and ICD–10 MS–DRGs) are posted on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* through the FY 2017 IPPS Final Rule Home Page.

a. Age Conflict Edit

In the MCE, the Age conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age conflict edit and are listed in the manual and written in the software program:

- Newborn—Age of 0 years; a subset of diagnoses intended only for newborns and neonates (for example, fetal distress, perinatal jaundice).
- Pediatric—Age is 0–17 years inclusive (for example, Reye's syndrome, routine child health exam).
- Maternity—Age range is 12–55 years inclusive (for example, diabetes in pregnancy, antepartum pulmonary complication).
- Adult—Age range is 15–124 years inclusive (for example, senile delirium, mature cataract).

(1) Newborn Diagnosis Category

Under the ICD–10–CM Official Guidelines for Coding and Reporting (available on the Web site at: *https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-CM-and-GEMs.html*), there are general guidelines and chapter-specific coding guidelines. The chapter-specific guidelines state that diagnosis codes from Chapter 16 (Certain Conditions Originating in the Perinatal Period) may be reported throughout the life of the patient if the condition is still present. The requestors noted that several codes from this Chapter 16 appear on the ICD–10 MCE Version 33 Age conflict edit for the newborn diagnosis category. Codes from this chapter are included in the P00 through P96 code range. Therefore, the requestors believed that because the chapter-specific guidelines state that codes within this chapter may be reported throughout the life of a patient, all codes within this range (P00 through P96) should be removed from the newborn diagnosis category on the Age conflict edit code list.

As we discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25000 through 25001), we examined the newborn diagnosis category on the age conflict edit list in the ICD–9–CM MCE Version 32 in comparison to the ICD–9–CM chapter-specific guidelines. Under ICD–9–CM, Chapter 15 (Certain Conditions Originating in the Perinatal Period) includes codes within the 760 through 779 range. We found that the same chapter-specific guideline under ICD–10 exists under ICD–9–CM: Diagnosis codes from Chapter 15 may be reported throughout the life of the patient if the condition is still present. Similar to the ICD–10 MCE Version 33 newborn diagnosis category in the Age conflict edit code list, we noted that several codes from this Chapter 15 appear on the ICD–9–CM MCE Version 32 Age conflict edit for the newborn diagnosis category.

Because the full definition of the chapter-specific guideline for ''Certain Conditions Originating in the Perinatal Period'' clearly states the codes within the chapter may be reported throughout the life of the patient *if the condition is still present,* we believe that,

historically, under ICD–9–CM, this was the rationale for inclusion of the diagnosis codes that were finalized for the newborn diagnosis category under the Age conflict edit (in code range 760 through 779). For example, under ICD–9–CM, there are four diagnosis codes in the 760.6x series that specifically include the term ''newborn'' in the title. These diagnosis codes are:

- 760.61 (Newborn affected by amniocentesis);
- 760.62 (Newborn affected by other in utero procedure);
- 760.63 (Newborn affected by other surgical operations on mother during pregnancy); and
- 760.64 (Newborn affected by previous surgical procedure on mother not associated with pregnancy).

Under the ICD–9–CM classification, the chapter-specific guidelines in Chapter 15 (Certain Conditions Originating in the Perinatal Period) state that, for coding and reporting purposes, the perinatal period is defined as before birth through the 28th day following birth. As such, for coding and reporting purposes, a patient that is beyond the 28th day of life is no longer considered a newborn. Therefore, we believe that the diagnosis codes listed on the newborn diagnosis category in the Age conflict edit code list are, in fact, appropriate because they identify what the title of Chapter 15 describes (certain conditions specific to beginning in the perinatal period); that is, a newborn. The intent of the diagnosis codes included on the Age conflict edit code list is to identify claims where any one of the listed diagnoses is reported for a patient who is beyond the 28th day of life. If that definition is met according to the patient's date of birth, the edit is correctly triggered in those cases.

Transitioning to the ICD–10 MCE was based on replication of the ICD–9–CM based MCE (in parallel with the transition to the ICD–10 MS–DRGs, which was based on replication of the ICD–9–CM MS–DRGs). Therefore, the diagnosis codes included in the newborn diagnosis category on the Age conflict edit code list in the ICD–10 MCE are a replication of the diagnosis code descriptions included on the newborn diagnosis category on the Age conflict edit code list under the ICD–9–CM MCE. However, the chapter-specific guideline in ICD–10–CM Chapter 16, section C.16.e. (Low birth weight and immaturity status), specifies that codes within category P07 (Disorders of newborn related to short gestation and low birth weight, not elsewhere classified) are for use for a child or adult who was premature or had a low birth weight as a newborn and this condition is affecting the patient's current health status. Therefore, we agree that codes within the range of P07.00 through P07.39 should not be listed under newborn diagnosis category on the Age conflict edit code list in the ICD–10 MCE. It is unclear why this range of codes within category P07 is distinguished separately when under the General Perinatal Rules for Chapter 16 (Certain Conditions Originating in the Perinatal Period), section I.C.16.a.1. states that diagnosis codes from Chapter 16 may be reported throughout the life of the patient if the condition is still present. In addition, the guideline at section I.C.16.a.4. states that ''should a condition originate in the perinatal period, and continue throughout the life of the patient, the perinatal code should continue to be used regardless of the patient's age.'' According to these general guidelines, we could assume that potentially *all* codes within Chapter 16 in the code range of P00 through P96 should be considered for removal from the newborn diagnosis category on the Age conflict edit code list. However, a subsequent section of Chapter 16, section 1.C.16.c.2. (Codes for conditions specified as having implication for future health care needs), instructs users to assign codes for conditions that have been specified by the provider as having implications for future health care needs. Immediately below that instruction is a note which states: ''This guideline should not be used for adult patients.''

The ICD–10–CM Official Guidelines for Coding and Reporting are updated separately from the IPPS rulemaking process. Due to the confusion with the chapter-specific guidelines for codes in Chapter 16 and how they impact the newborn diagnosis category on the Age conflict edit code list, we believe it would be beneficial to fully evaluate the intent of these guidelines with the Centers for Disease Control's (CDC's) National Center for Health Statistics (NCHS) because NCHS has the lead responsibility for the ICD–10–CM diagnosis codes.

In the meantime, to address claims processing concerns related to the newborn diagnosis category on the Age conflict edit code list, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25001), we proposed to remove all the ICD–10–CM diagnoses in the code range of P00 through P96 from the newborn diagnosis category in the Age conflict code edit list for the ICD–10 MCE for FY 2017. We invited public comments on our proposal. We also solicited public comments on the appropriateness of the other diagnosis codes currently listed under the newborn diagnosis category in the Age conflict edit in the ICD–10 MCE Version 33. We refer readers to Table 6P.1a. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for review of the diagnosis codes we proposed to remove.

In addition, for FY 2017, we indicated that we were examining the need to revise the description for the newborn diagnosis category in the Age conflict edit under the MCE. The current description as written, Newborn—Age of 0 years; a subset of diagnoses intended only for newborns and neonates (*e.g.,* fetal distress, perinatal jaundice), is not consistent with the instructions for reporting the diagnosis codes in Chapter 16. We invited public comments on our proposal to revise the description of the newborn diagnosis category in the Age conflict edit under the MCE.

Comment: Several commenters supported the proposal to remove all the ICD–10–CM diagnoses in the code range of P00 through P96 from the newborn diagnosis category in the Age conflict code edit list. The commenters did not believe the newborn guidelines were in conflict with each other or required any modifications, as the specific references noted in the proposed rule address unrelated reporting issues. However, the commenters indicated that they planned to submit recommendations directly to the CDC to revise an instructional note that appears at the beginning of Chapter 16 which they believe may be a contributing factor to confusion surrounding the proper application of codes within the chapter.

Response: We appreciate the commenters' support. We also appreciate the commenters' review of the newborn guidelines and their plan to submit a recommendation to the CDC regarding the instructional note that appears at the beginning of Chapter 16.

We wish to clarify for the commenters that the focus of our proposal was on the removal of codes from the newborn diagnosis category in the Age conflict code edit list. Our discussion involving the references to the guidelines was to simply note the confusion with the guidelines and how those guidelines impact the codes listed under newborn diagnosis category in the Age conflict code edit list. Following that discussion, we stated our belief that it would be beneficial to discuss the intent of the guidelines with CDC.

Comment: Many commenters supported the proposal for the MCE

changes related to the Age conflict edit description.

Response: We appreciate the commenters' support and believe a revised description of the newborn edit better defines the diagnoses that are subject to it.

After consideration of the public comments we received, we are finalizing our proposal to remove all the ICD–10–CM diagnoses in the code range of P00 through P96 from the newborn diagnosis category in the Age conflict code edit list for the ICD–10 MCE for FY 2017. The procedure codes listed in Table 6P.1a. associated with this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) are the finalized list of procedure codes that will be removed from the newborn diagnosis category in the Age conflict code edit list in the ICD–10 MCE Version 34 effective October 1, 2016.

We also are finalizing our proposal to revise the description of the newborn diagnosis category under the ICD–10 MCE from ''Newborn. Age of 0 years; a subset of diagnoses intended only for newborns and neonates (*e.g.,* fetal distress, perinatal jaundice)'' to ''Perinatal/Newborn. Age 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 (*e.g.,* tetanus neonatorum, health examination for newborn under 8 days old)'' in the ICD–10 MCE Version 34, effective October 1, 2016.

(2) Pediatric Diagnosis Category

Under the ICD–10 MCE Version 33, the pediatric diagnosis category for the Age conflict edit considers the age range of 0 to 17 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only. The code list for the pediatric diagnosis category in the Age conflict edit currently includes 12 diagnosis codes that fall within the F90 through F98 code range. These codes were included as a result of replication from the ICD–9–CM MCE Version 32 and the draft ICD–10 MCE Version 32.

We received a request to review the 12 ICD–10–CM diagnosis codes listed in the following table because they appear to conflict with guidance in the ICD–10–CM classification.

ICD–10–CM diagnosis code	Description
F93.0	Separation anxiety disorder of childhood.
F93.8	Other childhood emotional disorders.
F93.9	Childhood emotional disorder, unspecified.
F94.1	Reactive attachment disorder of childhood.
F94.2	Disinhibited attachment disorder of childhood.
F94.8	Other childhood disorders of social functioning.
F94.9	Childhood disorder of social functioning, unspecified.
F98.21	Rumination disorder of infancy.
F98.29	Other feeding disorders of infancy and early childhood.
F98.3	Pica of infancy and childhood.
F98.8	Other specified behavioral and emotional disorders with onset usually occurring in childhood and adolescence.
F98.9	Unspecified behavioral and emotional disorders with onset usually occurring in childhood and adolescence.

Under the ICD–10–CM Tabular List of Diseases and Injuries, Chapter 5 (Mental, Behavioral and Neurodevelopmental Disorders) contains a section titled ''Behavioral and emotional disorders with onset usually occurring in childhood and adolescence'' which includes codes for the F90 to F98 code range. At the beginning of this tabular section is an instructional ''note'' that states: ''Codes within categories F90–F98 may be used regardless of the age of a patient. These disorders generally have onset within the childhood or adolescent years, but may continue throughout life or not be diagnosed until adulthood.''

Because the note specifically states that these codes may be used regardless of the age of a patient, we believe they should not be included on the pediatric diagnosis category on the Age conflict edit code list. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25001 through 25002), we proposed to remove the 12 codes that fall within the F90 through F98 code range currently listed for the pediatric diagnosis category on the ICD–10 MCE age conflict edit code list, effective October 1, 2016, for FY 2017. We invited public comments on our proposal.

Comment: Several commenters supported the proposal to address the replication issue for the pediatric diagnosis category on the ICD–10 MCE Age conflict edit code list by removing the 12 ICD–10–CM diagnosis codes in the F90 through F98 code range currently listed.

Response: We appreciate the commenters' support of our proposal. We also agree that removal of the specified ICD–10–CM diagnosis codes from the edit code list will resolve the replication issue and enable proper reporting of the conditions regardless of the patient's age.

After consideration of the public comments we received, we are finalizing our proposal to remove the 12 ICD–10–CM diagnosis codes in the F90 through F98 code range displayed earlier in this section from the pediatric diagnosis category Age conflict edit code list in the ICD–10 MCE Version 34, effective October 1, 2016.

We also received a request to review whether another group of diagnosis codes is clinically incorrect for the ICD–10 MCE Version 33 pediatric diagnosis category in the Age conflict edit. The requestor stated that ICD–10–CM diagnosis codes describing infantile and juvenile cataracts, by their titles, appear to merit inclusion on the pediatric diagnosis category on the Age conflict edit code list. However, according to the requestor, the diagnosis is not constrained to a patient's age, but rather the ''infantile'' versus ''juvenile'' reference is specific to the type of cataract the patient has. These diagnosis codes that are currently listed for the pediatric diagnosis category in the ICD–10 MCE Age conflict edit code list are as follows:

ICD–10–CM diagnosis code	Description
H26.001	Unspecified infantile and juvenile cataract, right eye.
H26.002	Unspecified infantile and juvenile cataract, left eye.
H26.003	Unspecified infantile and juvenile cataract, bilateral.
H26.009	Unspecified infantile and juvenile cataract, unspecified eye.
H26.011	Infantile and juvenile cortical, lamellar, or zonular cataract, right eye.
H26.012	Infantile and juvenile cortical, lamellar, or zonular cataract, left eye.
H26.013	Infantile and juvenile cortical, lamellar, or zonular cataract, bilateral.
H26.019	Infantile and juvenile cortical, lamellar, or zonular cataract, unspecified eye.
H26.031	Infantile and juvenile nuclear cataract, right eye.
H26.032	Infantile and juvenile nuclear cataract, left eye.
H26.033	Infantile and juvenile nuclear cataract, bilateral.
H26.039	Infantile and juvenile nuclear cataract, unspecified eye.
H26.041	Anterior subcapsular polar infantile and juvenile cataract, right eye.
H26.042	Anterior subcapsular polar infantile and juvenile cataract, left eye.
H26.043	Anterior subcapsular polar infantile and juvenile cataract, bilateral.
H26.049	Anterior subcapsular polar infantile and juvenile cataract, unspecified eye.
H26.051	Posterior subcapsular polar infantile and juvenile cataract, right eye.
H26.052	Posterior subcapsular polar infantile and juvenile cataract, left eye.
H26.053	Posterior subcapsular polar infantile and juvenile cataract, bilateral.
H26.059	Posterior subcapsular polar infantile and juvenile cataract, unspecified eye.
H26.061	Combined forms of infantile and juvenile cataract, right eye.
H26.062	Combined forms of infantile and juvenile cataract, left eye.
H26.063	Combined forms of infantile and juvenile cataract, bilateral.
H26.069	Combined forms of infantile and juvenile cataract, unspecified eye.
H26.09	Other infantile and juvenile cataract.

Our clinical advisors reviewed the list of diagnoses presented above and confirmed that these diagnosis codes are appropriate to include in the ICD–10 MCE for the pediatric diagnosis category in the Age conflict edit because the diseases described by these codes are typically diagnosed in early childhood and treated very rapidly to prevent amblyopia. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25002), for FY 2017, we did not propose to remove these codes under the pediatric diagnosis category in the Age conflict edit. We proposed to maintain this list in the ICD–10 MCE Version 34, effective October 1, 2016. We invited public comments on our proposal.

Comment: Commenters supported the proposal to retain the list of ICD–10–CM diagnosis codes describing infantile and juvenile cataracts in the pediatric diagnosis category for the Age conflict edit.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the ICD–10–CM diagnosis codes displayed earlier in this section describing infantile and juvenile cataracts in the pediatric diagnosis category for the Age conflict edit in the ICD–10 MCE Version 34, effective October 1, 2016.

As stated earlier, for the pediatric diagnosis category in the Age conflict edit, the MCE considers the age range of 0 through 17 years inclusive. In the ICD–10 MCE Version 33, there are four diagnosis codes describing the body mass index (BMI) for pediatric patients in the pediatric diagnosis category on the Age conflict edit code list. The four ICD–10–CM diagnosis codes describing the BMI percentiles for pediatric patients are as follows:

ICD–10–CM diagnosis code	Description
Z68.51	Body mass index (BMI) pediatric, less than 5th percentile for age.
Z68.52	Body mass index (BMI) pediatric, 5th percentile to less than 85th percentile for age.
Z68.53	Body mass index (BMI) pediatric, 85th percentile to less than 95th percentile for age.
Z68.54	Body mass index (BMI) pediatric, greater than or equal to 95th percentile for age.

Under the ICD–10–CM Tabular List of Diseases and Injuries, the BMI pediatric diagnosis codes are designated for use in persons 2 through 20 years of age. The percentiles are based on the growth charts published by the CDC. As a result of the age discrepancy between the MCE pediatric diagnosis category in the Age conflict edit (ages 0 through 17) and the Tabular reference for the BMI pediatric codes (ages 2 through 20), in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25003), we proposed to remove ICD–10–CM diagnosis codes Z68.51, Z68.52, Z68.53, and Z68.54 from the ICD–10 MCE pediatric diagnosis category on the Age conflict edit code list for Version 34, effective FY 2017. We invited public comments on our proposal.

Comment: Commenters supported the proposal to remove the four ICD–10–CM diagnosis codes describing body mass index (BMI) for pediatric patients from the pediatric diagnosis category on the Age conflict edit code list in the MCE. The commenters stated that this proposal would enable proper reporting of these codes.

Response: We appreciate the commenters' support. We agree that removal of the specified ICD–10–CM diagnosis codes discussed previously from the edit code list will resolve any age discrepancy issues in the reporting of the conditions regardless of the patient's age.

After consideration of the public comments we received, we are finalizing our proposal to remove the four ICD–10–CM diagnosis codes displayed earlier in this section that identify the body mass index for pediatric patients from the pediatric diagnosis category on the Age conflict

edit code list in the ICD–10 MCE Version 34, effective October 1, 2016.

One requestor also asked that CMS review the ICD–10–CM diagnosis codes currently included in ICD–10–CM category R62 (Lack of expected normal physiological development in childhood and adults) series. Specifically, the requestor noted that there are adult patients diagnosed with the conditions in subcategory R62.5 (Other and unspecified lack of expected normal physiological development in childhood) and that three of these conditions also were listed in the ICD–10 MCE Version 33 pediatric diagnosis category on the Age conflict edit code list. These three diagnosis codes are:

- R62.50 (Unspecified lack of expected normal physiological development in childhood);
- R62.52 (Short stature (child)); and
- R62.59 (Other lack of expected normal physiological development in childhood).

We acknowledge that subcategory R62.5 can be confusing with regard to how to appropriately report a condition diagnosed for an adult when the titles reference the terms ''child'' or ''childhood''. Therefore, we consulted with the ICD–10–CM classification staff at the NCHS to determine the intended use and reporting of the diagnosis codes R62.50, R62.52, and R62.59. The NCHS staff agreed that the three diagnosis codes should not be restricted to the pediatric ages as defined by the MCE. The NCHS staff stated the codes are appropriate to report for adult patients, noting that if a patient is diagnosed with short stature as a child, the patient could very well carry over that diagnosis into adulthood.

During our review of the issue relating to the subcategory R62.5 pediatric diagnosis category on the Age conflict edit code list, we identified another diagnosis code that also appeared appropriate to report for an adult patient. ICD–10–CM diagnosis code Y93.6A (Activity, physical games generally associated with school recess, summer camp and children) is one of several activity codes included in ICD–10–CM Chapter 20 (External Causes of Morbidity). This diagnosis code includes games such as dodge ball and capture the flag, which one can reasonably expect an adult to be engaged in for physical activity.

We discussed this diagnosis code with the NCHS staff to receive their input on the intent for coding and reporting the code. They agreed that ICD–10–CM diagnosis code Y93.6A is applicable for adults as well as children. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25003), for FY 2017, we proposed to remove ICD–10–CM diagnosis codes R62.50, R62.52, and R62.59 in subcategory R62.5 and ICD–10–CM diagnosis code Y93.6A from the ICD–10 MCE pediatric diagnosis category on the Age conflict edit code list. We invited public comment on our proposal.

Comment: Commenters supported the proposal to remove ICD–10–CM diagnosis codes R62.50, R62.52, and R62.59 in subcategory R62.5 and to also remove ICD–10–CM diagnosis code Y93.6A from the ICD–10 MCE pediatric diagnosis category on the Age conflict edit code list.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to remove the following four ICD–10–CM diagnosis codes from the pediatric diagnosis category on the Age conflict edit code list in the ICD–10 MCE Version 34, effective October 1, 2016.

- R62.50 (Unspecified lack of expected normal physiological development in childhood);
- R62.52 (Short stature (child));
- R62.59 (Other lack of expected normal physiological development in childhood); and
- Y93.6A (Activity, physical games generally associated with school recess, summer camp and children).

b. Sex Conflict Edit

In the MCE, the Sex conflict edit detects inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record; for example, a male patient with cervical cancer (diagnosis) or a female patient with a prostatectomy (procedure). In both instances, the indicated diagnosis or the procedure conflicts with the stated sex of the patient. Therefore, the patient's diagnosis, procedure, or sex is presumed to be incorrect.

We received a request to review ICD–10–CM diagnosis code Z79.890 (Hormone replacement therapy (postmenopausal)). This code is listed on the Diagnoses for females only edit code list. Therefore, when the diagnosis is reported for a male patient, the edit will be triggered. However, the requester noted that the term ''postmenopausal'' is enclosed in parentheses and is a ''non-essential modifier.'' A ''non-essential modifier'' is used in the ICD–10–CM classification to identify a supplementary word that may, or may not be present in the statement of a disease or procedure. In other words, the term in parentheses does not have to be documented to report the code. If the medical record documentation states a female patient is undergoing hormone replacement therapy, the documentation supports assignment of the case to ICD–10–CM diagnosis code Z79.890 (Hormone replacement therapy (postmenopausal)). There does not need to be a diagnostic statement that the patient is postmenopausal to assign the code. The requester asked that CMS review why this diagnosis code is being classified as applicable to females only because, in the absence of the non-essential modifier (postmenopausal), the code could also apply to males.

We note that the ICD–9–CM equivalent code, V07.4 Hormone replacement therapy (postmenopausal) has been on the female only edit since October 1, 1992 in the ICD–9–CM MCE. We consulted with the ICD–10–CM classification staff at the NCHS to determine the intended use and reporting of this diagnosis code. The staff at NCHS acknowledged that, historically, the intent of the ICD–9–CM diagnosis code was for females only. However, they agreed that, under ICD–10–CM, the diagnosis code Z79.890 can be reported for both men and women. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25003), we proposed to remove this diagnosis code from the Diagnoses for females only edit code list effective October 1, 2016. We invited public comments on our proposal.

Comment: Commenters supported the proposal to remove the ICD–10–CM diagnosis code describing hormone replacement therapy from the Diagnosis for females only edit code list in the ICD–10 MCE.

Response: We appreciate the commenters' support for our proposal. We agree it is appropriate to allow the reporting of the ICD–10–CM diagnosis code describing hormone replacement therapy for both male and female patients.

After consideration of the public comments we received, we are finalizing our proposal to remove ICD–10–CM diagnosis code Z79.890 (Hormone replacement therapy (postmenopausal)) from the Diagnosis for females only edit code list from the ICD–10 MCE Version 34, effective October 1, 2016.

We also considered the ICD–10–CM diagnosis codes listed in the table below that are included on the Diagnoses for females only edit code list.

ICD–10–CM diagnosis code	Description
Z44.30	Encounter for fitting and adjustment of external breast prosthesis, unspecified breast.
Z44.31	Encounter for fitting and adjustment of external right breast prosthesis.
Z44.32	Encounter for fitting and adjustment of external left breast prosthesis.
Z45.811	Encounter for adjustment or removal of right breast implant.
Z45.812	Encounter for adjustment or removal of left breast implant.
Z45.819	Encounter for adjustment or removal of unspecified breast implant.

These codes describe encounters for breast implants or prostheses. Our clinical advisors and the NCHS staff agree that diagnosis codes Z44.30, Z44.31, Z44.32, Z45.811, Z45.812, and Z45.819 are clinically appropriate to report for male patients and should not be restricted to females. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25004), we proposed to remove these diagnosis codes from the Diagnoses for females only edit code list in the ICD–10 MCE, effective October 1, 2016. We invited public comments on our proposal.

Comment: Commenters agreed that the ICD–10–CM diagnosis codes describing encounters for breast implants or prostheses are appropriate to report for male patients and should not be limited to females.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to remove the six ICD–10–CM diagnosis codes displayed earlier in this section that identify an encounter for fitting or adjustment of a breast implant or prosthesis from the Diagnoses for females only edit code list in the ICD–10 MCE Version 34, effective October 1, 2016.

c. Non-Covered Procedure Edit

In the MCE, the Non-covered procedure edit identifies procedures for which Medicare does not provide payment. Payment is not provided due to specific criteria that are established in the National Coverage Determination (NCD) process. We refer readers to the Web site at: *https://www.cms.gov/Medicare/Coverage/DeterminationProcess/howtorequestanNCD.html* for additional information on this process. In addition, there are procedures that would normally not be paid by Medicare but, due to the presence of certain diagnoses, are paid.

(1) Endovascular Mechanical Thrombectomy

We received several requests to review ICD–10–PCS procedure code 03CG3ZZ (Extirpation of matter from intracranial artery, percutaneous approach) which is currently listed as a non-covered procedure in the ICD–10 MCE Non-covered procedure edit code list. The comparable ICD–9–CM code translations for ICD–10–PCS code 03CG3ZZ are ICD–9–CM codes 17.54 (Percutaneous atherectomy of intracranial vessel(s)) and 39.74 (Endovascular removal of obstruction from head and neck vessel(s)).

The requestors noted that, under ICD–9–CM, endovascular mechanical thrombectomy of a cerebral artery to remove a clot that is causing an ischemic stroke was reported with procedure code 39.74 (Endovascular removal of obstruction from head and neck vessel(s)) and is a well-recognized procedure that has been covered by Medicare. After implementation of ICD–10 on October 1, 2015, claims that were correctly submitted for endovascular mechanical thrombectomy procedures with ICD–10–PCS procedure code 03CG3ZZ were triggering the Non-covered procedure edit. The requestors sought clarification as to whether there was a change in coverage or if there was a replication issue.

Under the ICD–9–CM MCE Version 32, procedure code 00.62 is listed on the Non-covered procedure edit code list. Percutaneous angioplasty of an intracranial vessel procedure (with and without stent) may be reported under ICD–10 with the ICD–10–PCS procedure codes listed in the following table:

ICD–10–PCS procedure code	Description
037G34Z	Dilation of intracranial artery with drug-eluting intraluminal device, percutaneous approach.
037G3DZ	Dilation of intracranial artery with intraluminal device, percutaneous approach.
037G3ZZ	Dilation of intracranial artery, percutaneous approach.
037G44Z	Dilation of intracranial artery with drug-eluting intraluminal device, percutaneous endoscopic approach.
037G4DZ	Dilation of intracranial artery with intraluminal device, percutaneous endoscopic approach.
037G4ZZ	Dilation of intracranial artery, percutaneous endoscopic approach.
057L3DZ	Dilation of intracranial vein with intraluminal device, percutaneous approach.
057L4DZ	Dilation of intracranial vein with intraluminal device, percutaneous endoscopic approach.

We discovered that a replication error occurred due to an outdated ICD–9–CM entry for procedure code 00.62. This error led to ICD–10–PCS procedure codes 03CG3ZZ (Extirpation of matter from intracranial artery, percutaneous approach) and 05CL3ZZ (Extirpation of matter from intracranial vein, percutaneous approach) being listed as comparable translations for ICD–9–CM code 00.62. As a result, ICD–10–PCS procedure code 03CG3ZZ was included on the ICD–10 MCE Version 33 Non-covered procedure edit code list.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25004), for FY 2017, we proposed to remove the ICD–10–PCS procedure codes listed in the following table from the ICD–10 MCE Version 34.0 Non-covered procedure edit code list.

ICD–10–PCS procedure code	Description
03CG3ZZ	Extirpation of matter from intracranial artery, percutaneous approach.
03CG4ZZ	Extirpation of matter from intracranial artery, percutaneous endoscopic approach.

ICD–10–PCS procedure code	Description
05CL3ZZ	Extirpation of matter from intracranial vein, percutaneous approach.
05CL4ZZ	Extirpation of matter from intracranial vein, percutaneous endoscopic approach.

We invited public comments on our proposal.

Comment: Many commenters supported the proposal to remove the four ICD–10–PCS procedure codes describing mechanical thrombectomy from the Non-covered procedure edit code list in the ICD–10 MCE to prevent further claims processing issues. Some commenters also recommended that CMS instruct the MACs to reprocess claims that were denied as a result of the codes being listed in the MCE. Other commenters suggested changes to the National Coverage Determination (NCD) for Intracranial Percutaneous Transluminal Angioplasty (PTA) with Stenting (20.7).

Response: We appreciate the commenters' support for our proposal. We agree that removal of the four ICD–10–PCS procedure codes that describe mechanical thrombectomy procedures from the non-covered procedure edit code list in the ICD–10 MCE will help resolve future claims processing and denial issues associated with the reporting of these codes.

In response to the comment that we instruct the MACs to reprocess any affected claims, we note that contractors began reprocessing affected claims at providers' request in March 2016. We recommend that providers who have experienced claims processing issues work with their local MACs to resolve any outstanding claims.

With regard to the commenters who suggested that changes be made to the NCD for Intracranial PTA with Stenting, we note that we issued instructions with updated changes on June 3, 2016 as a One-Time Notification, Pub. No. 100–20, Transmittal 1672, Change Request 9631, effective October 1, 2016.

After consideration of the public comments we received, we are finalizing our proposal to remove the four ICD–10–PCS procedure codes displayed earlier in this section from the non-covered procedure edit code list in the ICD–10 MCE Version 34, effective October 1, 2016.

(2) Radical Prostatectomy

We received a request to review ICD–10–PCS procedure codes related to a radical prostatectomy. Specifically, the requestor noted that when coding cases where the removal of the vas deferens is also performed, a Non-covered procedure edit is triggered. The requestor suggested that the edit for this procedure may be intended for cases where the removal of the vas deferens is being performed for sterilization (vasectomy) purposes. According to the requester, removal of the vas deferens also may be involved with removing the prostate in the radical prostatectomy procedure. The requestor suggested that CMS address this issue by revising the ICD–10 MCE Non-covered procedure edit code list to reflect noncoverage of the procedure codes when the removal of vas deferens procedure is being performed solely for sterilization (vasectomy) purposes.

Because radical procedures can have different meanings, depending on the procedure, the term ''radical'' is not always reliable information for coding and reporting the procedure. Under ICD–10–PCS, users are instructed to code separately the organs or structures that were actually removed and for which there is a distinctly defined body part. A radical prostatectomy is coded as a ''cluster'' under ICD–10–PCS. A ''cluster'' is the term used to describe the circumstance when a combination of ICD–10–PCS procedure codes are needed to fully satisfy the equivalent meaning of an ICD–9–CM procedure code for it to be considered a plausible translation.

The cluster definition for a radical prostatectomy in ICD–10–PCS currently consists of one of the following codes:

- 0VT00ZZ (Resection of prostate, open approach);
- 0VT04ZZ (Resection of prostate, percutaneous endoscopic approach);
- 0VT07ZZ (Resection of prostate, via natural or artificial opening); or
- 0VT08ZZ Resection of prostate, via natural or artificial opening endoscopic; in combination with one of the following codes:
- 0VT30ZZ (Resection of bilateral seminal vesicles, open approach); or
- 0VT34ZZ (Resection of bilateral seminal vesicles, percutaneous endoscopic approach).

As stated earlier, under ICD–10–PCS, users are instructed to code separately the organs or structures that were actually removed and for which there is a distinctly defined body part. Therefore, a patient who undergoes a radical prostatectomy that involves removal of the vas deferens would have this procedure reported separately, in addition to the options displayed in the ''cluster.''

The ICD–10–PCS procedure codes that may be reported for sterilization and involve the bilateral vas deferens include the following:

ICD–10–PCS procedure code	Description
0V5Q0ZZ	Destruction of bilateral vas deferens, open approach.
0V5Q3ZZ	Destruction of bilateral vas deferens, percutaneous approach.
0V5Q4ZZ	Destruction of bilateral vas deferens, percutaneous endoscopic approach.
0VBQ0ZZ	Excision of bilateral vas deferens, open approach.
0VBQ3ZZ	Excision of bilateral vas deferens, percutaneous approach.
0VBQ4ZZ	Excision of bilateral vas deferens, percutaneous endoscopic approach.
0VTQ0ZZ	Resection of bilateral vas deferens, open approach.
0VTQ4ZZ	Resection of bilateral vas deferens, percutaneous endoscopic approach.

The eight procedure codes listed above describing various methods to remove the bilateral vas deferens are currently listed on the ICD–10 MCE Version 33 Non-covered procedure edit code list.

The requester is correct in stating that the codes related to removal of the bilateral vas deferens are included on the ICD–10 MCE Version 33 Non-covered procedure edit code list to reflect a sterilization procedure. While the vast majority of sterilization procedures will involve reporting the

bilateral procedure codes, there are instances where one vas deferens may have been previously removed for other reasons and the remaining vas deferens requires sterilization. Therefore, the procedure codes describing removal of a unilateral vas deferens are also included on the ICD–10 MCE Version 33 Non-covered procedure edit code list to reflect a sterilization procedure. We agree that revising the language in the edit will resolve the issue of covered procedures being inappropriately subject to the edit.

In addition, while reviewing the Non-covered procedure edit list of codes that may be reported to identify sterilization procedures for males, we considered the procedure codes that may be reported to identify sterilization procedures for females. We examined the list of ICD–10–PCS procedure codes included on the ICD–10 MCE Version 33 Non-covered procedure edit code list that could reflect female sterilization (removal of fallopian tubes) and determined those codes also could be reported for other conditions and could be inappropriately subject to the current edit as well.

Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25005), for FY 2017, we proposed to create a new ICD–10 MCE Version 34 Non-covered procedure edit to reflect that procedures performed on males involving the unilateral or bilateral vas deferens and procedures performed on females involving the fallopian tubes are not covered procedures for sterilization purposes. The proposed new ICD–10 MCE Version 34 Non-covered procedure edit would be displayed as follows: ''G. Non-covered procedure. The procedure codes shown below are identified as non-covered procedures *only* when ICD–10–CM diagnosis code Z30.2 (Encounter for sterilization) is listed as the principal diagnosis.''

We referred readers to Table 6P.1b. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) to review the proposed list of noncovered procedure codes describing sterilization procedures for males and females for this proposed Non-covered procedure edit. We invited public comments on our proposal to create this new Non-covered procedure edit and also invited public comments on the proposed list of codes to describe sterilization procedures for the proposed edit.

Comment: Commenters supported the proposal to create a new ICD–10 MCE Version 34 Non-covered procedure edit to reflect that procedures performed on males involving the unilateral or bilateral vas deferens and procedures performed on females involving the fallopian tubes are not covered procedures for sterilization purposes. One commenter noted that there could be situations in which a patient is admitted for another condition and a sterilization procedure is performed during that episode of care. For example, the commenter stated a female may be admitted for a cesarean section and have a tubal ligation procedure during that same hospitalization. The commenter suggested that the proposed list of procedure codes be considered as non-covered when ICD–10–CM diagnosis code Z30.2 is reported as a principal or secondary diagnosis on the claim.

Response: We appreciate the commenters' support for our proposal. We also agree with the commenter that it is appropriate to list ICD–10–CM diagnosis code Z30.2 (Encounter for sterilization) as a principal or secondary diagnosis for purposes of the non-covered procedure edit.

After consideration of the public comments we received, we are finalizing our proposal to create a new ICD–10 MCE Version 34 Non-covered procedure edit. The new edit will be defined as follows: ''G. Non-covered procedure. The procedure codes shown below are identified as non-covered procedures *only* when ICD–10–CM diagnosis code Z30.2 (Encounter for sterilization) is listed as the principal diagnosis or secondary diagnosis.'' The procedure codes listed in Table 6P.1b. associated with this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) are the finalized list of non-covered procedure codes describing sterilization procedures for males and females for this finalized Non-covered procedure edit in the ICD–10 MCE Version 34, effective October 1, 2016.

d. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance which influences an individual's health status but does not actually describe a current illness or injury. There also are codes that are not specific manifestations but may be due to an underlying cause. These codes are considered unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable principal diagnosis edit code list that are considered ''acceptable'' when a specified secondary diagnosis is also coded and reported on the claim.

(1) Liveborn Infant

We received a request to examine ICD–10–CM diagnosis codes Z38.1 (Single liveborn infant, born outside hospital), Z38.4 (Twin liveborn infant, born outside hospital), and Z38.7 (Other multiple liveborn infant, born outside hospital), all of which are currently listed on the Unacceptable principal diagnosis edit code list for the ICD–10 MCE Version 33. The requestor believed that these codes are listed in error and suggested their removal.

The ICD–10–CM diagnosis code descriptions for liveborn infants differ from the ICD–9–CM diagnosis code descriptions for liveborn infants. The ICD–9–CM codes differentiate between a liveborn infant that was born prior to admission and hospitalized versus a liveborn infant that was born prior to admission and *not* hospitalized. The following codes in the ICD–9–CM MCE Version 32 included on the Unacceptable principal diagnosis edit code list are those that describe a liveborn infant that was born outside the hospital and not hospitalized:

ICD–9–CM diagnosis code	Description
V30.2	Single liveborn, born outside hospital and not hospitalized.
V31.2	Twin birth, mate liveborn, born outside hospital and not hospitalized.
V32.2	Twin birth, mate stillborn, born outside hospital and not hospitalized.
V33.2	Twin birth, unspecified whether mate liveborn or stillborn, born outside hospital and not hospitalized.
V34.2	Other multiple birth (three or more), mates all liveborn, born outside hospital and not hospitalized.
V35.2	Other multiple birth (three or more), mates all stillborn, born outside of hospital and not hospitalized.
V36.2	Other multiple birth (three or more), mates liveborn and stillborn, born outside hospital and not hospitalized.
V37.2	Other multiple birth (three or more), unspecified whether mates liveborn or stillborn, born outside of hospital.
V39.1	Liveborn, unspecified whether single, twin or multiple, born before admission to hospital.

ICD–9–CM diagnosis code	Description
V39.2	Liveborn, unspecified whether single, twin or multiple, born outside hospital and not hospitalized.

For replication purposes, the comparable ICD–10–CM diagnosis codes for the above listed codes are: Z38.1 (Single liveborn infant, born outside hospital); Z38.4 (Twin liveborn infant, born outside hospital); and Z38.7 (Other multiple liveborn infant, born outside hospital). There are no other ICD–10–CM diagnosis codes that describe a liveborn infant born outside a hospital.

The liveborn infant codes are an example of where a particular concept involving the place of birth is not the same between the ICD–9–CM and ICD–10–CM classification systems. Because the ICD–10–CM diagnosis codes do not include the same concept as the ICD–9–CM diagnosis codes regarding whether the liveborn infant was hospitalized or not, we agree it would not be appropriate to continue to include the ICD–10–CM diagnosis codes on the Unacceptable principal diagnosis list.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25006), for FY 2017, we proposed to remove ICD–10–CM diagnosis codes Z38.1, Z38.4, and Z38.7 from the Unacceptable principal diagnosis edit in the ICD–10 MCE Version 34. We invited public comments on our proposal.

Comment: Several commenters supported the proposal to remove the three ICD–10–CM diagnosis codes describing a liveborn infant born outside of the hospital from the Unacceptable principal diagnosis edit code list in the ICD–10 MCE.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to remove codes Z38.1 (Single liveborn infant, born outside hospital); Z38.4 (Twin liveborn infant, born outside hospital); and Z38.7 (Other multiple liveborn infant, born outside hospital) from the Unacceptable principal diagnosis edit code list in the ICD–10 MCE Version 34, effective October 1, 2016.

(2) Multiple Gestation

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25006 through 25007), we received a request to review the ICD–10–CM diagnosis codes related to multiple gestation that are currently listed on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list. The requestor expressed concern that these codes were included in the edit and suggested that CMS evaluate further to determine if they were appropriate.

In the ICD–10–CM classification, a single diagnosis code describes a multiple gestation and contains information pertaining to the placenta. This differs from the ICD–9–CM classification, where two diagnosis codes are required to separately report (1) multiple gestation with a delivery or complication and (2) multiple gestation with the status of the placenta.

In the ICD–9–CM MCE Version 32, only the ICD–9–CM diagnosis codes describing the status of the placenta are listed on the Unacceptable principal diagnosis edit code list. These ICD–9–CM diagnosis codes are:

ICD–9–CM diagnosis code	Description
V91.00	Twin gestation, unspecified number of placenta, unspecified number of amniotic sacs.
V91.01	Twin gestation, monochorionic/monoamniotic (one placenta, one amniotic sac).
V91.02	Twin gestation, monochorionic/diamniotic (one placenta, two amniotic sacs).
V91.03	Twin gestation, dichorionic/diamniotic (two placentae, two amniotic sacs).
V91.09	Twin gestation, unable to determine number of placenta and number of amniotic sacs.
V91.10	Triplet gestation, unspecified number of placenta and unspecified number of amniotic sacs.
V91.11	Triplet gestation, with two or more monochorionic fetuses.
V91.12	Triplet gestation, with two or more monoamniotic fetuses.
V91.19	Triplet gestation, unable to determine number of placenta and number of amniotic sacs.
V91.20	(Quadruplet gestation, unspecified number of placenta and unspecified number of amniotic sacs.
V91.21	Quadruplet gestation, with two or more monochorionic fetuses.
V91.22	Quadruplet gestation, with two or more monoamniotic fetuses.
V91.29	Quadruplet gestation, unable to determine number of placenta and number of amniotic sacs.
V91.90	Other specified multiple gestation, unspecified number of placenta and unspecified number of amniotic sacs.
V91.91	Other specified multiple gestation, with two or more monochorionic fetuses.
V91.92	Other specified multiple gestation, with two or more monoamniotic fetuses.
V91.99	Other specified multiple gestation, unable to determine number of placenta and number of amniotic sacs.

There are 68 ICD–10–CM diagnosis codes included on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list as comparable translations that describe multiple gestation and status of the placenta. The list of these codes was included in Table 6P.1c. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*).

Because only one, and not both, concepts from the ICD–9–CM classification was considered to be an unacceptable principal diagnosis (status of placenta) in the ICD–9–CM MCE, we agree this was a replication error that incorrectly included the ICD–10–CM diagnosis codes that identify both concepts (multiple gestation and status of placenta) in a single code on the ICD–10 MCE. The edit cannot isolate the status of placenta for the ICD–10 MCE because it is reported in combination with the multiple gestation as a single code. Therefore, it is inappropriate to include these codes on the Unacceptable principal diagnosis edit code list.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25007), for FY 2017, we proposed to remove the ICD–10–CM diagnosis codes listed in Table 6P.1c. associated with the proposed rule (which is available via Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from the ICD–10 MCE

Version 34 Unacceptable principal diagnosis list. We invited public comments on our proposal.

Comment: Commenters supported the proposal to remove the ICD–10–CM diagnosis codes listed describing multiple gestation from the Unacceptable principal diagnosis edit code list in the ICD–10 MCE.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to remove the ICD–10–CM diagnosis codes listed in Table 6P.1c. associated with this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from the ICD–10 MCE Version 34 Unacceptable principal diagnosis list, effective October 1, 2016.

(3) Supervision of High Risk Pregnancy

We received a request to review the ICD–10–CM diagnosis codes related to supervision of high risk pregnancy (elderly primigravida and multigravida) that are currently listed on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list. The requestor stated that these codes were not included in the edit under the ICD–9–CM MCE. According to the requester, the codes describing these conditions should be allowed for reporting as a principal diagnosis based on the ICD–10–CM Tabular List of Diseases instructions for Chapter 15 (Certain Conditions Originating in the Perinatal Period). The chapter-specific guidelines for ICD–10–CM state that ''diagnosis code O80 (Encounter for full-term uncomplicated delivery) should be assigned when a woman is admitted for a full-term normal delivery and delivers a single, healthy infant without any complications antepartum, during the delivery, or postpartum during the delivery episode. Code O80 is always a principal diagnosis. It is not to be used if any other code from Chapter 15 is needed to describe a current complication of the antenatal, delivery, or perinatal period.'' The requestor stated that obstetric patients admitted as inpatients often meet the definition of an elderly primigravida or elderly multigravida,[1] which is the appropriate condition to be reported as the principal diagnosis. However, because the codes describing this condition are listed on the Unacceptable principal diagnosis edit code list, they are unable to be reported.

The diagnosis codes describing high-risk patients admitted for delivery differ between the ICD–10–CM and ICD–9–CM classifications. Under ICD–9–CM, two diagnosis codes are required to separately report concept 1 of elderly primigravida or elderly multigravida and whether a delivery occurred and concept 2 of supervision of high-risk pregnancy with elderly primigravida or elderly multigravida. We display the codes that correspond to these concepts below and titled them as Code List 1 and Code List 2. A code from each list would be reported to fully describe the circumstances of the admission and the patient.

Code List 1—We note that the following codes are listed on the ICD–9–CM MCE Version 32 Unacceptable principal diagnosis edit code list:

ICD–9–CM diagnosis code	Description
V23.81	Supervision of high-risk pregnancy with elderly primigravida.
V23.82	Supervision of high-risk pregnancy with elderly multigravida.

Code List 2—We note that the following codes are *not* listed on the ICD–9–CM MCE Version 32 Unacceptable principal diagnosis edit code list. However, we display them here for the benefit of the reader in the discussion that follows.

ICD–9–CM diagnosis code	Description
659.50	Elderly primigravida, unspecified as to episode of care or not applicable.
659.51	Elderly primigravida, delivered, with or without mention of antepartum condition.
659.53	Elderly primigravida, antepartum condition or complication.
659.60	Elderly multigravida, unspecified as to episode of care or not applicable.
659.61	Elderly multigravida, delivered with or without mention of antepartum condition.
659.63	Elderly multigravida, antepartum condition or complication.

As noted above, in the ICD–9–CM MCE Version 32, only the ICD–9–CM diagnosis codes describing the supervision of high-risk pregnancy are listed on the Unacceptable principal diagnosis edit code list.

There are eight ICD–10–CM diagnosis codes included on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list that describe the concept of elderly primigravida or elderly multigravida and supervision of high-risk pregnancy, in a *single* code. As shown below, the concept of whether a delivery occurred is not included in the code description for the eight codes.

ICD–10–CM diagnosis code	Description
O09.511	Supervision of elderly primigravida, first trimester.
O09.512	Supervision of elderly primigravida, second trimester.
O09.513	Supervision of elderly primigravida, third trimester.
O09.519	Supervision of elderly primigravida, unspecified trimester.

[1] The ICD–10–CM classification defines an elderly primigravida or elderly multigravida as a complication of the pregnancy since the management and care of the expectant mother is affected by the fact they are an older patient.

ICD–10–CM diagnosis code	Description
O09.521	Supervision of elderly multigravida, first trimester.
O09.522	Supervision of elderly multigravida, second trimester.
O09.523	Supervision of elderly multigravida, third trimester.
O09.529	Supervision of elderly multigravida, unspecified trimester.

Because the concepts and coding guidelines between the ICD–9–CM and ICD–10–CM classifications differ greatly in how they define this subset of patients, in the FY 2017 IPPS/LTCH PPS proposed rule, we acknowledged that the eight ICD–10–CM diagnosis codes listed above should be removed from the ICD–10 MCE Unacceptable principal diagnosis edit code list to permit the reporting of these codes as principal diagnosis when the documentation supports such assignment.

We also note that during our analysis of the eight diagnosis codes describing elderly primigravida and elderly multigravida high risk pregnancy patients, we found additional codes on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list related to high-risk pregnancy that we believe should also be removed so as to permit the reporting of these codes as principal diagnosis when the documentation supports such assignment.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25007 through 25008), for FY 2017, we proposed to remove all the ICD–10–CM diagnosis codes related to high-risk pregnancy currently listed in Table 6P.1d. associated with the proposed rule (which is available via Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from the ICD–10 MCE Version 34 Unacceptable principal diagnosis edit code list. We invited public comment on our proposal.

Comment: Many commenters supported the proposal to remove the ICD–10–CM diagnosis codes related to high-risk pregnancy from the ICD–10 MCE Unacceptable principal diagnosis edit code list. However, some commenters did not support the proposal. The commenters stated their understanding that the codes from category O09, Supervision of high-risk pregnancy, should only be used for routine prenatal outpatient visits.

Response: We appreciate the commenters' support of our proposal. With regard to the commenters who did not support the proposal to remove the diagnosis codes related to high-risk pregnancy from the ICD–10 MCE Unacceptable principal diagnosis edit code list, we note that there is confusion with the correct reporting of these diagnosis codes. For example, in the Alphabetic Index to Diseases, the following entry is displayed:

- Pregnancy (childbirth) (labor) (puerperium) (*see also* Delivery and Puerperal)

□□ complicated by (care of) (management affected by)

□□ elderly

□□□ multigravida O09.52-

□□□ primigravida O09.51-.

Therefore, the classification is defining an elderly multigravida or elderly primigravida as a complication of the pregnancy. This entry could relate to Chapter 15, Section I.C.15.b.3 of the guidelines for episodes when no delivery occurs, which instructs users that the principal diagnosis should correspond to the principal complication of the pregnancy which necessitated the encounter for care. In other words, if an elderly primigravida is admitted to the hospital with no other complications and does not deliver during that admission, the classification appears to allow the reporting of a code from category O09, Supervision of high-risk pregnancy, as a principal diagnosis based on the Index entry. However, in Chapter 15, Section I.C.15.b.2. of the guidelines, the language instructs users that a code from category O90, Supervision of high-risk pregnancy, should be used as the first-listed diagnosis to report prenatal outpatient visits for high-risk patients.

We consulted with the staff at the CDC's NCHS to clarify the intent of the ICD–10–CM Alphabetic Index to Diseases entry and the Chapter 15 guidelines related to these codes. According to the CDC NCHS staff, the ICD–10–CM Guidelines have been updated for FY 2017 to explain the appropriate reporting of category O09 codes. The FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting are available via the Internet on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd10cm.htm*. We note that, historically, we have not provided coding advice in rulemaking with respect to policy. We collaborate with the American Hospital Association (AHA) through the Coding Clinic for ICD–10–CM and ICD–10–PCS to promote proper coding. In addition, a proposal to revise the ICD–10–CM Alphabetic Index to Diseases will be discussed at the September 13–14, 2016 ICD–10 Coordination and Maintenance Committee meeting.

After consideration of the public comments we received and the updated FY 2017 ICD–10–CM Official Guidelines for Coding and Reporting, we are not finalizing our proposal to remove all the ICD–10–CM diagnosis codes related to high-risk pregnancy currently listed in Table 6P.1d. associated with the proposed rule and this final rule (which is available via Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from the ICD–10 MCE Version 34 Unacceptable principal diagnosis edit code list. The ICD–10–CM diagnosis codes listed in Table 6P.1d. will continue to be subject to the Unacceptable principal diagnosis edit in the ICD–10 MCE Version 34, effective October 1, 2016.

e. Other MCE Issues

The following MCE discussion, proposals, and final policies are the result of internal review of other MCE issues.

(1) Procedure Inconsistent With Length of Stay Edit

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49411), we finalized a revision for the language of the ICD–10 MCE Version 33 edit for ''Procedure inconsistent with length of stay'' with regard to ICD–10–PCS procedure code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours). The current description of the code edit reads as follows: ''The following procedure code should only be coded on claims with a length of stay greater than four days.''

As we strive to assist providers with correct coding and reporting of this service, we proposed to further revise the description of this code edit. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25008), for FY 2017, we proposed to modify the edit description to read as follows: ''The following procedure code should only be coded on claims when the respiratory ventilation is provided for greater than

four consecutive days during the length of stay.''

We stated that we believe this proposed modification would further clarify the appropriate circumstances in which ICD–10–PCS code 5A1955Z may be reported. We invited public comments on our proposal.

Comment: Commenters supported the proposal to modify the description for the ''Procedure inconsistent with length of stay'' edit for ICD–10–PCS code 5A1955Z in the ICD–10 MCE.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are adopting as final the proposed revision of the description of the ''Procedure inconsistent with length of stay'' edit for ICD–10–PCS code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours) under the ICD–10 MCE from ''The following procedure code should only be coded on claims with a length of stay greater than four days'' to ''The following procedure code should only be coded on claims when the respiratory ventilation is provided for greater than four consecutive days during the length of stay'' in the ICD–10 MCE Version 34, effective October 1, 2016.

Also, consistent with the discussion in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49411 through 49412), we believe it would be beneficial to revise the title for ICD–10 MS–DRG 208 (Respiratory System Diagnosis with Ventilator Support <96 Hours). Currently, this ICD–10 MS–DRG title references terminology for mechanical ventilation ''< 96hours'' based on the GROUPER logic for MS–DRG 208, which includes ICD–10–PCS codes 5A1935Z (Respiratory ventilation, less than 24 consecutive hours) and 5A1945Z (Respiratory ventilation, 24–96 consecutive hours). Because ICD–10–PCS code 5A1945Z includes mechanical ventilation up to and including 96 hours, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25008), we proposed to modify the title of MS–DRG 208 by adding an ''equal'' sign (=) after the ''less than'' (<) sign to better reflect the GROUPER logic. We proposed to revise the title of ICD–10 MS–DRG 208 as follows, effective October 1, 2016: MS–DRG 208 (Respiratory System Diagnosis with Ventilator Support <=96 Hours). We invited public comments on our proposal.

Comment: Commenters supported the proposal to revise the title for ICD–10 MS–DRG 208.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to revise the title of MS–DRG 208 by adding an ''equal'' sign (=) after the ''less than'' (<) sign to better reflect the GROUPER logic. The finalized title for MS–DRG 208 (Respiratory System Diagnosis with Ventilator Support <=96 Hours) is included in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(2) Maternity Diagnoses

We identified three ICD–10–CM diagnosis codes that describe conditions related to pregnancy or the puerperium that are not currently listed on the ICD–10 MCE Version 33 Age conflict edit code list for maternity diagnoses. The diagnosis codes include:

- C58 (Malignant neoplasm of placenta);
- D39.2 (Neoplasm of uncertain behavior of placenta); and
- F53 (Puerperal psychosis).

To be consistent with other related conditions currently included on the Age conflict edit code list for maternity diagnoses, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25008), we proposed to add ICD–10–CM diagnosis codes C58 (Malignant neoplasm of placenta), D39.2 (Neoplasm of uncertain behavior of placenta), and F53 (Puerperal psychosis) to the Age conflict edit code list for maternity diagnoses.

We invited public comments on our proposals for changes to the FY 2017 ICD–10 MCE Version 34.

Comment: Many commenters supported the proposal to add ICD–10–CM diagnosis codes C58, D39.2, and F53 to the Age conflict edit code list for maternity diagnosis in the ICD–10 MCE. The commenters stated that the addition of these diagnosis codes is appropriate and consistent with related conditions currently on the edit code list for maternity diagnoses.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–CM diagnosis codes C58 (Malignant neoplasm of placenta), D39.2 (Neoplasm of uncertain behavior of placenta), and F53 (Puerperal psychosis) to the Age conflict edit code list for maternity diagnosis in the ICD–10 MCE Version 34, effective October 1, 2016.

(3) Manifestation Codes Not Allowed as Principal Diagnosis Edit

Section I.A.13. of the FY 2016 ICD–10–CM Official Guidelines for Coding and Reporting states that certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions, the classification has a coding convention that requires the underlying condition be sequenced first followed by the manifestation. Wherever such a combination exists, there is a ''use additional code'' note at the etiology code, and a ''code first'' note at the manifestation code. These instructional notes indicate proper sequencing order of the codes, etiology followed by manifestation.

We found that in the ICD–10–CM Tabular List of Diseases at category M02 (Postinfective and reactive arthropathies), a ''Code first underlying disease'' note exists. This would indicate that there are codes in that category that are manifestations of an underlying etiology. We then examined the ICD–10 MCE Version 33 to determine if diagnosis codes from that category were included on the Manifestation codes not allowed as principal diagnosis edit code list. Only three ICD–10–CM diagnosis codes from that category were listed:

- M02.88 (Other reactive arthropathies, vertebrae);
- M02.89 (Other reactive arthropathies, multiple sites); and
- M02.9 (Reactive arthropathy, unspecified).

Based on the instructional note at the M02 category level, the title at subcategory M02.8 (Other reactive arthropathies), and the three diagnosis codes listed above on the current ICD–10 MCE Version 33 Manifestation codes not allowed as principal diagnosis edit code list, it seems appropriate that all of the diagnosis codes in subcategory M02.8 should be identified as manifestation codes.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25008 through 25009), we proposed to add the ICD–10–CM diagnosis codes listed in the following table to the ICD–10 MCE Version 34 Manifestation codes not allowed as principal diagnosis edit code list.

ICD–10–CM diagnosis code	Description
M02.80	Other reactive arthropathies, unspecified site.

ICD–10–CM diagnosis code	Description
M02.811	Other reactive arthropathies, right shoulder.
M02.812	Other reactive arthropathies, left shoulder.
M02.819	Other reactive arthropathies, unspecified shoulder.
M02.821	Other reactive arthropathies, right elbow.
M02.822	Other reactive arthropathies, left elbow.
M02.829	Other reactive arthropathies, unspecified elbow.
M02.831	Other reactive arthropathies, right wrist.
M02.832	Other reactive arthropathies, left wrist.
M02.839	Other reactive arthropathies, unspecified wrist.
M02.841	Other reactive arthropathies, right hand.
M02.842	Other reactive arthropathies, left hand.
M02.849	Other reactive arthropathies, unspecified hand.
M02.851	Other reactive arthropathies, right hip.
M02.852	Other reactive arthropathies, left hip.
M02.859	Other reactive arthropathies, unspecified hip.
M02.861	Other reactive arthropathies, right knee.
M02.862	Other reactive arthropathies, left knee.
M02.869	Other reactive arthropathies, unspecified knee.
M02.871	Other reactive arthropathies, right ankle and foot.
M02.872	Other reactive arthropathies, left ankle and foot.
M02.879	Other reactive arthropathies, unspecified ankle and foot.

We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the ICD–10–CM codes in the table included in the proposed rule describing other reactive arthropathies to the Manifestation codes not allowed as principal diagnosis edit code list in the ICD–10 MCE.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes in subcategory M02.8 as displayed in the table in the proposed rule and above to the Manifestation codes not allowed as principal diagnosis edit code list in the ICD–10 MCE Version 34, effective October 1, 2016.

(4) Questionable Admission Edit

In the MCE, some diagnoses are not usually sufficient justification for admission to an acute care hospital. For example, if a patient is assigned ICD–10–CM diagnosis code R03.0 (Elevated blood pressure reading, without diagnosis of hypertension), the patient would have a questionable admission because an elevated blood pressure reading is not normally sufficient justification for admission to a hospital.

Upon review of the ICD–10–CM diagnosis codes listed under the ICD–10 MCE Version 33 Questionable Admission edit, our clinical advisors determined that certain diagnoses clinically warrant hospital admission. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25009), we proposed to remove the following diagnosis codes from the ICD–10 MCE Version 34.0 Questionable admission edit.

- T81.81XA (Complication of inhalation therapy, initial encounter);
- T88.4XXA (Failed or difficult intubation, initial encounter);
- T88.7XXA (Unspecified adverse effect of drug or medicament, initial encounter);
- T88.8XXA (Other specified complications of surgical and medical care, not elsewhere classified, initial encounter); and
- T88.9XXA (Complication of surgical and medical care, unspecified, initial encounter).

We invited public comments on our proposal.

Comment: A number of commenters supported the proposal to remove the ICD–10–CM diagnosis codes listed in the proposed rule from the Questionable admission edit in the ICD–10 MCE.

Response: We appreciate the commenters' support for our proposal.

After consideration of the public comments we received, we are finalizing our proposal to remove the five ICD–10–CM diagnosis codes listed in the proposed rule and above (T81.81XA, T88.4XXA, T88.7XXA, T88.8XXA, and T88.9XXA) from the ICD–10 MCE Questionable admission edit for the ICD–10 MCE Version 34, effective October 1, 2016.

(5) Removal of Edits and Future Enhancement

With the implementation of ICD–10, it is clear that there are several concepts that differ from the ICD–9–CM classification. These differences are evident in the MCE as discussed earlier in this section. Looking ahead to the needs and uses of coded data as the data continue to evolve from the reporting, collection, processing, coverage, payment and analysis aspect, we believe the need to ensure the accuracy of the coded data becomes increasingly significant.

The purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during Medicare claims processing. As shown in the FY 2016 ICD–10 MCE Version 33 manual file and an ICD–9–CM MCE Version 33.0A manual file (developed for analysis only), an edit code list exists according to the definition or criteria set forth for each specified type of edit. Over time, certain edits under the ICD–9–CM MCE became discontinued as they were no longer needed. However, the MCE manual has continued to make reference to these discontinued edits, including through the replication process with transitioning to ICD–10.

Currently, the FY 2016 ICD–10 MCE Version 33 manual file displays the following edits:

- 12. Open biopsy check. Effective October 1, 2010, the Open biopsy check edit was discontinued and will appear for claims processed using MCE Version 2.0–26.0 only.
- 13. Bilateral procedure. Effective with the ICD–10 implementation, the bilateral procedure edit will be discontinued.

Because these edits are no longer valid, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25009), we proposed to remove the reference to them, effective with the ICD–10 MCE manual and software Version 34, for FY 2017. We invited public comments on our proposal.

Comment: Commenters supported the proposal to remove the language referencing discontinued edits for the

open biopsy check and the bilateral procedure edit from the ICD–10 MCE.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to remove the references to the open biopsy check and the bilateral procedure edit from the ICD–10 MCE Version 34, effective October 1, 2016.

As we continue to evaluate the purpose and function of the MCE with respect to the transition to ICD–10, we encourage public input for future discussion. For instance, we recognize a need to further examine the current list of edits and the definitions of those edits. We encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data.

13. Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

Because the relative resource intensity of surgical classes can shift as a function of MS–DRG reclassification and recalibrations, for FY 2017, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications and recalibrations, to determine if the ordering of classes coincides with the intensity of resource utilization.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we proposed to make for FY 2017, as discussed in section II.F.4.c. of the preamble of the FY 2017 IPPS/LTCH PPS proposed rule, we proposed to maintain the existing surgical hierarchy in MDC 5 for proposed revised MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with MCC and without MCC, respectively) (81 FR 25010).

We invited public comments on our proposal.

Comment: A number of commenters supported the proposal to maintain the current surgical hierarchy in MDC 5 for proposed revised MS–DRGs 228 and 229.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current surgical hierarchy in MDC 5 for FY 2017. As discussed in section II.F.5.d. in the preamble of this final rule, we finalized the modification of MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively), effective with the ICD–10 MS–DRGs Version 34 on October 1, 2016.

14. Changes to the MS–DRG Diagnosis Codes for FY 2017

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25010), the tables identifying the proposed additions and deletions to the MCC severity levels list and the proposed additions and deletions to the CC severity levels list for FY 2017 were made available via the Internet on the CMS Web site at: *http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as follows:

- Table 6I.1—Proposed Additions to the MCC List—FY 2017;
- Table 6I.2—Proposed Deletions to the MCC List—FY 2017;
- Table 6J.1—Proposed Additions to the CC List—FY 2017; and
- Table 6J.2—Proposed Deletions to the CC List—FY 2017.

We did not receive any public comments on the proposed additions or deletions to the MCC and CC lists and, therefore, are adopting them as final, effective October 1, 2016. The final version of these four tables for FY 2017 are available via the Internet on the same CMS Web site cited above.

As we stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49414), certain ICD–10–CM diagnosis codes express conditions that, when coded in

ICD–9–CM, use two or more ICD–9–CM diagnosis codes. In the interest of ensuring that the ICD–10 MS–DRGs place a patient in the same MS–DRG, regardless of whether the patient claim was to be coded in ICD–9–CM or ICD–10, whenever one of these ICD–10–CM combination codes is used as principal diagnosis, the cluster of ICD–9–CM codes that would be coded on an ICD–9–CM claim is considered. If one of the ICD–9–CM codes in the cluster is a CC or an MCC, the single ICD–10–CM combination code used as a principal diagnosis must also imply that the CC or MCC is present. Appendix J of the ICD–10 MS–DRG Definitions Manual Version 33 includes two lists. Part 1 is the list of principal diagnosis codes where the ICD–10–CM code is its own MCC. Part 2 is the list of principal diagnosis codes where the ICD–10–CM code is its own CC. Appendix J of the ICD–10 MS–DRG Definitions Manual Version 33 is available via the internet on the CMS Web site at: *http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

For FY 2017, the ICD–10–CM diagnoses for which this implication must be made were listed in Table 6L (Proposed Principal Diagnosis Is Its Own MCC List—FY 2017), Table 6M (Proposed Principal Diagnosis Is Its Own CC List—FY 2017), and Table 6M.1 (Proposed Additions to the Principal Diagnosis is Its Own CC List—FY 2017) associated with the proposed rule, which were made available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, as described in section VI. of the Addendum to the proposed rule. We note that there were no proposed changes to Table 6L for FY 2017 and the list of ICD–10–CM diagnoses that will act as its own MCC when reported as a principal diagnosis remains unchanged from the FY 2016 list. Therefore, we did not develop Table 6L.1 (Additions to the Principal Diagnosis Is Its Own MCC List) or Table 6L.2 (Deletions to the Principal Diagnosis Is Its Own MCC List) for FY 2017.

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49414), ICD–9–CM diagnosis code 591 (Hydronephrosis) is classified as a CC. Under ICD–10–CM, hydronephrosis is reported with a combination code if the hydronephrosis is due to another condition, such as with new ICD–10–CM code N13.0 (Hydronephrosis with ureteropelvic junction obstruction), effective October 1, 2016. In ICD–10–CM, this finalized code is classified as a CC and, similar to existing ICD–10–CM codes N13.1 (Hydronephrosis with ureteral stricture, not elsewhere classified) and N13.2 (Hydronephrosis with renal and ureteral calculous obstruction), should be recognized as a principal diagnosis that acts as its own CC. Accordingly, ICD–10–CM code N13.0 (Hydronephrosis with ureteropelvic junction obstruction) was inclujded in Table 6M (Proposed Principal Diagnosis Is Its Own CC List—FY 2017) and Table 6M.1 (Proposed Additions to the Principal Diagnosis Is Its Own CC List—FY 2017), which were made available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We did not receive any public comments regarding this specific proposal and, therefore, are adopting it as final, effective October 1, 2016.

15. Complications or Comorbidity (CC) Exclusions List

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length of stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (non-CC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. CC Exclusions List for FY 2017

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. As previously indicated, we developed a list of diagnoses, using physician panels, to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity. In previous years, we made changes to the list of CCs, either by adding new CCs or deleting CCs already on the list.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541) for detailed information regarding revisions that were made to the CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 33 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual, which is available via the Internet on the CMS Web site at: *http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, and includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or an MCC when

reported as a secondary diagnosis. If the code designated as a CC or an MCC is allowed with all principal diagnoses, the phrase ''NoExcl'' (for no exclusions) follows the CC or MCC designation. For example, ICD–10–CM diagnosis code A17.83 (Tuberculous neuritis) has this ''NoExcl'' entry. For all other diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when used as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a non-CC. Part 2 is the list of diagnosis codes designated as an MCC only for patients discharged alive; otherwise, they are assigned as a non-CC.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25011), for FY 2017, we proposed changes to the ICD–10 MS–DRGs Version 34 CC Exclusion List. Therefore, we developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2017; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2017; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2017; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2017. Each of these principal diagnosis codes for which there is a CC exclusion was shown in Table 6G.2. with an asterisk and the conditions that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. Beginning with discharges on or after October 1 of each year, the indented diagnoses are not recognized by the GROUPER as valid CCs for the asterisked principal diagnoses. Tables 6G and 6H associated with the proposed rule are available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Comment: Several commenters supported the proposed changes to the CC Exclusion List as displayed in Table 6G.1., Table 6G.2., Table 6H.1., and Table 6H.2. that were associated with the proposed rule and made available via the Internet on the CMS Web site.

Response: We appreciate the commenters' support of our proposals.

We note that, for this FY 2017 IPPS/LTCH PPS final rule, we have developed Table 6K.—Complete List of CC Exclusions, which is available via the Internet at the same CMS Web site as Tables 6G and 6H. Table 6K. corresponds to the Part 1 list of Appendix C in the ICD–10 MS–DRG Definitions Manual as described above.

The complete documentation of the ICD–10 MS–DRG Version 34 GROUPER logic, including the current CC Exclusions List, is available via the Internet on the CMS Acute Inpatient PPS Web page at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

To capture new and deleted diagnosis and procedure codes, for FY 2017, we developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, and Table 6C—Invalid Diagnosis Codes to the proposed rule. However, they were not published in the Addendum to the proposed rule but were available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, as described in section VI. of the Addendum to the proposed rule.

For this final rule, we have developed Table 6D.—Invalid Procedure Codes, to reflect the deletion of 12 ICD–10–PCS procedure codes, effective October 1, 2016, as a result of public comments received after the March 9–10, 2016 ICD–10 Coordination and Maintenance Committee meeting.

We note that while we did not specifically develop a Table 6E.—Revised Diagnosis Code Titles for the proposed rule, a document containing the FY 2017 revised diagnosis code titles, as well as new diagnosis codes that have been finalized to date since implementation of the partial code freeze, was made available in advance in response to requests from the health care industry. During the March 9–10, 2016 ICD–10 Coordination and Maintenance Committee meeting, a discussion regarding this document was presented. Participants were informed that the document titled ''FY 2017 New Released ICD–10–CM Codes'' would contain the information that would otherwise be included for this table. This document has been posted along with the other March 9–10, 2016 ICD–10 Coordination and Maintenance Committee meeting materials on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm*.

In addition, we did not specifically develop a Table 6F.—Revised Procedure Code Titles for the proposed rule. However, a document containing the FY 2017 revised procedure code titles, as well as new procedure codes that have been finalized to date since implementation of the partial code freeze, was made available in advance in response to requests from the health care industry. During the March 9–10, 2016 ICD–10 Coordination and Maintenance Committee meeting, a discussion regarding this document was presented. Participants were informed that the document titled ''FY 2017 New Revised ICD–10–PCS Codes'' would contain the information that would otherwise be included for this table. This document is posted on the CMS Web site at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2016-03-09-MeetingMaterials.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending*.

After consideration of the public comments we received, we are making available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* the following final tables associated with this final rule:

- Table 6A.—New Diagnosis Codes—FY 2017;
- Table 6B.—New Procedure Codes—FY 2017;
- Table 6C.—Invalid Diagnosis Codes—FY 2017;
- Table 6D.—Invalid Procedure Codes—FY 2017;
- Table 6E.—Revised Diagnosis Code Titles—FY 2017;
- Table 6F.—Revised Procedure Code Titles—FY 2017;
- Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2017;
- Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2017;
- Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2017;
- Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2017;
- Table 6I.—Complete MCC List—FY 2017;
- Table 6I.1.—Additions to the MCC List—FY 2017;
- Table 6I.2.–Deletions to the MCC List—FY 2017;
- Table 6J.—Complete CC List—FY 2017;
- Table 6J.1.—Additions to the CC List—FY 2017;
- Table 6J.2.—Deletions to the CC List —FY 2017;
- Table 6K.—Complete List of CC Exclusions—FY 2017;
- Table 6L.—Principal Diagnosis Is Its Own MCC List—FY 2017;
- Table 6M.—Principal Diagnosis Is Its Own CC List—FY 2017; and
- Table 6M.1.—Additions to the Principal Diagnosis Is Its Own CC List—FY 2017

16. Review of Procedure Codes in MS DRGs 981 Through 983; 984 Through 986; and 987 Through 989

Each year, we review cases assigned to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively); MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively); and MS–DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to determine whether it would be appropriate to change the procedures assigned among these MS–DRGs. MS–DRGs 981 through 983, 984 through 986, and 987 through 989 are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These MS–DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group. Under ICD–9–CM, MS–DRGs 984 through 986 are assigned to those discharges in which one or more of the following prostatic procedures are performed and are unrelated to the principal diagnosis:

- 60.0 (Incision of prostate);
- 60.12 (Open biopsy of prostate);
- 60.15 (Biopsy of periprostatic tissue);
- 60.18 (Other diagnostic procedures on prostate and periprostatic tissue);
- 60.21 (Transurethral prostatectomy);
- 60.29 (Other transurethral prostatectomy);
- 60.61 (Local excision of lesion of prostate);
- 60.69 (Prostatectomy, not elsewhere classified);
- 60.81 (Incision of periprostatic tissue);
- 60.82 (Excision of periprostatic tissue);
- 60.93 (Repair of prostate);
- 60.94 (Control of (postoperative) hemorrhage of prostate);
- 60.95 (Transurethral balloon dilation of the prostatic urethra);
- 60.96 (Transurethral destruction of prostate tissue by microwave thermotherapy);
- 60.97 (Other transurethral destruction of prostate tissue by other thermotherapy); and
- 60.99 (Other operations on prostate).

Under the ICD–10 MS–DRGs Version 33, the comparable ICD–10–PCS code translations for the above list of codes are available in Table 6P.2. associated with the FY 2017 proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). All remaining O.R. procedures are assigned to MS–DRGs 981 through 983 and 987 through 989, with MS–DRGs 987 through 989 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis.

We refer the reader to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50544 through 50545) for detailed information regarding modifications that were made to the former ICD–9–CM CMS DRG 468 (MS–DRGs 981 through 983), CMS DRG 476 (MS–DRGs 984 through 986), and CMS DRG 477 (MS–DRGs 987 through 989) with regard to the movement of procedure codes. We note that no procedure codes were moved from these DRGs from FY 2008 through FY 2016.

Our review of MedPAR claims data showed that there are no cases that merited movement or should logically be reassigned from ICD–10 MS–DRGs 984 through 986 to any of the other MDCs. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25012), for FY 2017, we did not propose to change the procedures assigned among these MS–DRGs. We invited public comments on our proposal to maintain the current structure of these MS–DRGs.

Comment: Many commenters supported the proposal to maintain the current structure of MS–DRGs 984, 985, and 986 under the ICD–10 MS–DRGs.

Response: We appreciate the commenters' support of our proposal. We note that while the comparable ICD–10–PCS code translations for the above list of ICD–9–CM codes were made available in Table 6P.2. associated with the FY 2017 proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*), we wish to clarify that the table was not intended to be a representation of the current ICD–10 MS–DRG GROUPER Version 33 logic. Rather, it was to simply demonstrate what the ICD–9–CM to ICD–10–PCS code translations were for purposes of review and comment. For example, the translations that were listed in Table 6P.2 of the FY 2017 proposed rule included six ICD–10–PCS procedure codes that are not included in the current ICD–10 MS–DRG GROUPER Version 33 logic for MS–DRGs 984, 985, and 986. Although these six ICD–10–PCS procedure codes are considered comparable translations of the corresponding ICD–9–CM procedure codes, these ICD–10–PCS procedure codes are currently designated as non-O.R. codes and, therefore, are not defined as prostatic O.R. codes for purposes of MS–DRG assignment under the ICD–10 MS–DRG Version 33 Definitions Manual under Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

In addition, as discussed in section II.F.19.c.1.b. of the FY 2017 proposed rule (81 FR 25025), we proposed to change the status of a number of ICD–10–PCS procedure codes from O.R. to non-O.R. Among the list in Table 6P.4b. associated with the proposed rule were procedures describing the endoscopic/transorifice removal of drainage, infusion, intraluminal or monitoring devices. Four of these codes (which were proposed to change from an O.R. to non-O.R. status) identify procedures performed on the prostate and seminal vesicles and are currently included in the ICD–10 MS–DRG GROUPER Version 33 logic for MS–DRGs 984, 985, and 986. These four procedure codes were also listed in Table 6P.2.—List of ICD–10–PCS code translations for prostatic procedures in MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively), are currently designated as O.R. codes, and were proposed to change to a non-O.R. status. As discussed in section II.F.19.c.(1)(b) of the preamble of this final rule, we received public support for changing the status of the codes listed in Table 6P.4b. and are finalizing our proposal.

To reflect our finalized policy to designate these four codes as non-O.R. codes, as discussed in section II.F.19.c.(1)(b) of the preamble of this final rule, and also to remove the six ICD–10–PCS procedure codes that are not included in the current ICD–10 MS–DRG GROUPER Version 33 logic for MS–DRGs 984, 985 and 986, we are removing the following 10 ICD–10–PCS procedure codes from Table 6P.2 (which was associated with the FY 2017 proposed rule and available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-FeeforServicePayment/AcuteInpatientPPS/index.html*):

- 0T7D7ZZ (Dilation of urethra, via natural or artificial opening);
- 0T7D8ZZ (Dilation of urethra, via natural or artificial opening endoscopic);
- 0VB03ZX (Excision of prostate, percutaneous approach, diagnostic);

- 0VB04ZX (Excision of prostate, percutaneous endoscopic approach, diagnostic);
- 0VB07ZX (Excision of prostate, via natural or artificial opening, diagnostic);
- 0VB08ZX (Excision of prostate, via natural or artificial opening endoscopic, diagnostic);
- 0VP470Z (Removal of drainage device from prostate and seminal vesicles, via natural or artificial opening);
- 0VP473Z (Removal of infusion device from prostate and seminal vesicles, via natural or artificial opening);
- 0VP480Z (Removal of drainage device from prostate and seminal vesicles, via natural or artificial opening endoscopic); and
- 0VP483Z (Removal of infusion device from prostate and seminal vesicles, via natural or artificial opening endoscopic).

In addition, we are finalizing the list of ICD–10–PCS procedure codes that are assigned to MS–DRGs 984, 985, and 986 for FY 2017. The list of codes displayed in Table 6P.2 associated with this final rule represents the ICD–10 MS–DRG GROUPER logic for MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

a. Moving Procedure Codes From MS–DRGs 981 Through 983 or MS–DRGs 987 Through 989 Into MDCs

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. As we discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25012), upon review of the claims data from the December 2015 update of the FY 2015 MedPAR file, we did not find any cases that merited movement or that should logically be assigned to any of the other MDCs. Therefore, in the proposed rule for FY 2017, we did not propose to remove any procedures from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned. We invited public comments on our proposal to maintain the current structure of these MS–DRGs.

Comment: Several commenters supported our proposal to not move any procedure codes out of MS–DRGs 981, 982, 983, 987, 988, or 989.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments we received, we are finalizing our proposal to not move any procedures from MS–DRGs 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively), or from MS–DRGs 987, 988, or 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned for ICD–10 MS–DRGs Version 34, effective October 1, 2016.

b. Reassignment of Procedures Among MS–DRGs 981 Through 983, 984 Through 986, and 987 Through 989

We also reviewed the list of ICD–10–PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, 984 through 986, or 987 through 989, to ascertain whether any of those procedures should be reassigned from one of those three groups of MS–DRGs to another of the three groups of MS–DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

As we discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25012), there are no cases representing shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical, or that merited movement so that cases should logically be assigned to any of the other MDCs. Therefore, for FY 2017, we did not propose to move any procedure codes among these MS–DRGs. We invited public comments on our proposal.

Comment: Several commenters supported our proposal to not move any procedure codes among MS–DRGs 981, 982, 983, 984, 985, 986, 987, 988, or 989.

Response: We appreciate the commenters' support for our proposal.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current structure for MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively); MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively); and MS–DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) with regard to not reassigning any procedure codes among these MS–DRGs for FY 2017. As discussed in section II.F.16. of the preamble of this final rule, we are removing four procedure codes from MS–DRGs 984, 985, and 986, as they were included in the codes listed in Table 6P.4b that were finalized to change from being designated as O.R. codes to non-O.R. status in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

c. Adding Diagnosis or Procedure Codes to MDCs

As we discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25012 through 25016), based on the review of cases in the MDCs, we proposed to add multiple diagnosis and procedure codes to MDCs for FY 2017 to address replication issues. We discuss each of these proposals below.

(1) Angioplasty of Extracranial Vessel

In the ICD–9–CM MS–DRGs Version 32, procedures describing angioplasty of an extracranial vessel were assigned to MDC 1 (Diseases and Disorders of the Nervous System) under MS–DRGs 037, 038, and 039 (Extracranial Procedures with MCC, with CC, or without CC/MCC, respectively). Under ICD–9–CM, more than one ICD–9–CM code could be reported for these procedures, depending on the approach that was documented. For example, ICD–9–CM procedure code 00.61 (Percutaneous angioplasty of extracranial vessel(s)) would have been appropriately reported

if the percutaneous approach was documented, and procedure code 39.50 (Angioplasty of other non-coronary vessel(s)) would have been appropriately reported if a specified approach was not documented.

A replication issue for 41 ICD–10–PCS procedure codes describing angioplasty with the open approach was identified after implementation of the ICD–10 MS–DRGs Version 33. In the code translation, these 41 ICD–10–PCS procedure codes were grouped and assigned to ICD–10 MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). However, these procedure codes should have been grouped to ICD–10 MS–DRGs 037 through 039 when a principal diagnosis was reported under MDC 1.

To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25012 through 25013), we proposed to add the 41 ICD–10–PCS procedure codes listed in the following table to ICD–10 MS–DRGs 037 through 039 under MDC 1.

ICD–10–PCS procedure code	Description
037H04Z	Dilation of right common carotid artery with drug-eluting intraluminal device, open approach.
037H0DZ	Dilation of right common carotid artery with intraluminal device, open approach.
037H0ZZ	Dilation of right common carotid artery, open approach.
037J04Z	Dilation of left common carotid artery with drug-eluting intraluminal device, open approach.
037J0DZ	Dilation of left common carotid artery with intraluminal device, open approach.
037J0ZZ	Dilation of left common carotid artery, open approach.
037K04Z	Dilation of right internal carotid artery with drug-eluting intraluminal device, open approach.
037K0DZ	Dilation of right internal carotid artery with intraluminal device, open approach.
037K0ZZ	Dilation of right internal carotid artery, open approach.
037L04Z	Dilation of left internal carotid artery with drug-eluting intraluminal device, open approach.
037L0DZ	Dilation of left internal carotid artery with intraluminal device, open approach.
037L0ZZ	Dilation of left internal carotid artery, open approach.
037M04Z	Dilation of right external carotid artery with drug-eluting intraluminal device, open approach.
037M0DZ	Dilation of right external carotid artery with intraluminal device, open approach.
037M0ZZ	Dilation of right external carotid artery, open approach.
037N04Z	Dilation of left external carotid artery with drug-eluting intraluminal device, open approach.
037N0DZ	Dilation of left external carotid artery with intraluminal device, open approach.
037N0ZZ	Dilation of left external carotid artery, open approach.
037P04Z	Dilation of right vertebral artery with drug-eluting intraluminal device, open approach.
037P0DZ	Dilation of right vertebral artery with intraluminal device, open approach.
037P0ZZ	Dilation of right vertebral artery, open approach.
037Q04Z	Dilation of left vertebral artery with drug-eluting intraluminal device, open approach.
037Q0DZ	Dilation of left vertebral artery with intraluminal device, open approach.
037Q0ZZ	Dilation of left vertebral artery, open approach.
037Y04Z	Dilation of upper artery with drug-eluting intraluminal device, open approach.
037Y0DZ	Dilation of upper artery with intraluminal device, open approach.
037Y0ZZ	Dilation of upper artery, open approach.
057M0DZ	Dilation of right internal jugular vein with intraluminal device, open approach.
057M0ZZ	Dilation of right internal jugular vein, open approach.
057N0DZ	Dilation of left internal jugular vein with intraluminal device, open approach.
057N0ZZ	Dilation of left internal jugular vein, open approach.
057P0DZ	Dilation of right external jugular vein with intraluminal device, open approach.
057P0ZZ	Dilation of right external jugular vein, open approach.
057Q0DZ	Dilation of left external jugular vein with intraluminal device, open approach.
057Q0ZZ	Dilation of left external jugular vein, open approach.
057R0DZ	Dilation of right vertebral vein with intraluminal device, open approach.
057R0ZZ	Dilation of right vertebral vein, open approach.
057S0DZ	Dilation of left vertebral vein with intraluminal device, open approach.
057S0ZZ	Dilation of left vertebral vein, open approach.
057T0DZ	Dilation of right face vein with intraluminal device, open approach.
057T0ZZ	Dilation of right face vein, open approach.

We invited public comments on our proposal to add the above listed codes to ICD–10 MS–DRGs 037, 038, and 039 (Extracranial Procedures with MCC, with CC, or without CC/MCC, respectively) under MDC 1, effective October 1, 2016, for the ICD–10 MS–DRGs Version 34.

Comment: Several commenters supported the proposal to add the codes listed in the table in the proposed rule to ICD–10 MS–DRGs 037, 038, and 039. The commenters also acknowledged CMS' continued efforts for accurate replication.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze the replication issues between the ICD–9 and ICD–10 based MS–DRGs brought to our attention.

After consideration of the public comments we received, we are finalizing our proposal to add the above listed codes to ICD–10 MS–DRGs 037, 038, and 039 (Extracranial Procedures with MCC, with CC, or without CC/MCC, respectively) under MDC 1 for the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(2) Excision of Abdominal Arteries

In the ICD–9–CM MS–DRGs Version 32, procedures involving excision of a vessel and anastomosis, such as those performed for the treatment of an abdominal artery aneurysm (aneurysmectomy), are identified with procedure code 38.36 (Resection of vessel with anastomosis, abdominal arteries) and are assigned to the following MDCs and MS–DRGs:

- MDC 5 (Diseases and Disorders of the Circulatory System): MS–DRGs 270 through 272 (Other Major Cardiovascular Procedures with MCC,

with CC and without CC/MCC, respectively);

- MDC 6 (Diseases and Disorders of the Digestive System): MS–DRGs 356 through 358 (Other Digestive System O.R. Procedures with MCC, with CC and without CC/MCC, respectively);
- MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): MS–DRGs 673 through 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC and without CC/MCC, respectively);
- MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): MS–DRGs 907 through 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively); and
- MDC 24 (Multiple Significant Trauma): MS–DRG 957 through 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC and without CC/MCC, respectively).

A replication issue for 34 ICD–10–PCS procedure codes describing aneurysmectomy procedures with the open and percutaneous endoscopic approach was identified after implementation of the ICD–10 MS–DRGs Version 33. For example, cases with a principal diagnosis of I72.2 (Aneurysm of renal artery) and procedure code 04BA0ZZ (Excision of left renal artery, open approach) are resulting in assignment to ICD–10 MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) instead of to MDC 11 in MS–DRGs 673 through 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25013 through 25014), we proposed to add the 34 ICD–10–PCS procedure codes listed in the following table that are comparable translations of ICD–9–CM procedure code 38.36 to ICD–10 MDCs 6, 11, 21, and 24. We noted that there is no replication issue related to MDC 5 as the ICD–10–PCS procedure codes listed in the table below group there appropriately.

ICD–10–PCS procedure code	Description
04B10ZZ	Excision of celiac artery, open approach.
04B14ZZ	Excision of celiac artery, percutaneous endoscopic approach.
04B20ZZ	Excision of gastric artery, open approach.
04B24ZZ	Excision of gastric artery, percutaneous endoscopic approach.
04B30ZZ	Excision of hepatic artery, open approach.
04B34ZZ	Excision of hepatic artery, percutaneous endoscopic approach.
04B40ZZ	Excision of splenic artery, open approach.
04B44ZZ	Excision of splenic artery, percutaneous endoscopic approach.
04B50ZZ	Excision of superior mesenteric artery, open approach.
04B54ZZ	Excision of superior mesenteric artery, percutaneous endoscopic approach.
04B60ZZ	Excision of right colic artery, open approach.
04B64ZZ	Excision of right colic artery, percutaneous endoscopic approach.
04B70ZZ	Excision of left colic artery, open approach.
04B74ZZ	Excision of left colic artery, percutaneous endoscopic approach.
04B80ZZ	Excision of middle colic artery, open approach.
04B84ZZ	Excision of middle colic artery, percutaneous endoscopic approach.
04B90ZZ	Excision of right renal artery, open approach.
04B94ZZ	Excision of right renal artery, percutaneous endoscopic approach.
04BA0ZZ	Excision of left renal artery, open approach.
04BA4ZZ	Excision of left renal artery, percutaneous endoscopic approach.
04BB0ZZ	Excision of inferior mesenteric artery, open approach.
04BB4ZZ	Excision of inferior mesenteric artery, percutaneous endoscopic approach.
04BC0ZZ	Excision of right common iliac artery, open approach.
04BC4ZZ	Excision of right common iliac artery, percutaneous endoscopic approach.
04BD0ZZ	Excision of left common iliac artery, open approach.
04BD4ZZ	Excision of left common iliac artery, percutaneous endoscopic approach.
04BE0ZZ	Excision of right internal iliac artery, open approach.
04BE4ZZ	Excision of right internal iliac artery, percutaneous endoscopic approach.
04BF0ZZ	Excision of left internal iliac artery, open approach.
04BF4ZZ	Excision of left internal iliac artery, percutaneous endoscopic approach.
04BH0ZZ	Excision of right external iliac artery, open approach.
04BH4ZZ	Excision of right external iliac artery, percutaneous endoscopic approach.
04BJ0ZZ	Excision of left external iliac artery, open approach.
04BJ4ZZ	Excision of left external iliac artery, percutaneous endoscopic approach.

We stated that adding these procedures to those MDCs in the ICD–10 MS–DRGs Version 34 will result in a more accurate replication for the same procedure under the ICD–9–CM MS–DRGs Version 32. We also proposed that these procedure codes be assigned to the corresponding MS–DRGs in each respective MDC as listed above. We stated that the proposed changes would eliminate erroneous assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for these procedures.

We invited public comments on our proposal to add the above listed codes to MDCs 6, 11, 21, and 24 in the corresponding MS–DRGs, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

Comment: Several commenters supported the proposal to add the codes listed in the table in the proposed rule to MDCs 6, 11, 21 and 24 in the corresponding ICD–10 MS–DRGs. The commenters also acknowledged CMS' continued efforts for accurate replication.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze the replication issues between the ICD–9 and ICD–10 based MS–DRGs brought to our attention.

After consideration of the public comments we received, we are finalizing our proposal to add the codes

listed in the table in the proposed rule and above to the following MDCs and MS–DRGs for the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

- MDC 6 (Diseases and Disorders of the Digestive System): MS–DRGs 356 through 358 (Other Digestive System O.R. Procedures with MCC, with CC and without CC/MCC, respectively);
- MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): MS–DRGs 673 through 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC and without CC/MCC, respectively);
- MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): MS–DRGs 907 through 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively); and
- MDC 24 (Multiple Significant Trauma): MS–DRG 957 through 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC and without CC/MCC, respectively).

(3) Excision of Retroperitoneal Tissue

In the ICD–9–CM MS–DRGs Version 32, procedures involving excision of a retroperitoneal lesion (or tissue), such as those performed for the treatment of a neoplasm, are identified with procedure code 54.4 (Excision or destruction of peritoneal tissue) and are assigned to a number of MDCs and MS–DRGs across a variety of body systems, some of which include the following:

- MDC 6 (Diseases and Disorders of the Digestive System): MS–DRGs 356 through 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively);
- MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas): MS–DRGs 423 through 425 (Other Hepatobiliary or Pancreas O.R. Procedures with MCC, with CC, and without CC/MCC, respectively); and
- MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders): MS–DRGs 628 through 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for the ICD–10–PCS procedure codes describing excision of retroperitoneum that involves MDC 6 was identified after implementation of the ICD–10 MS–DRGs Version 33. These procedure codes are ICD–10–PCS codes 0WBH0ZZ (Excision of retroperitoneum, open approach), 0WBH3ZZ (Excision of retroperitoneum, percutaneous approach), and 0WBH4ZZ (Excision of retroperitoneum, percutaneous endoscopic approach). For example, when an ICD–10–CM diagnosis code such as D20.0 (Benign neoplasm of soft tissue of retroperitoneum) is reported with any one of these three ICD–10–PCS procedure codes, the case is assigned to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25014), we proposed to add the three ICD–10–PCS procedure codes to MDC 6 in MS–DRGs 356 through 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). We stated that this would result in a more accurate replication of the comparable procedure under the ICD–9–CM MS–DRGs Version 32. The proposed changes also would eliminate erroneous assignment to MS–DRGs 981 through 983 for these procedures.

We invited public comments on our proposal to add the three ICD–10–PCS codes describing excision of retroperitoneum to MDC 6 in MS–DRGs 356 through 358, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

Comment: Several commenters supported the proposal to add ICD–10–PCS procedure codes 0WBH0ZZ, 0WBH3ZZ, and 0WBH4ZZ describing excision of retroperitoneum to MDC 6 in MS–DRGs 356 through 358. The commenters also acknowledged CMS' continued efforts for accurate replication.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze the replication issues between the ICD–9 and ICD–10 based MS–DRGs brought to our attention.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS codes 0WBH0ZZ (Excision of retroperitoneum, open approach), 0WBH3ZZ (Excision of retroperitoneum, percutaneous approach), and 0WBH4ZZ (Excision of retroperitoneum, percutaneous endoscopic approach) to MDC 6 in MS–DRGs 356 through 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) for the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(4) Occlusion of Vessels: Esophageal Varices

In the ICD–9–CM MS–DRGs Version 32, procedures including ligation or surgical occlusion of esophageal varices are identified with procedure code 42.91 (Ligation of esophageal varices) and are assigned to MDC 6 (Diseases and Disorders of the Digestive System) under MS–DRGs 326 through 328 (Stomach, Esophageal and Duodenal Procedures with MCC, with CC, and without CC/MCC, respectively) and MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas) under MS–DRGs 423 through 425 (Other Hepatobiliary or Pancreas O.R. procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for MDC 7 involving ICD–10–PCS procedure codes 06L30CZ (Occlusion of esophageal vein with extraluminal device, open approach) and 06L30DZ (Occlusion of esophageal vein with intraluminal device, open approach) was identified in the ICD–10 MS–DRGs Version 33 after implementation on October 1, 2015. For instance, when an ICD–10–CM diagnosis code such as K70.30 (Alcoholic cirrhosis of liver without ascites) is reported with either one of the ICD–10–PCS procedure codes, it results in assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25015), we proposed to add the two ICD–10–PCS procedure codes describing occlusion of esophageal vein to MDC 7 under MS–DRGs 423 through 425. We stated that this would result in a more accurate replication of the comparable procedure under the ICD–9–CM MS–DRGs Version 32. We stated that the proposed changes also would eliminate erroneous assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for these procedures.

We invited public comments on our proposal to add ICD–10–PCS procedure codes 06L30CZ and 06L30DZ to MDC 7 under MS–DRGs 423 through 425, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

Comment: Several commenters supported the proposal to add ICD–10–PCS procedure codes 06L30CZ and 06L30DZ to MDC 7 under MS–DRGs 423 through 425. The commenters also acknowledged CMS' continued efforts for accurate replication.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze the replication issues between the ICD–9 and ICD–10 based MS–DRGs brought to our attention.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS procedure codes 06L30CZ

(Occlusion of esophageal vein with extraluminal device, open approach) and 06L30DZ (Occlusion of esophageal vein with intraluminal device, open approach) to MDC 7 under MS–DRGs 423 through 425 (Other Hepatobiliary or Pancreas O.R. procedures with MCC, with CC, and without CC/MCC, respectively) for the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(5) Excision of Vulva

In the ICD–9–CM MS–DRGs Version 32, procedures involving excision of the vulva are identified with procedure code 71.3 (Other local excision or destruction of vulva and perineum) and are assigned to the following MDCs and MS–DRGs:

- MDC 9 (Diseases & Disorders of the Skin, Subcutaneous Tissue and Breast): MS–DRGs 579 through 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively); and
- MDC 13 (Diseases & Disorders of the Female Reproductive System): MS–DRG 746 (Vagina, cervix and vulva procedures with CC/MCC) and MS–DRG 747 (Vagina, Cervix and Vulva procedures without CC/MCC).

A replication issue involving ICD–10–PCS procedure code 0UBMXZZ (Excision of vulva, external approach) was identified after implementation of the ICD–10 MS–DRGs Version 33. For example, when cases with an ICD–10–CM principal diagnosis of code D07.1 (Carcinoma in situ of vulva) are reported with ICD–10–PCS procedure code 0UBMXZZ (Excision of vulva, external approach), they are resulting in assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25015), we proposed to add ICD–10–PCS procedure code 0UBMXZZ to MDC 13 under MS–DRGs 746 and 747. We stated that adding procedure code 0UBMXZZ to MDC 13 in MS–DRGs 746 and 747 would result in a more accurate replication of the comparable procedure under the ICD–9–CM MS–DRGs Version 32. The proposed changes also would eliminate erroneous assignment to MS–DRGs 981 through 983 for these procedures. In addition, the proposed changes would be consistent with the assignment of other clinically similar procedures, such as ICD–10–PCS procedure code 0WBNXZZ (Excision of female perineum, external approach). Finally, we noted that there is no replication issue for MDC 9 regarding this procedure code.

We invited public comment on our proposal to add ICD–10–PCS procedure code 0UBMXZZ to MDC 13 in MS–DRGs 746 and 747, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

Comment: Several commenters supported the proposal to add ICD–10–PCS procedure code 0UBMXZZ to MDC 13 under MS–DRGs 746 and 747. The commenters also acknowledged CMS' continued efforts for accurate replication.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze the replication issues between the ICD–9 and ICD–10 based MS–DRGs brought to our attention.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS procedure code 0UBMXZZ (Excision of vulva, external approach) to MDC 13 under MS–DRG 746 (Vagina, cervix and vulva procedures with CC/MCC) and MS–DRG 747 (Vagina, Cervix and Vulva procedures without CC/MCC) for the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(6) Lymph Node Biopsy

In the ICD–9–CM MS–DRGs Version 32, procedures involving a lymph node biopsy are identified with procedure code 40.11 (Biopsy of lymphatic structure), which may be assigned to several MDCs representing various body systems. Under the ICD–10 MS–DRGs Version 33, this procedure has 114 ICD–10–PCS procedure codes considered to be comparable translations that describe diagnostic drainage or excision of specified lymphatic structures and also warrant assignment to the same MDCs across various body systems.

A replication issue for the lymph node biopsy procedure involving MDC 4 (Diseases and Disorders of the Respiratory System) under the ICD–10 MS–DRGs Version 33 was identified after implementation on October 1, 2015. For example, when a respiratory system diagnosis is reported with the comparable ICD–10–PCS procedure code 07B74ZX (Excision of thorax lymphatic, percutaneous endoscopic approach, diagnostic), the case is assigned to MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25015 through 25016), we proposed to add ICD–10–PCS procedure code 07B74ZX to MDC 4 under MS–DRGs 166 through 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) to more accurately replicate assignment of the comparable procedure code under the ICD–9–CM MS–DRGs Version 32.

While reviewing that specific example, we also identified two other comparable ICD–10–PCS procedure code translations of ICD–9–CM procedure code 40.11 (Biopsy of lymphatic structure) describing diagnostic excision of thoracic lymphatic structures that were not replicated consistent with the ICD–9–CM MS–DRGs Version 32. These are ICD–10–PCS procedure codes 07B70ZX (Excision of thorax lymphatic, open approach, diagnostic) and 07B73ZX (Excision of thorax lymphatic, percutaneous approach, diagnostic). Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25015 through 25016), we proposed to add these two ICD–10–PCS procedure codes to MDC 4 in MS–DRGs 166 through 168 as well.

We stated that adding ICD–10–PCS procedure codes 07B74ZX, 07B70ZX, and 07B73ZX that describe diagnostic excision of thoracic lymphatic structures to MDC 4 under MS–DRGs 166 through 168 would result in a more accurate replication of the comparable procedure under ICD–9–CM MS–DRGs Version 32. We also stated that the proposed changes would eliminate erroneous assignment to MS–DRGs 987 through 989 for these procedures.

We invited public comments on our proposal to add ICD–10–PCS procedure codes 07B74ZX, 07B70ZX, and 07B73ZX to MDC 4 under MS–DRGs 166 through 168, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

Comment: Several commenters expressed support for our proposal to add ICD–10–PCS procedure codes 07B74ZX, 07B70ZX, and 07B73ZX to MDC 4 under MS–DRGs 166 through 168. The commenters also acknowledged CMS' continued efforts for accurate replication.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze the replication issues between the ICD–9 and ICD–10 based MS–DRGs brought to our attention.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS procedure codes 07B74ZX (Excision of thorax lymphatic, percutaneous endoscopic approach, diagnostic), 07B70ZX (Excision of thorax lymphatic, open approach, diagnostic) and 07B73ZX (Excision of

thorax lymphatic, percutaneous approach, diagnostic) to MDC 4 under MS–DRGs 166 through 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) for the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(7) Obstetrical Laceration Repair

A replication issue for eight ICD–10–PCS procedure codes describing procedures that may be performed for the repair of obstetrical lacerations was identified after implementation of the ICD–10 MS–DRGs Version 33. These codes are:

ICD–10–PCS procedure code	Description
0DQQ0ZZ	Repair anus, open approach.
0DQQ3ZZ	Repair anus, percutaneous approach.
0DQQ4ZZ	Repair anus, percutaneous endoscopic approach.
0DQQ7ZZ	Repair anus, via natural or artificial opening.
0DQQ8ZZ	Repair anus, via natural or artificial opening endoscopic.
0DQR0ZZ	Repair anal sphincter, open approach.
0DQR3ZZ	Repair anal sphincter, percutaneous approach.
0DQR4ZZ	Repair anal sphincter, percutaneous endoscopic approach.

We discovered that the ICD–10 MDC and MS–DRG assignment are not consistent with other ICD–10–PCS procedure codes that identify and describe clinically similar procedures for the repair of obstetrical lacerations which are coded and reported based on the extent of the tear. For example, ICD–10–PCS procedure code 0DQP0ZZ (Repair rectum, open approach) is appropriately assigned to MDC 14 (Pregnancy, Childbirth and the Puerperium) under MS–DRG 774 (Vaginal Delivery with Complicating Diagnoses). This procedure may be performed in the treatment of a fourth-degree perineal laceration involving the rectal mucosa. In contrast, ICD–10–PCS procedure code 0DQR0ZZ (Repair anal sphincter, open approach), when reported for repair of a perineal laceration, currently results in assignment to MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis).

To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25016), we proposed to add these eight ICD–10–PCS procedure codes to MDC 14 in MS–DRG 774. We stated that the proposed changes would eliminate erroneous assignment to MS–DRGs 987 through 989 for these procedures.

We invited public comments on our proposal to add the eight listed codes to MDC 14 under MS–DRG 774, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

Comment: Several commenters supported the proposal to add the eight ICD–10–PCS procedure codes listed in the proposed rule to MDC 14 under MS–DRG 774. The commenters also acknowledged CMS' continued efforts for accurate replication.

One commenter who agreed with the proposal to add the eight ICD–10–PCS procedure codes to MDC 14 under MS–DRG 774 also recommended that CMS consider adding the following six ICD–10–PCS procedure codes to MDC 14 in MS–DRG 774:

- 0UQJ0ZZ (Repair clitoris, open approach);
- 0UQJXZZ (Repair clitoris, external approach);
- 0TQDXZZ (Repair urethra, external approach);
- 0KQM0ZZ (Repair perineum muscle, open approach);
- 0KQM3ZZ (Repair perineum muscle, percutaneous approach); and
- 0KQM4ZZ (Repair perineum muscle, percutaneous endoscopic approach).

The commenter acknowledged that, although procedures involving repair of clitoral and urethral lacerations during delivery are rare, they do occur and require intervention. The commenter noted that its organization observed cases grouping to the Unrelated MS–DRG when reporting any one of these six procedure codes.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze the replication issues between the ICD–9 and ICD–10 based MS–DRGs brought to our attention.

With regard to the recommendation that we consider the addition of ICD–10–PCS procedure codes describing repair of the clitoris, urethra, and perineum muscle to MDC 14 in MS–DRG 774, we note that the code describing repair of the urethra (0TQDXZZ) is currently listed under MDC 14 in MS–DRG 774 as displayed under the list titled ''Third Condition,'' as well as in the ICD–10 MS–DRG Version 33 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index. However, the codes describing repair of the perineum muscle and repair of the clitoris with various approaches are not listed in the two above-mentioned locations. The three codes describing repair of the perineum muscle (0KQM0ZZ, 0KQM3ZZ, and 0KQM4ZZ) are currently assigned to the following MDCs and MS–DRGs:

- MDC 1 (Diseases and Disorders of the Nervous System): MS–DRGs 040 through 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or Peripheral Neurostimulator, and without CC/MCC, respectively);
- MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue): MS–DRG 500 through 502 (Soft Tissue Procedures with MCC, with CC and without CC/MCC, respectively);
- MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast): MS–DRGs 579 through 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively);
- MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): MS–DRGs 907 through 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively); and
- MDC 24 (Multiple Significant Trauma): MS–DRG 957 through 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC and without CC/MCC).

The two ICD–10–PCS procedure codes describing repair of the clitoris (0UQJ0ZZ and 0UQJXZZ) are currently assigned to MDC 13 (Diseases and Disorders of the Female Reproductive System) in MS–DRGs 746 and 747 (Vagina, Cervix and Vulva Procedures with CC/MCC and without CC/MCC, respectively).

As the codes describing repair of the perineum muscle and repair of the clitoris are not currently listed in the Definitions Manual under MDC 14 in MS–DRG 774, it is understandable that, depending on what ICD–10–CM

diagnosis code was entered, a case could accurately result in assignment to one of the Unrelated MS–DRGs based on the current GROUPER logic. Because it is unclear what ICD–10–CM diagnosis codes the commenter entered into the ICD–10 MS–DRG GROUPER along with the specified ICD–10–PCS procedure codes describing repair of the clitoris, urethra or perineum, we were not able to fully duplicate the commenter's exact issue with respect to the Unrelated MS–DRG assignment. We ran test cases through the ICD–10 MS–DRG Version 33 GROUPER software which resulted in an Unrelated MS–DRG assignment for repair of the urethra, while repair of the perineum muscle codes resulted in appropriate assignment to MS–DRG 774 (Vaginal Delivery with Complicating Diagnoses) when a listed diagnosis code from that specific MS–DRG (which is defined as a complicating diagnosis) was entered. Thus, it appears that there may be a discrepancy between the code list in the ICD–10 MS–DRG Version 33 Definitions Manual and the GROUPER software for those specific codes describing repair of the urethra and repair of the perineum muscle. However, we agree that the codes describing repair of urethra and repair of perineum muscle could be performed during an episode of care involving a vaginal delivery and merit assignment to MS–DRG 774.

In our review of the commenter's recommendation to add the two codes describing repair of the clitoris (0UQJ0ZZ and 0UQJXZZ), we examined whether or not these procedures could be performed during the course of an admission involving a delivery. Our medical advisors agreed that, clinically, a tear involving the clitoris may occur during a vaginal delivery and, therefore, it is appropriate to add these procedures to MS–DRG 774.

We note that the code lists as currently displayed in the ICD–10 MS–DRG Version 33 Definitions Manual for MS–DRG 774 require further analysis to clarify what constitutes a vaginal delivery to satisfy the ICD–10 MS–DRG logic. For example, the Definitions Manual currently states that three conditions must be met, the first of which is a vaginal delivery. To satisfy this first condition, codes that describe conditions or circumstances from among three lists of codes must be reported. The first list is comprised of ICD–10–CM diagnosis codes that may be reported as a principal or secondary diagnosis. These diagnosis codes describe conditions in which it is assumed that a vaginal delivery has occurred. The second list of codes are a list of ICD–10–PCS procedure codes that also describe circumstances in which it is assumed that a vaginal delivery occurred. The third list of codes identifies diagnoses describing the outcome of the delivery. Therefore, if any code from one of those three lists is reported, the first condition (vaginal delivery) is considered to be met for assignment to MS–DRG 774.

Our concern with the first list of ICD–10–CM diagnosis codes as currently displayed in the Definitions Manual under the first condition is that not all of the conditions necessarily reflect that a *vaginal* delivery occurred. Several of the diagnosis codes listed could also reflect that a cesarean delivery occurred. For example, ICD–10–CM diagnosis code O10.02 (Pre-existing essential hypertension complicating childbirth) does not specify that a vaginal delivery took place; yet it is included in the list of conditions that may be reported as a principal or secondary diagnosis in the GROUPER logic for a vaginal delivery. The reporting of this code could also be appropriate for a delivery that occurred by cesarean section. Therefore, we plan to conduct further analysis of the diagnosis code lists in MS–DRG 774 for FY 2018.

As noted above, the second list of codes for the first condition are comprised of ICD–10–PCS procedure codes. We acknowledge that the current list of procedure codes in MS–DRG 774 appropriately describe that a vaginal delivery occurred. In addition, there are unique procedure codes in ICD–10–PCS that distinguish a vaginal delivery from a cesarean delivery.

After consideration of the public comments we received, we are finalizing our proposal and the commenters' recommendation to add the list of ICD–10–PCS procedure codes in the following table to MS–DRG 774 effective October 1, 2016, for the ICD–10 MS–DRGs Version 34. We also are clarifying that the procedure codes describing repair of perineum muscle currently group to MS–DRG 774 and will continue this assignment for FY 2017.

ICD–10–PCS procedure code	Description
0DQQ0ZZ	Repair anus, open approach.
0DQQ3ZZ	Repair anus, percutaneous approach.
0DQQ4ZZ	Repair anus, percutaneous endoscopic approach.
0DQQ7ZZ	Repair anus, via natural or artificial opening.
0DQQ8ZZ	Repair anus, via natural or artificial opening endoscopic.
0DQR0ZZ	Repair anal sphincter, open approach.
0DQR3ZZ	Repair anal sphincter, percutaneous approach.
0DQR4ZZ	Repair anal sphincter, percutaneous endoscopic approach.
0TQDXZZ	Repair urethra, external approach.
0UQJ0ZZ	Repair clitoris, open approach.
0UQJXZZ	Repair clitoris, external approach.

17. Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

a. ICD–10 Coordination and Maintenance Committee

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention, and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was to be made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other

communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html*. The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*.

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the previously mentioned process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2017 at a public meeting held on September 22–23, 2015, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 13, 2015.

The Committee held its 2016 meeting on March 9–10, 2016. It was announced at this meeting that any new ICD–10–CM/PCS codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by May 2016 would be included in the October 1, 2016 update to ICD–10–CM/ICD–10–PCS. As discussed in earlier sections of this preamble, there are new and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, and Table 6C.—Invalid Diagnosis Codes for the proposed rule and this final rule, which are available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Because of the length of these tables, they were not published in the Addendum to the proposed rule or this final rule. Rather, they are available via the Internet as discussed in section VI. of the Addendum to the proposed rule and this final rule.

Live Webcast recordings of the discussions of procedure codes at the Committee's September 22–23, 2015 meeting and March 9–10, 2016 meeting can be obtained from the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/03_meetings.asp*. The minutes of the discussions of diagnosis codes at the September 23–24, 2015 meeting and March 9–10, 2016 meeting are found at: *http://www.cdc.gov/nchs/icd/icd9cm_maintenance.html*. These Web sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by Email to: *nchc@cdc.gov*.

Questions and comments concerning the procedure codes should be addressed to: Patricia Brooks, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, CMS, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850. Comments may be sent by Email to: *ICDProcedureCodeRequest@cms.hhs.gov*.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS system by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

The ICD–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 2 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS Web site. Final decisions on code title revisions are currently made by March 1 so that these titles can be included in the IPPS proposed rule. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS Web sites in June of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the

December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee Meeting minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this new April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were no requests approved for an expedited April l, 2016 implementation of a code at the September 22–23, 2015 Committee meeting. Therefore, there were no new codes implemented on April 1, 2016.

ICD–9–CM addendum and code title information is published on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/01overview.asp#TopofPage*. ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*. Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can also be found on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd10.htm*. Information on new, revised, and deleted ICD–10–CM/ICD–10–PCS codes is also provided to the AHA for publication in the *Coding Clinic for ICD–10.* AHA also distributes information to publishers and software vendors.

CMS also sends copies of all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

The code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

b. Code Freeze

In the January 16, 2009 ICD–10–CM and ICD–10–PCS final rule (74 FR 3340), there was a discussion of the need for a partial or total freeze in the annual updates to both ICD–9–CM and ICD–10–CM and ICD–10–PCS codes. The public comment addressed in that final rule stated that the annual code set updates should cease l year prior to the implementation of ICD–10. The commenters stated that this freeze of code updates would allow for instructional and/or coding software programs to be designed and purchased early, without concern that an upgrade would take place immediately before the compliance date, necessitating additional updates and purchases.

HHS responded to comments in the ICD–10 final rule that the ICD–9–CM Coordination and Maintenance Committee has jurisdiction over any action impacting the ICD–9–CM and ICD–10 code sets. Therefore, HHS indicated that the issue of consideration of a moratorium on updates to the ICD–9–CM, ICD–10–CM, and ICD–10–PCS code sets in anticipation of the adoption of ICD–10–CM and ICD–10–PCS would be addressed through the Committee at a future public meeting.

The code freeze was discussed at multiple meetings of the ICD–9–CM Coordination and Maintenance Committee and public comment was actively solicited. The Committee evaluated all comments from participants attending the Committee meetings as well as written comments that were received. The Committee also considered the delay in implementation of ICD–10 until October 1, 2014. There was an announcement at the September 19, 2012 ICD–9–CM Coordination and Maintenance Committee meeting that a partial freeze of both ICD–9–CM and ICD–10 codes would be implemented as follows:

- The last regular annual update to both ICD–9–CM and ICD–10 code sets was made on October 1, 2011.
- On October 1, 2012 and October 1, 2013, there were only limited code updates to both ICD–9–CM and ICD–10 code sets to capture new technology and new diseases.
- On October 1, 2014, there were to be only limited code updates to ICD–10 code sets to capture new technology and diagnoses as required by section 503(a) of Public Law 108–173. There were to be no updates to ICD–9–CM on October 1, 2014.
- On October 1, 2015, 1 year after the originally scheduled implementation of ICD–10, regular updates to ICD–10 were to begin.

On May 15, 2014, CMS posted an updated Partial Code Freeze schedule on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-9-CM-Coordination-and-Maintenance-Committee-Meetings.html*. This updated schedule provided information on the extension of the partial code freeze until 1 year after the implementation of ICD–10. As stated earlier, on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted, which specified that the Secretary may not adopt ICD–10 prior to October 1, 2015. On August 4, 2014, the Department published a final rule with a compliance date to require the use of ICD–10 beginning October 1, 2015. The final rule also required HIPAA-covered entities to continue to use ICD–9–CM through September 30, 2015. Accordingly, the updated schedule for the partial code freeze was as follows:

- The last regular annual updates to both ICD–9–CM and ICD–10 code sets were made on October 1, 2011.
- On October 1, 2012, October 1, 2013, and October 1, 2014, there were only limited code updates to both the ICD–9–CM and ICD–10 code sets to capture new technologies and diseases as required by section 1886(d)(5)(K) of the Act.
- On October 1, 2015, there were only limited code updates to ICD–10 code sets to capture new technologies and diagnoses as required by section 1886(d)(5)(K) of the Act. There were no updates to ICD–9–CM, as it will no longer be used for reporting.
- On October 1, 2016 (1 year after implementation of ICD–10), regular updates to ICD–10 will begin.

The ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee announced that it would continue to meet twice a year during the freeze. At these meetings, the public was encouraged to comment on whether

or not requests for new diagnosis and procedure codes should be created based on the need to capture new technology and new diseases. Any code requests that do not meet the criteria will be evaluated for implementation within ICD–10 1 year after the implementation of ICD–10, once the partial freeze is ended.

Complete information on the partial code freeze and discussions of the issues at the Committee meetings can be found on the ICD–10 Coordination and Maintenance Committee Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html.* A summary of the September 19, 2012 Committee meeting, along with both written and audio transcripts of this meeting, is posted on the Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2012-09-19-MeetingMaterials.html.*

This partial code freeze dramatically decreased the number of codes created each year as shown by the following information.

TOTAL NUMBER OF CODES AND CHANGES IN TOTAL NUMBER OF CODES PER FISCAL YEAR

ICD–9–CM codes			ICD–10–CM and ICD–10–PCS codes		
Fiscal year	No.	Change	Fiscal year	No.	Change
FY 2009 (October 1, 2008):			FY 2009:		
Diagnoses	14,025	348	ICD–10–CM	68,069	+5
Procedures	3,824	56	ICD–10–PCS	72,589	−14,327
FY 2010 (October 1, 2009):			FY 2010:		
Diagnoses	14,315	290	ICD–10–CM	69,099	+1,030
Procedures	3,838	14	ICD–10–PCS	71,957	−632
FY 2011 (October 1, 2010):					
Diagnoses	14,432	117	ICD–10–CM	69,368	+269
Procedures	3,859	21	ICD–10–PCS	72,081	+124
FY 2012 (October 1, 2011):			FY 2012:		
Diagnoses	14,567	135	ICD–10–CM	69,833	+465
Procedures	3,877	18	ICD–10–PCS	71,918	−163
FY 2013 (October 1, 2012)			FY 2013:		
Diagnoses	14,567	0	ICD–10–CM	69,832	−1
Procedures	3,878	1	ICD–10–PCS	71,920	+2
FY 2014 (October 1, 2013):			FY 2014:		
Diagnoses	14,567	0	ICD–10–CM	69,823	−9
Procedures	3,882	4	ICD–10–PCS	71,924	+4
FY 2015 (October 1, 2014):			FY 2015:		
Diagnoses	14,567	0	ICD–10–CM	69,823	0
Procedures	3,882	0	ICD–10–PCS	71,924	0
FY 2016 (October 1, 2015):			FY 2016:		
Diagnoses	14,567	0	ICD–10–CM	69,823	0
Procedures	3,882	0	ICD–10–PCS	71,924	0
FY 2017(October 1, 2016)			FY 2017:		
Diagnoses	14,567	0	ICD–10–CM	71,486	0
Procedures	3,882	0	ICD–10–PCS	75,789	0

As mentioned previously, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed at the ICD–10 Coordination and Maintenance Committee meeting. The public has supported only a limited number of new codes during the partial code freeze, as can be seen by previously shown data. We have gone from creating several hundred new codes each year to creating only a limited number of new ICD–9–CM and ICD–10 codes.

At the September 22–23, 2015 and March 9–10, 2016 Committee meetings, we discussed any requests we had received for new ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that were to be implemented on October 1, 2016. We did not discuss ICD–9–CM codes. Because the partial code freeze will end on October 1, 2016, the public no longer had to comment on whether or not new ICD–10–CM and ICD–10–PCS codes should be created based on the partial code freeze criteria. We invited public comments on any code requests discussed at the September 22–23, 2015 and March 9–10, 2016 Committee meetings for implementation as part of the October 1, 2016 update. The deadline for commenting on code proposals discussed at the September 22–23, 2015 Committee meeting was November 13, 2015. The deadline for commenting on code proposals discussed at the March 9–10, 2016 Committee meeting was April 8, 2016.

18. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that has been recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Changes for FY 2017

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25019), for FY 2017, we proposed not to add any MS–DRGs to the policy for replaced devices offered without cost or with a credit. We proposed to continue to include the

existing MS–DRGs currently subject to the policy as displayed in the table below.

MDC	MS–DRG	MS–DRG Title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC.
1	023	Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis with MCC or Chemo Implant.
1	024	Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis without MCC.
1	025	Craniotomy & Endovascular Intracranial Procedures with MCC.
1	026	Craniotomy & Endovascular Intracranial Procedures with CC.
1	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC.
1	040	Peripheral/Cranial Nerve & Other Nervous System Procedure with MCC.
1	041	Peripheral/Cranial Nerve & Other Nervous System Procedure with CC or Peripheral Neurostimulator.
1	042	Peripheral/Cranial Nerve & Other Nervous System Procedure without CC/MCC.
3	129	Major Head & Neck Procedures with CC/MCC or Major Device.
3	130	Major Head & Neck Procedures without CC/MCC.
5	215	Other Heart Assist System Implant.
5	216	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheter with MCC.
5	217	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheter with CC.
5	218	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheter without CC/MCC.
5	219	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheter with MCC.
5	220	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheter with CC.
5	221	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheter without CC/MCC.
5	222	Cardiac Defibrillator Implant with Cardiac Catheter with AMI/Heart Failure/Shock with MCC.
5	223	Cardiac Defibrillator Implant with Cardiac Catheter with AMI/Heart Failure/Shock without MCC.
5	224	Cardiac Defibrillator Implant with Cardiac Catheter without AMI/Heart Failure/Shock with MCC.
5	225	Cardiac Defibrillator Implant with Cardiac Catheter without AMI/Heart Failure/Shock without MCC.
5	226	Cardiac Defibrillator Implant without Cardiac Catheter with MCC.
5	227	Cardiac Defibrillator Implant without Cardiac Catheter without MCC.
5	242	Permanent Cardiac Pacemaker Implant with MCC.
5	243	Permanent Cardiac Pacemaker Implant with CC.
5	244	Permanent Cardiac Pacemaker Implant without CC/MCC.
5	245	AICD Generator Procedures.
5	258	Cardiac Pacemaker Device Replacement with MCC.
5	259	Cardiac Pacemaker Device Replacement without MCC.
5	260	Cardiac Pacemaker Revision Except Device Replacement with MCC.
5	261	Cardiac Pacemaker Revision Except Device Replacement with CC.
5	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC.
5	266	Endovascular Cardiac Valve Replacement with MCC.
5	267	Endovascular Cardiac Valve Replacement without MCC.
5	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.
5	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.
5	270	Other Major Cardiovascular Procedures with MCC.
5	271	Other Major Cardiovascular Procedures with CC.
5	272	Other Major Cardiovascular Procedures without CC/MCC.
8	461	Bilateral or Multiple Major Joint Procedures Of Lower Extremity with MCC.
8	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC.
8	466	Revision of Hip or Knee Replacement with MCC.
8	467	Revision of Hip or Knee Replacement with CC.
8	468	Revision of Hip or Knee Replacement without CC/MCC.
8	469	Major Joint Replacement or Reattachment of Lower Extremity with MCC.
8	470	Major Joint Replacement or Reattachment of Lower Extremity without MCC.

We solicited public comments on our proposal to continue to include the existing MS–DRGs currently subject to the policy and to not add any additional MS–DRGs to the policy. We indicated that the final list of MS–DRGs subject to the policy for FY 2017 would be listed in this FY 2017 IPPS/LTCH PPS final rule, as well as issued to providers in the form of a Change Request (CR).

We did not receive any public comments opposing our proposal to continue to include the existing MS–DRGs currently subject to the policy and to not add any additional MS–DRGs. Therefore, we are finalizing the list of MS–DRGs in the table included in the proposed rule and above that will be subject to the replaced devices offered without cost or with a credit policy effective October 1, 2016.

19. Other Policy Changes

a. MS–DRG GROUPER Logic

(1) Operations on Products of Conception

In the ICD–9–CM MS–DRGs Version 32, intrauterine operations that may be performed in an attempt to correct a fetal abnormality are identified by ICD–9–CM procedure code 75.36 (Correction of fetal defect). This procedure code is designated as an O.R. procedure and is assigned to MDC 14 (Pregnancy, Childbirth and the Puerperium) in MS–DRG 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or Dilation and Curettage).

A replication issue for 208 ICD–10–PCS comparable code translations that describe operations on the products of conception (fetus) to correct fetal defects was identified during an internal review. These 208 procedure codes were inadvertently omitted from the MDC 14 GROUPER logic for ICD–10 MS–DRG 768. To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25020), we proposed to add the 208 ICD–10–PCS procedure codes shown in Table 6P.3a. associated with the proposed rule (which is available via the Internet on the CMS Web site at:

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index) to MDC 14 in MS–DRG 768, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the 208 ICD–10–PCS procedure codes describing operations to correct fetal defects to MDC 14 in MS–DRG 768. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to add the 208 ICD–10–PCS procedure codes shown in Table 6P.3a. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) to MDC 14 in MS–DRG 768 in ICD–10 MS–DRGs Version 34, effective October 1, 2016.

Separate from the replication issue described above, during our internal review, we also concluded that the proposed MS–DRG logic for these intrauterine procedures under ICD–10 may not accurately represent a subset of the 208 ICD–10–PCS procedure codes (listed in Table 6P.3a.). For example, the GROUPER logic for MS–DRG 768 requires that a vaginal delivery occur during the same episode of care in which an intrauterine procedure is performed. However, this scenario may not be clinically consistent with all pregnant patients who undergo fetal surgery. For example, a pregnant patient whose fetus is diagnosed with a congenital diaphragmatic hernia (CDH) may undergo a fetoscopic endoluminal tracheal occlusion (FETO) procedure in which the pregnant patient does not subsequently deliver during the same hospital stay. The goal of this specific fetal surgery is to allow the fetus to remain in utero until its lungs have developed to increase the chance of survival. Therefore, this scenario of a patient who has fetal surgery but does not have a delivery during the same hospital stay is not appropriately captured in the GROUPER logic. We believe that further analysis is warranted regarding a future proposal for a new MS–DRG to better recognize this subset of patients.

In past rulemaking (72 FR 24700 and 24705), we have acknowledged that CMS does not have the expertise or data to maintain the DRGs in clinical areas that have very low volume in the Medicare population, including for conditions associated with and/or occurring in the maternal-fetal patient population. Additional information is needed to fully and accurately evaluate all the possible fetal conditions that may fall under similar scenarios to the one described above before making a specific proposal. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25020), we solicited public comments on two clinical concepts for consideration for a possible future proposal for the FY 2018 ICD–10 MS–DRGs Version 35: (1) The ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that describe fetal abnormalities for which fetal surgery may be performed in the absence of a delivery during the same hospital stay; and (2) the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that describe fetal abnormalities for which fetal surgery may be performed with a subsequent delivery during the same hospital stay. This second concept is the structure of current MS–DRG 768. We indicated that commenters should submit their code recommendations for these concepts to the following email address *MSDRGClassificationChange@cms.hhs.gov* by December 7, 2016. We encouraged public comments as we consider these enhancements for the FY 2018 ICD–10 MS–DRGs Version 35.

(2) Other Heart Revascularization

In the ICD–9–CM MS–DRGs Version 32, revascularization procedures that are performed to restore blood flow to the heart are identified with procedure code 36.39 (Other heart revascularization). This procedure code is designated as an O.R. procedure and is assigned to MDC 5 (Diseases and Disorders of the Circulatory System) in MS–DRGs 228 through 230 (Other Cardiothoracic Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for 16 ICD–10–PCS comparable code translations that describe revascularization procedures was identified after implementation of the ICD–10 MS–DRGs Version 33. These 16 procedure codes were inadvertently omitted from the MDC 5 GROUPER logic for ICD–10 MS–DRGs 228 through 230. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25021), we noted that, as discussed in section II.F.5.d. of the preamble of the proposed rule, we proposed to delete MS–DRG 230 and revise MS–DRG 229. Accordingly, to resolve this replication issue, we proposed to add the 16 ICD–10–PCS procedure codes listed in the table below to MDC 5 in MS–DRG 228 and proposed revised MS–DRG 229.

ICD–10–PCS procedure code	Description
0210344	Bypass coronary artery, one site from coronary vein with drug-eluting intraluminal device, percutaneous approach.
02103D4	Bypass coronary artery, one site from coronary vein with intraluminal device, percutaneous approach.
0210444	Bypass coronary artery, one site from coronary vein with drug-eluting intraluminal device, percutaneous endoscopic approach.
02104D4	Bypass coronary artery, one site from coronary vein with intraluminal device, percutaneous endoscopic approach.
0211344	Bypass coronary artery, two sites from coronary vein with drug-eluting intraluminal device, percutaneous approach.
02113D4	Bypass coronary artery, two sites from coronary vein with intraluminal device, percutaneous approach.
0211444	Bypass coronary artery, two sites from coronary vein with drug-eluting intraluminal device, percutaneous endoscopic approach.
02114D4	Bypass coronary artery, two sites from coronary vein with intraluminal device, percutaneous endoscopic approach.
0212344	Bypass coronary artery, three sites from coronary vein with drug-eluting intraluminal device, percutaneous approach.
02123D4	Bypass coronary artery, three sites from coronary vein with intraluminal device, percutaneous approach.
0212444	Bypass coronary artery, three sites from coronary vein with drug-eluting intraluminal device, percutaneous endoscopic approach.
02124D4	Bypass coronary artery, three sites from coronary vein with intraluminal device, percutaneous endoscopic approach.
0213344	Bypass coronary artery, four or more sites from coronary vein with drug-eluting intraluminal device, percutaneous approach.
02133D4	Bypass coronary artery, four or more sites from coronary vein with intraluminal device, percutaneous approach.
0213444	Bypass coronary artery, four or more sites from coronary vein with drug-eluting intraluminal device, percutaneous endoscopic approach.
02134D4	Bypass coronary artery, four or more sites from coronary vein with intraluminal device, percutaneous endoscopic approach.

We invited public comments on our proposal to add the above listed ICD–10–PCS procedure codes to MDC 5 in MS–DRG 228 and proposed revised MS–DRG 229 (Other Cardiothoracic Procedures with and without MCC, respectively), effective October 1, 2016, in ICD–10 MS–DRGs Version 34.

Comment: Commenters supported the proposal to add the 16 ICD–10–PCS procedure codes describing revascularization procedures to MDC 5 in MS–DRGs 228 and proposed revised MS–DRG 229. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs. We note that, as discussed in section II.F.15.b. of the proposed rule, we made a document consisting of procedure code updates publicly available. This document included the titles to the above list of codes that were revised in response to public comments received during the partial code freeze. The revised code titles reflect the term ''artery'' where the current term ''site'' is displayed and reflect the term ''arteries'' where the current term ''sites'' is displayed in the table above. A complete list of all the revised ICD–10–PCS procedure code titles is shown in Table 6F.—Revised Procedure Code Titles associated with this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*).

After consideration of the public comments we received, we are finalizing our proposal to add the ICD–10–PCS procedure codes in the proposed rule and above in this final rule, with their revised code titles as shown in Table 6F.—Revised Procedure Code Titles, to MDC 5 in MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) in ICD–10 MS–DRGs Version 34, effective October 1, 2016. We also note that, as discussed in section II.F.5.d. of this final rule, the proposal to collapse MS–DRGs 228, 229, and 230 from three severity levels into two severity levels was finalized.

(3) Procedures on Vascular Bodies: Chemoreceptors

In the ICD–9–CM MS–DRGs Version 32, procedures performed on the sensory receptors are identified with ICD–9–CM procedure code 39.89 (Other operations on carotid body, carotid sinus and other vascular bodies). This procedure code is designated as an O.R. procedure and is assigned to MDC 5 (Diseases and Disorders of the Circulatory System) in MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for 234 ICD–10–PCS comparable code translations that describe these procedures was identified after implementation of the ICD–10 MS–DRGs Version 33. These 234 procedure codes were inadvertently omitted from the MDC 5 GROUPER logic for ICD–10 MS–DRGs 252 through 254. To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25021), we proposed to add the 234 ICD–10–PCS procedure codes listed in Table 6P.3b. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) to MDC 5 in MS–DRGs 252, 253, and 254, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the 234 ICD–10–PCS procedure codes describing procedures performed on the sensory receptors to MDC 5 in MS–DRGs 252, 253, and 254. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to add the 234 ICD–10–PCS procedure codes listed in Table 6P.3b. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) to MDC 5 in MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) in ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(4) Repair of the Intestine

In the ICD–9–CM MS–DRGs Version 32, the procedure for a repair to the intestine may be identified with procedure code 46.79 (Other repair of intestine). This procedure code is designated as an O.R. procedure and is assigned to MDC 6 (Diseases and Disorders of the Digestive System) in MS–DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for four ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These four procedure codes are:

- 0DQF0ZZ (Repair right large intestine, open approach);
- 0DQG0ZZ (Repair left large intestine, open approach);
- 0DQL0ZZ (Repair transverse colon, open approach); and
- 0DQM0ZZ (Repair descending colon, open approach).

These four ICD–10–PCS codes were inadvertently omitted from the MDC 6 GROUPER logic for ICD–10 MS–DRGs 329 through 331. To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25021), we proposed to add the four ICD–10–PCS procedure codes to MDC 6 in MS–DRGs 329, 330, and 331, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the four ICD–10–PCS procedure codes describing repair of the intestine to MDC 6 in MS–DRGs 329, 330, and 331. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS procedure codes 0DQF0ZZ, 0DQG0ZZ, 0DQL0ZZ, and 0DQM0ZZ listed in the proposed rule and above in this final rule to MDC 6 in MS–DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively) in ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(5) Insertion of Infusion Pump

In the ICD–9–CM MS–DRGs Version 32, the procedure for insertion of an infusion pump is identified with procedure code 86.06 (Insertion of totally implantable infusion pump), which is designated as an O.R. procedure and assigned to a number of MDCs and MS–DRGs across various body systems. We refer readers to the ICD–9–CM MS–DRG Definitions Manual Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, which is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-*

Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Rule-Data-Files.html, for the complete list of MDCs and MS–DRGs to which procedure code 86.06 is assigned.

A replication issue for 16 ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These 16 procedure codes are listed in the table below:

ICD–10–PCS procedure code	Description
0JHD0VZ	Insertion of infusion pump into right upper arm subcutaneous tissue and fascia, open approach.
0JHD3VZ	Insertion of infusion pump into right upper arm subcutaneous tissue and fascia, percutaneous approach.
0JHF0VZ	Insertion of infusion pump into left upper arm subcutaneous tissue and fascia, open approach.
0JHF3VZ	Insertion of infusion pump into left upper arm subcutaneous tissue and fascia, percutaneous approach.
0JHG0VZ	Insertion of infusion pump into right lower arm subcutaneous tissue and fascia, open approach.
0JHG3VZ	Insertion of infusion pump into right lower arm subcutaneous tissue and fascia, percutaneous approach.
0JHH0VZ	Insertion of infusion pump into left lower arm subcutaneous tissue and fascia, open approach.
0JHH3VZ	Insertion of infusion pump into left lower arm subcutaneous tissue and fascia, percutaneous approach.
0JHL0VZ	Insertion of infusion pump into right upper leg subcutaneous tissue and fascia, open approach.
0JHL3VZ	Insertion of infusion pump into right upper leg subcutaneous tissue and fascia, percutaneous approach.
0JHM0VZ	Insertion of infusion pump into left upper leg subcutaneous tissue and fascia, open approach.
0JHM3VZ	Insertion of infusion pump into left upper leg subcutaneous tissue and fascia, percutaneous approach.
0JHN0VZ	Insertion of infusion pump into right lower leg subcutaneous tissue and fascia, open approach.
0JHN3VZ	Insertion of infusion pump into right lower leg subcutaneous tissue and fascia, percutaneous approach.
0JHP0VZ	Insertion of infusion pump into left lower leg subcutaneous tissue and fascia, open approach.
0JHP3VZ	Insertion of infusion pump into left lower leg subcutaneous tissue and fascia, percutaneous approach.

These codes were inadvertently omitted from the MDCs and MS–DRGs to which they should be assigned (consistent with the assignment of ICD–9–CM procedure code 86.06) to accurately replicate the ICD–9–CM MS–DRG logic. To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25021 through 25022), we proposed to add the 16 ICD–10–PCS procedure codes listed in the table above to the corresponding MDCs and MS–DRGs, as set forth in the ICD–9–CM MS–DRG Definitions Manual—Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as described earlier, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the 16 ICD–10–PCS procedure codes describing insertion of an infusion pump listed in the proposed rule to the corresponding MDCs and MS–DRGs for ICD–9–CM code 86.06. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to add the 16 ICD–10–PCS procedure codes describing insertion of an infusion pump listed in the proposed rule and above in this final rule to the corresponding MDCs and MS–DRGs for ICD–9–CM code 86.06, as set forth in the ICD–9–CM MS–DRG Definitions Manual—Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index which is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Rule-Data-Files.html* in ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(6) Procedures on the Bursa

In the ICD–9–CM MS–DRGs Version 32, procedures that involve cutting into the bursa are identified with procedure code 83.03 (Bursotomy). This procedure code is designated as an O.R. procedure and is assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 500, 501, and 502 (Soft Tissue Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for six ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These six procedure codes are:

- 0M850ZZ (Division of right wrist bursa and ligament, open approach);
- 0M853ZZ (Division of right wrist bursa and ligament, percutaneous approach);
- 0M854ZZ (Division of right wrist bursa and ligament, percutaneous endoscopic approach);
- 0M860ZZ (Division of left wrist bursa and ligament, open approach);
- 0M863ZZ (Division of left wrist bursa and ligament, percutaneous approach); and
- 0M864ZZ (Division of left wrist bursa and ligament, percutaneous endoscopic approach).

These codes were inadvertently omitted from the MDC 8 GROUPER logic for ICD–10 MS–DRGs 500, 501, and 502. To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25022), we proposed to add the six ICD–10–PCS procedure codes listed above to MDC 8 in MS–DRGs 500, 501, and 502, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the 6 ICD–10–PCS procedure codes describing procedures that involve cutting into the bursa listed in the proposed rule to MDC 8 in MS–DRGs 500, 501, and 502. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to add the six ICD–10–PCS procedure codes listed in the proposed rule and above in this final rule to MDC 8 in MS–DRGs 500, 501, and 502 (Soft Tissue Procedures with MCC, with CC, and without CC/MCC, respectively) in ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(7) Procedures on the Breast

In the ICD–9–CM MS–DRGs Version 32, procedures performed for a simple repair to the skin of the breast may be identified with procedure code 86.59 (Closure of skin and subcutaneous tissue of other sites). This procedure

code is designated as a non-O.R. procedure. Therefore, this procedure code does not have an impact on MS–DRG assignment.

A replication issue for two ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These two procedure codes are: 0HQVXZZ (Repair bilateral breast, external approach) and 0HQYXZZ (Repair supernumerary breast, external approach). These ICD–10–PCS procedures codes were inadvertently assigned to ICD–10 MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC, respectively) in the ICD–10 MS–DRG GROUPER logic. To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25022), we proposed to remove these two ICD–10–PCS procedure codes from MS–DRGs 981, 982, and 983, to designate them as non-O.R. procedures, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We invited public comments on our proposal.

Comment: Commenters supported the proposal to designate the two ICD–10–PCS codes (0HQVXZZ and 0HQYXZZ) as non-O.R. procedures. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

One commenter expressed concern with the proposal, noting that the proposed change may result in unintended consequences for other procedures because these ICD–10–PCS codes can also be considered comparable translations of ICD–9–CM procedure code 85.89 (Other mammoplasty), which is designated as an O.R. procedure.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs. We also acknowledge the concerns of the commenter who stated that our proposal could result in unintended consequences. We note that a large number of ICD–9–CM procedure codes that have a fourth digit of 9 (XX.X9) and include the term ''other'' as part of the code title are designated as O.R. procedures under the ICD–9–CM MS–DRGs Version 32. The intent of these codes is to capture procedures that are not able to be identified elsewhere in the classification system with another procedure code. These codes are often very vague and generally do not distinguish what approach is used for a specific anatomic site according to the body system in which it was assigned. Therefore, when these ''other'' ICD–9–CM procedure codes went through the process of the ICD–10 MS–DRG conversion, they understandably satisfied almost every available option (root operation, body part, approach, among others) within the structure of the specified ICD–10–PCS section, respective of the body system.

As such, while we recognize that ICD–10–PCS procedure codes 0HQVXZZ (Repair bilateral breast, external approach) and 0HQYXZZ (Repair supernumerary breast, external approach) can be considered comparable translations of ICD–9–CM procedure code 85.89 (Other mammoplasty), which is designated as an O.R. procedure, we note that, under ICD–10–PCS, there also are more appropriate root operations that could logically be reported to identify that a mammoplasty was performed. For example, a mammoplasty may involve breast augmentation to enhance the appearance, size, or contour of the breast, in which case the ICD–10–PCS root operation ''Alteration'' could be reported. In the case where a mammoplasty was performed for breast reduction purposes, the ICD–10–PCS root operation ''Excision'' could be reported. For cases where mammoplasty is performed for breast reconstruction after mastectomy, the ICD–10–PCS root operations ''Supplement'' or ''Replacement'' could be reported. We believe that, from a clinical perspective, a mammoplasty would not necessarily be coded using the root of Repair with an external approach under ICD–10–PCS.

In addition, we note that the ICD–10–PCS procedure codes describing unilateral repair of the breast with an external approach are currently designated as non-O.R. procedures under the ICD–10 MS–DRGs Version 33. Therefore, the proposal to make bilateral repair of the breast with an external approach non-O.R. would be consistent with those codes.

After consideration of the public comments we received, we are finalizing our proposal to designate ICD–10–PCS procedure codes 0HQVXZZ (Repair bilateral breast, external approach) and 0HQYXZZ (Repair supernumerary breast, external approach) as non-O.R. codes in ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(8) Excision of Subcutaneous Tissue and Fascia

In the ICD–9–CM MS–DRGs Version 32, procedures involving excision of the skin and subcutaneous tissue are identified with procedure code 86.3 (Other local excision of lesion or tissue of skin and subcutaneous tissue). This procedure code is designated as a non-O.R. procedure that affects MS–DRG assignment for MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC and without CC/MCC, respectively) in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast).

A replication issue for 19 ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These 19 procedure codes are listed in the table below.

ICD–10–PCS code	Description
0JB03ZZ	Excision of scalp subcutaneous tissue and fascia, percutaneous approach.
0JB43ZZ	Excision of anterior neck subcutaneous tissue and fascia, percutaneous approach.
0JB53ZZ	Excision of posterior neck subcutaneous tissue and fascia, percutaneous approach.
0JB63ZZ	Excision of chest subcutaneous tissue and fascia, percutaneous approach.
0JB73ZZ	Excision of back subcutaneous tissue and fascia, percutaneous approach.
0JB83ZZ	Excision of abdomen subcutaneous tissue and fascia, percutaneous approach.
0JB93ZZ	Excision of buttock subcutaneous tissue and fascia, percutaneous approach.
0JBB3ZZ	Excision of perineum subcutaneous tissue and fascia, percutaneous approach.
0JBC3ZZ	Excision of pelvic region subcutaneous tissue and fascia, percutaneous approach.
0JBD3ZZ	Excision of right upper arm subcutaneous tissue and fascia, percutaneous approach.
0JBF3ZZ	Excision of left upper arm subcutaneous tissue and fascia, percutaneous approach.
0JBG3ZZ	Excision of right lower arm subcutaneous tissue and fascia, percutaneous approach.
0JBH3ZZ	Excision of left lower arm subcutaneous tissue and fascia, percutaneous approach.
0JBL3ZZ	Excision of right upper leg subcutaneous tissue and fascia, percutaneous approach.
0JBM3ZZ	Excision of left upper leg subcutaneous tissue and fascia, percutaneous approach.

ICD–10–PCS code	Description
0JBN3ZZ	Excision of right lower leg subcutaneous tissue and fascia, percutaneous approach.
0JBP3ZZ	Excision of left lower leg subcutaneous tissue and fascia, percutaneous approach.
0JBQ3ZZ	Excision of right foot subcutaneous tissue and fascia, percutaneous approach.
0JBR3ZZ	Excision of left foot subcutaneous tissue and fascia, percutaneous approach.

These codes were inadvertently omitted from the ICD–10 MS–DRG GROUPER logic for MDC 9 in MS–DRGs 579, 580, and 581. To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25022 through 25023), we proposed to add the 19 ICD–10–PCS procedure codes listed in the table above to MDC 9 in MS–DRGs 579, 580, and 581, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the 19 ICD–10–PCS procedure codes describing procedures that involve cutting the subcutaneous tissue and fascia listed in the table in the proposed rule to MDC 9 in MS–DRGs 579, 580, and 581. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to add the 19 ICD–10–PCS procedure codes listed in the table in the proposed rule and above in this final rule to MDC 9 in MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC and without CC/MCC, respectively) in ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(9) Shoulder Replacement

In the ICD–9–CM MS–DRGs Version 32, procedures that involve replacing a component of bone from the upper arm are identified with procedure code 78.42 (Other repair or plastic operations on bone, humerus). This procedure code is designated as an O.R. procedure and is assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 492, 493, and 494 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC, with CC, and without CC/MCC, respectively).

A replication issue for two ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These two procedure codes are: 0PRC0JZ (Replacement of right humeral head with synthetic substitute, open approach) and 0PRD0JZ (Replacement of left humeral head with synthetic substitute, open approach). These two codes were inadvertently omitted from the ICD–10 MS–DRG GROUPER logic for MDC 8 in MS–DRGs 492, 493, and 494. To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25023), we proposed to add these two ICD–10–PCS procedure codes to MDC 8 in MS–DRGs 492, 493, and 494, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the two ICD–10–PCS procedure codes describing procedures that involve shoulder replacement listed in the proposed rule to MDC 8 in MS–DRGs 492, 493, and 494. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS codes 0PRC0JZ (Replacement of right humeral head with synthetic substitute, open approach) and 0PRD0JZ (Replacement of left humeral head with synthetic substitute, open approach) to MDC 8 in MS–DRGs 492, 493, and 494 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC, with CC, and without CC/MCC, respectively) in ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(10) Reposition

In the ICD–9–CM MS–DRGs Version 32, procedures that involve the percutaneous repositioning of an area in the vertebra are identified with procedure code 81.66 (Percutaneous vertebral augmentation). This procedure code is designated as an O.R. procedure and is assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for four ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These four procedure codes are:

- 0PS33ZZ (Reposition cervical vertebra, percutaneous approach);
- 0PS43ZZ (Reposition thoracic vertebra, percutaneous approach);
- 0QS03ZZ (Reposition lumbar vertebra, percutaneous approach); and
- 0QS13ZZ (Reposition sacrum, percutaneous approach).

These four ICD–10 PCS procedure codes were inadvertently omitted from the ICD–10 MS–DRG GROUPER logic for MDC 8 and MS–DRGs 515, 516, and 517. To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25023), we proposed to add these four ICD–10–PCS procedure codes to MDC 8 in MS–DRGs 515, 516, and 517, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the four ICD–10–PCS procedure codes describing repositioning of vertebra listed in the proposed rule to MDC 8 in MS–DRGs 515, 516, and 517. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS codes 0PS33ZZ (Reposition cervical vertebra, percutaneous approach); 0PS43ZZ (Reposition thoracic vertebra, percutaneous approach), 0QS03ZZ (Reposition lumbar vertebra, percutaneous approach), and 0QS13ZZ (Reposition sacrum, percutaneous approach) to MDC 8 in MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue Procedures with MCC, with CC, and without CC/MCC, respectively) in ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(11) Insertion of Infusion Device

In the ICD–9–CM MS–DRGs Version 32, the procedure for insertion of an infusion pump is identified with procedure code 86.06 (Insertion of totally implantable infusion pump) which is designated as an O.R. procedure and assigned to a number of MDCs and MS–DRGs, one of which is MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for 49 ICD–10–PCS comparable code translations that describe insertion of an infusion device into a joint or disc was identified after implementation of the ICD–10 MS–DRGs Version 33. These 49 procedure codes appear to describe procedures that utilize a specific type of infusion device known as an infusion pump and were inadvertently omitted from the ICD–10 MS–DRG GROUPER logic for MDC 8. To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25023), we proposed to add the 49 ICD–10–PCS procedure codes shown in Table 6P.3c. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) to MDC 8 in MS–DRGs 515, 516, and 517, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We invited public comments on our proposal.

Comment: Several commenters supported the proposal to add the 49 ICD–10–PCS procedure codes describing open insertion of an infusion device into a joint or disc to MDC 8 in MS–DRGs 515, 516, and 517. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

One commenter reported that standard surgical practice does not support procedures involving infusion devices (as well as removal of tracheostomy and occlusion of esophageal vein which are discussed in sections II.F.19.c.1.c. and section II.F.19.c.1.j. of the preamble of this final rule) being performed outside of an operating room setting. This commenter asserted that because these types of procedures are complex, necessitate a sterile environment and general anesthesia support, physicians would rarely perform them in a setting other than the operating room.

However, other commenters did not agree that procedures describing the insertion of an infusion device into a joint or disc should be classified the same as ICD–9–CM code 86.06 (Insertion of totally implantable infusion pump). One commenter noted that the 49 ICD–10–PCS procedure codes describe an *infusion device* which the ICD–10–PCS classification categorizes as an *infusion catheter,* and there are separate ICD–10–PCS device values that specifically describe an *infusion device, pump.* This commenter disagreed with the proposal to assign the 49 ICD–10–PCS procedure codes into MS–DRGs 515, 516, and 517, stating that an infusion pump cannot be inserted into a joint, while a catheter can. The commenter noted that, similar to our discussion in section II.F.19.c.1.k. of the preamble of the proposed rule, these ICD–10–PCS procedures codes reasonably correlate to the insertion of a common infusion catheter versus the insertion of a totally implantable infusion pump.

Another commenter expressed concern with the potential coding and payment impacts as a result of the proposal and noted that while an infusion catheter and an infusion pump may be inserted together, they are separate devices with different levels of resource utilization. The commenter stated that implantable infusion pumps are resource-intensive for hospitals and designated appropriately as O.R. procedures in contrast to infusion catheters.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs. It is not clear if the commenter who stated that standard surgical practice does not support procedures involving infusion devices being performed outside of an operating room was referring to procedures involving an infusion pump versus procedures involving an infusion device as classified under ICD–10–PCS. We note that, as stated above, under ICD–9–CM, procedure code 86.06 describes the insertion of a totally implantable infusion pump. Under ICD–10–PCS, the term ''implantable'' is not utilized with the infusion device, pump, or infusion codes.

In response to the commenters who disagreed with our proposal, we acknowledge that the ICD–10–PCS classification categorizes the device values for an *infusion device* (catheter) separately from the device values that describe an *infusion device, pump.* In addition, our clinical advisors support the commenters' observation that an infusion device, pump is not inserted into a joint space, but rather the infusion device, catheter would be inserted into the joint space.

It is understandable that the term ''infusion device'' can be interpreted in different ways because the type of infusion device used is sometimes dependent on whether the prescribed treatment will be administered intermittently (for example, for chemotherapy) or continuously (for example, insulin therapy) and the mechanism used to pump in the drug may vary (for example, battery, electricity, or pressure). Taking these characteristics into account, an ''infusion device'' could be literally implanted in the body or parts of the device could be found outside of the body. For example, a subcutaneously implanted reservoir may function as an infusion device when it is accessed via a needle attached to another catheter that transports the intended drug to the reservoir. Transport of the drug is via an external mechanical pump. In comparison to the aforementioned example of a subcutaneous reservoir with catheter as an ''infusion device'' are the elastomeric pumps which rely on the pressure generated by the elastic constriction created when the pump is filled with the drug to be administered. Elastomeric pumps do not rely upon any electronics or additional sources of energy to maintain the flow rate. Elastomeric pumps are typically single-use and disposable. In view of the different types of pumps used for short-term and long-term treatment purposes and the different interpretations of the infusion device codes, we will continue to analyze if further revisions to these codes are needed in ICD–10–PCS to ensure accurate assignment under the ICD–10 MS–DRGs. We also will continue to work with the AHA through the Coding Clinic for ICD–10–CM and ICD–10–PCS to promote proper coding.

After consideration of the public comments we received, we are not finalizing our proposal to assign the 49 ICD–10–PCS procedure codes describing insertion of an infusion device to MDC 8 in MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) for FY 2017. Consistent with the discussion in section II.F.19.c.(1)(k) of the preamble of the proposed rule and the same section of this final rule, the 49 ICD–10–PCS procedure codes shown in Table 6P.3c. associated with the proposed rule and updated for this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/*

Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index) will take the attributes of ICD–9–CM procedure code 99.99 (Other miscellaneous procedures), a non-O.R. procedure in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(12) Bladder Neck Repair

In the ICD–9–CM MS–DRGs Version 32, a procedure involving a bladder repair is identified with procedure code 57.89 (Other repair of bladder) which is designated as an O.R. procedure and assigned to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) in MS–DRGs 653, 654, and 655 (Major Bladder Procedures with MCC, with CC, and without CC/MCC, respectively) and MDC 13 (Diseases and Disorders of the Female Reproductive System) in MS–DRGs 749 and 750 (Other Female Reproductive System O.R. Procedures with CC/MCC and without CC/MCC, respectively).

A replication issue for five ICD–10–PCS comparable code translations that describe a bladder neck repair was identified after implementation of the ICD–10 MS–DRGs Version 33. These five procedure codes are:

- 0TQC0ZZ (Repair Bladder Neck, Open Approach);
- 0TQC3ZZ (Repair Bladder Neck, Percutaneous Approach);
- 0TQC4ZZ (Repair Bladder Neck, Percutaneous Endoscopic Approach);
- 0TQC7ZZ (Repair Bladder Neck, Via Natural or Artificial Opening); and
- 0TQC8ZZ (Repair Bladder Neck, Via Natural or Artificial Opening Endoscopic).

These five ICD–10–PCS procedure codes were inadvertently omitted from the ICD–10 MS–DRG GROUPER logic for MDC 11 in MS–DRGs 653, 654, and 655 and MDC 13 in MS–DRGs 749 and 750. To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25023 through 25024), we proposed to add these five ICD–10–PCS procedure codes to MDC 11 in MS–DRGs 653, 654, and 655 (Major Bladder Procedures with MCC, with CC, and without CC/MCC, respectively) and MDC 13 in MS–DRGs 749 and 750 (Other Female Reproductive System O.R. Procedures with CC/MCC and without CC/MCC, respectively) in ICD–10 MS–DRGs Version 34, effective October 1, 2016. We invited public comments on our proposal.

Comment: Commenters supported the proposal to add the five ICD–10–PCS procedure codes describing bladder neck repair listed in the proposed rule to MDC 11 in MS–DRGs 653, 654 and 655 and to MDC 13 in MS–DRGs 749 and 750. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to add the ICD–10–PCS procedure codes 0TQC0ZZ (Repair Bladder Neck, Open Approach), 0TQC3ZZ (Repair Bladder Neck, Percutaneous Approach), 0TQC4ZZ (Repair Bladder Neck, Percutaneous Endoscopic Approach), 0TQC7ZZ (Repair Bladder Neck, Via Natural or Artificial Opening), and 0TQC8ZZ (Repair Bladder Neck, Via Natural or Artificial Opening Endoscopic) to MDC 11 in MS–DRGs 653, 654, and 655 (Major Bladder Procedures with MCC, with CC, and without CC/MCC, respectively) and MDC 13 in MS–DRGs 749 and 750 (Other Female Reproductive System O.R. Procedures with CC/MCC and without CC/MCC, respectively) in ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(13) Future Consideration

We note that commenters have suggested that there are a number of procedure codes that may not appear to be clinically feasible due to a specific approach or device value in relation to a unique body part in a given body system. These commenters have not identified a comprehensive list of codes to be deleted. However, they have suggested that CMS examine these codes further. Due to the multiaxial structure of ICD–10–PCS, the current system allows for multiple possibilities for a given procedure, some of which may not currently be used. As our focus to refine the ICD–10 MS–DRGs continues, for FY 2018, we will begin to conduct an analysis of where such ICD–10–PCS codes may exist. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25024), we welcomed suggestions from the public of code refinements that could address the issue of current ICD–10–PCS codes that capture procedures that would not reasonably be performed. We indicated that commenters should submit their recommendations for these code refinements to the following email address: *MSDRGClassificationChanges@cms.hhs.gov* by December 7, 2016.

We also noted in the proposed rule that any suggestions that are received by December 7, 2016 to update ICD–10–PCS, including creating new codes or deleting existing codes, will be addressed by the ICD–10 Coordination and Maintenance Committee. Proposals to address the modification of any ICD–10–PCS codes are discussed at the ICD–10 Coordination and Maintenance Committee meetings held in March and September of each year. We refer the reader to section II.F.17. of the preamble of the proposed rule and this final rule for information related to this process to request updates to ICD–10–PCS.

b. Issues Relating to MS–DRG 999 (Ungroupable)

Under the ICD–9–CM MS–DRGs Version 32, a diagnosis of complications of an obstetric surgical wound after delivery is identified with diagnosis code 674.32 (Other complications of obstetrical surgical wounds, delivered, with mention of postpartum complication) and is assigned to MDC 14 (Pregnancy, Childbirth and the Puerperium) under MS–DRG 769 (Postpartum and Post Abortion Diagnoses with O.R. Procedure) or MS–DRG 776 (Postpartum and Post Abortion Diagnoses without O.R. Procedure). A replication issue under the ICD–10 MS–DRGs Version 33 for this condition was identified after implementation on October 1, 2015. Under ICD–10–CM, diagnosis code O90.2 (Hematoma of obstetric wound) is the comparable translation for ICD–9–CM diagnosis code 674.32. We discovered that cases where a patient has been readmitted to the hospital after a delivery and ICD–10–CM diagnosis code O90.2 is reported as the principal diagnosis are resulting in assignment to MS–DRG 999 (Ungroupable).

In the ICD–9–CM diagnosis code description, the concept of ''delivery'' is included in the code title. This concept is not present in the ICD–10–CM classification and has led to a replication issue for patients who delivered during a previous stay and are subsequently readmitted for the complication. To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25024), we proposed to add ICD–10–CM diagnosis code O90.2 to MDC 14 under MS–DRGs 769 and 776. This refinement would be consistent with the ICD–9–CM diagnosis code assignment and result in a more accurate replication of the ICD–9–CM MS–DRGs Version 32.

We invited public comments on our proposal to add ICD–10–CM diagnosis code O90.2 to MS–DRG 769 and MS–DRG 776 in MDC 14, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

Comment: Commenters supported the proposal to add ICD–10–CM diagnosis code O90.2 (Hematoma of obstetric wound) to MDC 14 in MS–DRGs 769 and 776. The commenters also

expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–CM diagnosis code O90.2 (Hematoma of obstetric wound) to MDC 14 in MS–DRG 769 (Postpartum and Post Abortion Diagnoses with O.R. Procedure) or MS–DRG 776 (Postpartum and Post Abortion Diagnoses without O.R. Procedure) in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

c. Other Operating Room (O.R.) and Non-O.R. Issues

(1) O.R. Procedures to Non-O.R. Procedures

For the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25024 through 25026), we continued our efforts to address the MS–DRG replication issues between ICD–9–CM logic and ICD–10 that were brought to our attention. As a result of analyzing those specific requests, we identified areas in the ICD–10–PCS classification where additional refinements could further support our replication efforts. We discuss these below.

We evaluated specific groups of ICD–10–PCS procedure codes with respect to their current operating room (O.R.) designation that were determined to be inconsistent with the ICD–9–CM procedure codes from which the designation was initially derived. Our review demonstrated that these ICD–10–PCS procedure codes should instead have the attributes of a more logical ICD–9–CM procedure code translation for MS–DRG replication purposes. As specified below, we proposed to change the status of ICD–10–PCS procedure codes from being designated as O.R. to non-O.R. for the ICD–10 MS–DRGs Version 34. For each group summarized below, the detailed code lists are shown in Tables 6P.4a. through 6P.4k. (ICD–10–CM and ICD–10–PCS Codes for Proposed MCE and MS–DRG Changes—FY 2017) associated with the proposed rule, which are available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

(a) Endoscopic/Transorifice Insertion

We found 72 ICD–10–PCS procedure codes describing an endoscopic/transorifice (via natural or artificial opening) insertion of infusion and monitoring devices into various tubular body parts that, when coded under ICD–9–CM, would reasonably correlate to other noninvasive catheterization and monitoring types of procedure codes versus an ''incision of [body part]'' or ''other operation on a [body part]'' procedure code. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25024 through 25025), we proposed that the 72 ICD–10–PCS procedure codes in Table 6P.4a. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We invited public comments on this proposal.

Comment: Commenters supported the proposal to change the designation of 72 ICD–10–PCS procedure codes describing an endoscopic/transorifice (via natural or artificial opening) insertion of infusion and monitoring devices into various tubular body parts. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

Comment: One commenter who agreed with our proposal also recommended that CMS remove the following two ICD–10–PCS procedure codes from the O.R. procedure list: 0DH67UZ (Insertion of Feeding Device into Stomach, Via Natural or Artificial Opening); and 0DH68UZ (Insertion of Feeding Device into Stomach, Via Natural or Artificial Opening Endoscopic). According to the commenter, these two ICD–10–PCS procedure codes are comparable translations of ICD–9–CM procedure code 96.6 (Enteral infusion of concentrated nutritional substances), which is designated as a non-O.R. procedure.

Response: We thank the commenter for their support of our proposal. With respect to the commenter's recommendation that we change the designation of the two ICD–10–PCS procedure codes (0DH67UZ and 0DH68UZ), we note that these procedure codes are currently designated as non-O.R. procedures in the ICD–10 MS–DRGs Version 33 Definitions Manual. Therefore, no change is needed. These procedure codes will remain non-O.R. procedures in ICD–10 Version 34.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 72 ICD–10–PCS procedure codes in Table 6P.4a. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). These 72 ICD–10–PCS procedure codes will be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C replace the ICD–9–CM procedure codes and descriptions reflected in column D in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(b) Endoscopic/Transorifice Removal

We found 155 ICD–10–PCS procedure codes describing an endoscopic/transorifice (via natural or artificial opening) removal of common devices such as a drainage device, infusion device, intraluminal device, or monitoring device from various tubular body parts that, when coded under ICD–9–CM, would reasonably correlate to other nonoperative removal of a wide range of devices/appliances procedure codes versus an ''incision of [body part]'' or ''other operation on a [body part]'' procedure code. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25025), we proposed that the 155 ICD–10–PCS procedure codes in Table 6P.4b. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We invited public comments on this proposal.

Comment: Commenters supported the proposal to change the designation of 155 ICD–10–PCS procedure codes describing the endoscopic/transorifice (via natural or artificial opening) removal of common devices such as a drainage device, infusion device, intraluminal device, or monitoring device from various tubular body parts. The commenters also expressed

appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 155 ICD–10–PCS procedure codes in Table 6P.4b. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). These 155 ICD–10–PCS procedure codes will be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C replace the ICD–9–CM procedure codes and descriptions reflected in column D in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(c) Tracheostomy Device Removal

We found five ICD–10–PCS procedure codes describing removal of a tracheostomy device with various approaches such that, when coded under ICD–9–CM, would reasonably correlate to the nonoperative removal of a tracheostomy device procedure code versus an ''incision of [body part]'' or ''other operation on a [body part]'' procedure code. We acknowledge that, under ICD–10–PCS, an ''open'' approach is defined as ''cutting through.'' However, this procedure was designated as non-O.R. under ICD–9–CM. For replication purposes, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25025), we proposed that the five ICD–10–PCS procedure codes in Table 6P.4c. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We invited public comments on this proposal.

Comment: Several commenters supported the proposal to change the designation of five ICD–10–PCS procedure codes describing the removal of a tracheostomy device with various approaches. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

Comment: One commenter stated that standard surgical practice does not support procedures involving removal of tracheostomy being performed outside of an operating room setting. This commenter also stated that these procedure codes were considered valid O.R. procedures under ICD–9–CM.

Response: We disagree with the commenter's statements. We note that removal of a tracheostomy frequently occurs at the bedside and is performed by nonoperative, manual removal of the tracheostomy tube. As discussed in the FY 2017 IPPS/LTCH PPS proposed rule and above in this final rule, under ICD–9–CM, removal of tracheostomy was designated as a non-O.R. procedure.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the five ICD–10–PCS procedure codes in Table 6P.4c. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). These five ICD–10–PCS procedure codes are assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C replace the ICD–9–CM procedure codes and descriptions reflected in column D in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(d) Endoscopic/Percutaneous Insertion

We found 117 ICD–10–PCS procedure codes describing the endoscopic/percutaneous insertion of infusion and monitoring devices into vascular and musculoskeletal body parts that, when coded under ICD–9–CM, would reasonably correlate to other noninvasive catheterization and monitoring types of procedure codes versus an ''incision of [body part]'' or ''other operation on a [body part]'' procedure code. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25025), we proposed that the 117 ICD–10–PCS procedure codes in Table 6P.4d. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are less accurate correlations. We invited public comments on this proposal.

Comment: Commenters supported the proposal to change the designation of 117 ICD–10–PCS procedure codes describing the endoscopic/percutaneous insertion of infusion and monitoring devices into vascular and musculoskeletal body parts. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 117 ICD–10–PCS procedure codes in Table 6P.4d. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). These 117 ICD–10–PCS procedure codes are assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C replace the ICD–9–CM procedure codes and descriptions reflected in column D in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(e) Percutaneous Removal

We found 124 ICD–10–PCS procedure codes describing the percutaneous removal of drainage, infusion and monitoring devices from vascular and musculoskeletal body parts that, when coded under ICD–9–CM, would reasonably correlate to the nonoperative removal of a wide range of devices/appliances procedure codes versus an ''incision of [body part]'' or ''other operation on a [body part]'' procedure code. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25025), we proposed that the 124 ICD–10–PCS procedure codes in Table 6P.4e. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and

descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We invited public comments on this proposal.

Comment: Commenters supported the proposal to change the designation of 124 ICD–10–PCS procedure codes describing the percutaneous removal of drainage, infusion and monitoring devices from vascular and musculoskeletal body parts. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 124 ICD–10–PCS procedure codes in Table 6P.4e. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). These 124 ICD–10–PCS procedure codes are assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C replace the ICD–9–CM procedure codes and descriptions reflected in column D in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(f) Percutaneous Drainage

We found 518 ICD–10–PCS procedure codes describing the percutaneous therapeutic drainage of all body sites that do not have specific percutaneous drainage codes. The list includes procedure codes for drainage with or without placement of a drainage device. Exceptions to this are cranial, intracranial and the eye where small incisions are the norm and appropriately classified as O.R. These 518 ICD–10–PCS procedures codes, when coded under ICD–9–CM, would reasonably correlate to the nonoperative puncture or drainage of various body sites and other miscellaneous procedures versus an ''incision of [body part]'' procedure code. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25025), we proposed that the 518 ICD–10–PCS procedure codes in Table 6P.4f. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We invited public comments on this proposal.

Comment: Several commenters supported the proposal to change the designation of 518 ICD–10–PCS procedure codes describing the percutaneous therapeutic drainage of various body sites with or without placement of a drainage device. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

Comment: Other commenters who agreed with our proposal also recommended that CMS change the designation of ICD–10–PCS procedure code 0W9G3ZX (Drainage of Peritoneal Cavity, Percutaneous Approach, Diagnostic) from O.R. to non-O.R. The commenters noted that the nondiagnostic version of the same code (7th character Z) is designated non-O.R. and suggested that ICD–9–CM procedure code 54.91(Percutaneous abdominal drainage) is a more accurate translation for the diagnostic version of the ICD–10–PCS procedure code.

Response: We thank the commenters for their support of our proposal. With respect to the commenters' recommendation that we change the designation of ICD–10–PCS procedure code 0W9G3ZX from O.R. to non-O.R., we note that the comparable translation under ICD–9–CM for replication purposes was procedure code 54.29 (Other diagnostic procedures on abdominal region), which is designated as an O.R. code. However, we agree with the commenters that diagnostic drainage of the peritoneal cavity is more accurately replicated with ICD–9–CM procedure code 54.91 (Percutaneous abdominal drainage) for reporting diagnostic paracentesis procedures and it is designated as a non-O.R. procedure. Therefore, we agree that the designation of ICD–10–PCS procedure code 0W9G3ZX (Drainage of peritoneal cavity, percutaneous approach, diagnostic) should also be changed from O.R. to non-O.R.

Comment: Another commenter who agreed with the proposal also recommended that CMS change the designation of all the diagnostic versions of the ICD–10–PCS procedures codes in Table 6P.4f. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html).*

Response: We acknowledge the commenter's support of our proposal. We note that, due to the volume of 518 ICD–10–PCS procedure codes listed in Table 6P.4f. and the timeframe that we have available to evaluate and assess the impact of additional recommendations submitted in response to proposals, we were not able to analyze all diagnostic versions for the full list of codes for FY 2017. We will review the list as part of our annual update process for FY 2018.

After consideration of the public comments we received, we are finalizing the recommendation to change the designation of ICD–10–PCS procedure code 0W9G3ZX (Drainage of Peritoneal Cavity, Percutaneous Approach, Diagnostic) from O.R. to non-O.R. We also are finalizing our proposal to change the designation of the 518 ICD–10–PCS procedure codes in Table 6P.4f. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). These 518 ICD–10–PCS procedure codes are assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C replace the ICD–9–CM procedure codes and descriptions reflected in column D in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(g) Percutaneous Inspection

We found 131 ICD–10–PCS procedure codes describing the percutaneous inspection of body part sites, with the exception of the cranial cavity and brain, whose designation is not consistent with other percutaneous inspection codes. When coded under ICD–9–CM, these procedure codes would reasonably correlate to the ''other nonoperative examinations'' and ''other diagnostic procedures on [body part]'' codes where the approach is not specified and the codes are designated as non-O.R. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25025), we proposed that the 131 ICD–10–PCS procedure codes in Table 6P.4g. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be

assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We invited public comments on this proposal.

Comment: Commenters supported the proposal to change the designation of 131 ICD–10–PCS procedure codes describing the percutaneous inspection of various body sites. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 131 ICD–10–PCS procedure codes in Table 6P.4g. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). These 131 ICD–10–PCS procedure codes are assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C replace the ICD–9–CM procedure codes and descriptions reflected in column D in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(h) Inspection Without Incision

We found 40 ICD–10–PCS procedure codes describing the inspection of various body sites with endoscopic/transorifice and external approaches. Under ICD–9–CM, these codes would reasonably correlate to ''other diagnostic procedures on [body part]'' codes where the approach is not specified and the codes are designated as non-O.R. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25026), we proposed that the 40 ICD–10–PCS codes in Table 6P.4h. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM code specified in column C. The ICD–9–CM codes and descriptions in column C would replace the ICD–9–CM codes and descriptions reflected in column D, which are considered less accurate correlations. We invited public comments on this proposal.

Comment: Commenters supported the proposal to change the designation of 40 ICD–10–PCS procedure codes describing the inspection of various body sites with endoscopic/transorifice and external approaches. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 40 ICD–10–PCS procedure codes in Table 6P.4h. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). These 40 ICD–10–PCS procedure codes are assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C replace the ICD–9–CM procedure codes and descriptions reflected in column D in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(i) Dilation of Stomach

We found six ICD–10–PCS procedure codes describing the dilation of stomach and pylorus body sites with various approaches whose designation is not consistent with all other gastrointestinal body parts dilation codes. Under ICD–9–CM, where a unique dilation code exists, the approach is not specified and these codes are designated as non-O.R. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25026), we proposed that the six ICD–10–PCS procedure codes in Table 6P.4i. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM code specified in column C. The ICD–9–CM codes and descriptions in column C would replace the ICD–9–CM codes and descriptions reflected in column D, which are considered less accurate correlations. We invited public comments on this proposal.

Comment: Commenters supported the proposal to change the designation of six ICD–10–PCS procedure codes describing the dilation of stomach and pylorus body sites with various approaches. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the six ICD–10–PCS procedure codes in Table 6P.4i. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). These six ICD–10–PCS procedure codes are assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C replace the ICD–9–CM procedure codes and descriptions reflected in column D in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(j) Endoscopic/Percutaneous Occlusion

We found six ICD–10–PCS codes describing percutaneous occlusion of esophageal vein with and without a device that, when coded under ICD–9–CM would reasonably correlate to the endoscopic excision or destruction of the vessel versus an open surgical procedure. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25026), we proposed that the six ICD–10–PCS procedure codes in Table 6P.4j. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM code specified in column C. The ICD–9–CM codes and descriptions in column C would replace the ICD–9–CM codes and descriptions reflected in column D, which are considered less accurate correlations. We invited public comments on this proposal.

Comment: Several commenters supported the proposal to change the designation of six ICD–10–PCS procedure codes describing the percutaneous occlusion of esophageal vein with and without a device. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential

replication issues between the ICD–9 and ICD–10 based MS–DRGs.

Comment: One commenter stated that standard surgical practice does not support procedures involving occlusion of the esophageal vein being performed outside of an operating room setting. This commenter also stated that these procedure codes were considered valid O.R. procedures under ICD–9–CM.

Response: We disagree with the commenter's statements. We note that percutaneous occlusion of the esophageal vein does not utilize the resources to be designated as an O.R. procedure. In addition, under ICD–9–CM, the endoscopic excision or destruction of lesion or tissue of esophagus for occlusion of esophageal vein was designated as a non-O.R. procedure.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the six ICD–10–PCS procedure codes in Table 6P.4j. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). These six ICD–10–PCS procedure codes are assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C replace the ICD–9–CM procedure codes and descriptions reflected in column D in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(k) Infusion Device

We found 82 ICD–10–PCS codes describing the insertion of an infusion device to various body parts that, when coded under ICD–9–CM, would reasonably correlate to the insertion of a common infusion catheter versus the insertion of a totally implantable infusion pump. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25026), we proposed that the 82 ICD–10–PCS procedure codes in Table 6P.4k. associated with the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) be assigned the attributes of the ICD–9–CM code specified in column C. The ICD–9–CM codes and descriptions in column C would replace the ICD–9–CM codes and descriptions reflected in column D, which are considered less accurate correlations. We invited public comments on this proposal.

Comment: Commenters supported the proposal to change the designation of 82 ICD–10–PCS procedure codes describing the insertion of an infusion device to various parts. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 82 ICD–10–PCS procedure codes in Table 6P.4k. associated with the proposed rule and this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). These 82 ICD–10–PCS procedure codes are assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C replace the ICD–9–CM procedure codes and descriptions reflected in column D in the ICD–10 MS–DRGs Version 34, effective October 1, 2016.

(2) Non-O.R. Procedures to O.R. Procedures

(a) Drainage of Pleural Cavity

In the ICD–9–CM MS–DRGs Version 32 Definitions Manual under Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, procedure code 34.06 (Thoracoscopic drainage of pleural cavity) is designated as an O.R. procedure code and is assigned to MS–DRGs 166 through 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 4 (Diseases and Disorders of the Respiratory System).

A replication issue regarding the procedure code designation and MS–DRG assignment for the comparable code translations under the ICD–10 MS–DRGs Version 33 was brought to our attention after implementation on October 1, 2015. The replication issue involves the following four ICD–10–PCS procedure codes:

- 0W9940Z (Drainage of right pleural cavity with drainage device, percutaneous endoscopic approach);
- 0W994ZZ (Drainage of right pleural cavity, percutaneous endoscopic approach);
- 0W9B40Z (Drainage of left pleural cavity with drainage device, percutaneous endoscopic approach); and
- 0W9B4ZZ (Drainage of left pleural cavity, percutaneous endoscopic approach).

In the ICD–10 MS–DRGs Version 33, these four ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. We agree that this was a replication error and the designation and MS–DRG assignment should be consistent with the designation and MS–DRG assignment of ICD–9–CM procedure code 34.06.

To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25026), we proposed to add ICD–10–PCS procedure codes 0W9940Z, 0W994ZZ, 0W9B40Z, and 0W9B4ZZ to the FY 2017 ICD–10 MS–DRGs Version 34 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 166 through 168 in MDC 4. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of four ICD–10–PCS procedure codes describing percutaneous endoscopic drainage of the pleural cavity with or without a drainage device. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the four ICD–10–PCS procedure codes describing percutaneous endoscopic drainage of the pleural cavity with or without a drainage device (0W9940Z, 0W994ZZ, 0W9B40Z, and 0W9B4ZZ) from non-O.R. to O.R. These procedure codes are added to the ICD–10 MS–DRGs Version 34 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index and assigned to MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively), effective October 1, 2016.

(b) Drainage of Cerebral Ventricle

In the ICD–9–CM MS–DRGs Version 32 Definitions Manual under Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, procedure code 02.22 (Intracranial ventricular shunt or anastomosis) is designated as an O.R. procedure code and is assigned to MS–DRGs 023 through 027, collectively referred to as

the ''Craniotomy'' MS–DRGs, in MDC 1 (Diseases and Disorders of the Nervous System).

A replication issue regarding the procedure code designation and MS–DRG assignment for the comparable code translations under the ICD–10 MS–DRGs Version 33 was brought to our attention after implementation on October 1, 2015. The replication issue involves the following ICD–10–PCS procedure codes:

ICD–10–PCS procedure code	Description
009130Z	Drainage of cerebral meninges with drainage device, percutaneous approach.
00913ZZ	Drainage of cerebral meninges, percutaneous approach.
009140Z	Drainage of cerebral meninges with drainage device, percutaneous endoscopic approach.
00914ZZ	Drainage of cerebral meninges with drainage device, percutaneous endoscopic approach.
009230Z	Drainage of dura mater with drainage device, percutaneous approach.
00923ZZ	Drainage of dura mater, percutaneous approach.
009240Z	Drainage of dura mater with drainage device, percutaneous endoscopic approach.
00924ZZ	Drainage of dura mater, percutaneous endoscopic approach.
009430Z	Drainage of subdural space with drainage device, percutaneous approach.
00943ZZ	Drainage of subdural space, percutaneous approach.
009440Z	Drainage of subdural space with drainage device, percutaneous endoscopic approach.
00944ZZ	Drainage of subdural space, percutaneous endoscopic approach.
009530Z	Drainage of subarachnoid space with drainage device, percutaneous approach.
00953ZZ	Drainage of subarachnoid space, percutaneous approach.
009540Z	Drainage of subarachnoid space with drainage device, percutaneous endoscopic approach.
00954ZZ	Drainage of subarachnoid space, percutaneous endoscopic approach.
00963ZZ	Drainage of cerebral ventricle, percutaneous approach.
00964ZZ	Drainage of cerebral ventricle, percutaneous endoscopic approach.

In the ICD–10 MS–DRGs Version 33, these ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. We agree that this was a replication error and their translation should be consistent with the designation and MS–DRG assignment of ICD–9–CM procedure 02.22.

To resolve this replication issue, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25026 through 25027), we proposed to add the ICD–10–PCS procedure codes listed above to the FY 2017 ICD–10 MS–DRGs Version 34 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 023 through 027 in MDC 1. We invited public comments on our proposal.

Comment: Commenters supported the proposal to change the designation of 18 ICD–10–PCS procedure codes describing endoscopic/percutaneous drainage of intracranial sites with or without a drainage device. The commenters also expressed appreciation for CMS' continued efforts towards addressing replication issues.

Response: We appreciate the commenters' support of our proposal and of our efforts to analyze potential replication issues between the ICD–9 and ICD–10 based MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 18 ICD–10–PCS procedure codes listed above describing endoscopic/percutaneous drainage of intracranial sites with or without a drainage device from non-O.R. to O.R. These procedure codes are added to the ICD–10 MS–DRGs Version 34 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index and assigned to MS–DRGs 023 and 024 (Craniotomy with Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis with MCC or Chemotherapy Implant and without MCC, respectively) and to MS–DRGs 025, 026 and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively), effective October 1, 2016.

(3) FY 2018 Refinements

As discussed earlier in this section, for FY 2017, we continued our efforts to address the MS–DRG replication issues between the ICD–9–CM logic and ICD–10 that were brought to our attention. As a result of analyzing specific requests, additional areas in the ICD–10 classification were identified where we proposed modifications to more accurately replicate the logic of ICD–9–CM and to reassign ICD–10 codes based on the different clinical concepts and definitions of the codes under the ICD–10 classification.

In response to some of the proposals set forth in the FY 2017 IPPS/LTCH PPS proposed rule pertaining to changing the designation of an ICD–10–PCS procedure code from O.R. to non-O.R., we received detailed comments and recommendations for consideration that we were not able to fully evaluate for FY 2017. We appreciate the extensive and thorough analysis that the commenters performed and their suggestions for further refinements. As the commenters' recommendations included analysis of over 800 procedure codes for redesignation, we plan to conduct a comprehensive review and analyze these codes for our FY 2018 refinement efforts.

20. Out of Scope Public Comments Received

We received public comments regarding five MS–DRG issues that were outside of the scope of the proposals included in the FY 2017 IPPS/LTCH PPS proposed rule. These comments were as follows:

- Several commenters requested the inclusion of ICD–10–PCS code 02L73ZK (Occlusion of left atrial appendage, percutaneous approach) that describes what is known as the LARIAT procedure in the FY 2017 MS–DRG proposal for the transcatheter mitral valve repair procedure.
- Commenters provided comments on ICD–10–CM diagnosis codes that were not approved at the time of issuance of the proposed rule.
- One commenter requested the creation of new MS–DRGs for the treatment of orphan diseases.
- Comments were submitted regarding the complexity, time commitment, and payment for transesophageal echocardiography services performed for a MitraClip procedure.

We consider these public comments to be outside of the scope of the proposed rule and, therefore, we are not addressing them in this final rule. As stated in section II.F.1.b. of the preamble of this final rule, we encourage individuals with comments about MS–DRG classification to submit these comments no later than December 7 of each year so that they can be considered for possible inclusion in the annual proposed rule and, if included, may be subjected to public review and comment. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

G. Recalibration of the FY 2017 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

As we discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25027), in developing the FY 2017 system of weights, we used two data sources: claims data and cost report data. As in previous years, the claims data source is the MedPAR file. This file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2015 MedPAR data used in this final rule include discharges occurring on October 1, 2014, through September 30, 2015, based on bills received by CMS through March 31, 2016, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). The FY 2015 MedPAR file used in calculating the relative weights includes data for approximately 9,770,558 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the March 31, 2016 update of the FY 2015 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the relative weights for FY 2017 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the FY 2017 relative weights are based on the ICD–9–CM diagnoses and procedures codes from the FY 2015 MedPAR claims data, grouped through the ICD–9–CM version of the FY 2017 GROUPER (Version 34).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, we used cost report data from the March 31, 2016 update of the FY 2014 HCRIS for calculating the FY 2017 cost-based relative weights.

2. Methodology for Calculation of the Final Relative Weights

As we explain in section II.E.2. of the preamble of this final rule, we calculated the FY 2017 relative weights based on 19 CCRs, as we did for FY 2016. The methodology we used to calculate the FY 2017 MS–DRG cost-based relative weights based on claims data in the FY 2015 MedPAR file and data from the FY 2014 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the FY 2017 MS–DRG classifications discussed in sections II.B. and II.F. of the preamble of this final rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2015 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.
- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $10.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, special equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood charges, and anesthesia charges were also deleted.
- At least 92.1 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates

program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (that is, as if hospitals were not participating in those models under the BPCI initiative). The BPCI initiative, developed under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Under the BPCI initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. For FY 2017, as we proposed, we are continuing to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

Once the MedPAR data were trimmed and the statistical outliers were removed, the charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2014 cost report data.

The 19 cost centers that we used in the relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the proposed 19 national cost center CCRs. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25028), we stated that if stakeholders have comments about the groupings in this table, we may consider those comments as we finalize our policy. However, we did not receive any comments on the groupings in this table, and therefore, we are finalizing the groupings as proposed.

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS–2552–10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS–2552–10	Medicare Charges from HCRIS (Worksheet D–3, Column & line number) Form CMS–2552–10
Routine Days	Private Room Charges.	011X and 014X	Adults & Pediatrics (General Routine Care).	C_1_C5_30	C_1_C6_30	D3_HOS_C2_30
	Semi-Private Room Charges.	012X, 013X and 016X–019X.				
	Ward Charges	015X.				
Intensive Days	Intensive Care Charges.	020X	Intensive Care Unit	C_1_C5_31	C_1_C6_31	D3_HOS_C2_31
	Coronary Care Charges.	021X	Coronary Care Unit	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32
			Burn Intensive Care Unit.	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
			Surgical Intensive Care Unit.	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34
			Other Special Care Unit.	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
Drugs	Pharmacy Charges	025X, 026X and 063X.	Intravenous Therapy	C_1_C5_64	C_1_C6_64 C_1_C7_64	D3_HOS_C2_64
			Drugs Charged To Patient.	C_1_C5_73	C_1_C6_73	D3_HOS_C2_73

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS–2552–10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS–2552–10	Medicare Charges from HCRIS (Worksheet D–3, Column & line number) Form CMS–2552–10
Supplies and Equipment.	Medical/Surgical Supply Charges.	0270, 0271, 0272, 0273, 0274, 0277, 0279, and 0621, 0622, 0623.	Medical Supplies Charged to Patients.	C_1_C5_71	C_1_C7_73 C_1_C6_71	D3_HOS_C2_71
	Durable Medical Equipment Charges.	0290, 0291, 0292 and 0294–0299.	DME–Rented	C_1_C5_96	C_1_C7_71 C_1_C6_96	D3_HOS_C2_96
	Used Durable Medical Charges.	0293	DME–Sold	C_1_C5_97	C_1_C7_96 C_1_C6_97	D3_HOS_C2_97
Implantable Devices		0275, 0276, 0278, 0624.	Implantable Devices Charged to Patients.	C_1_C5_72	C_1_C7_97 C_1_C6_72	D3_HOS_C2_72
Therapy Services	Physical Therapy Charges.	042X	Physical Therapy	C_1_C5_66	C_1_C7_72 C_1_C6_66	D3_HOS_C2_66
	Occupational Therapy Charges.	043X	Occupational Therapy.	C_1_C5_67	C_1_C7_66 C_1_C6_67	D3_HOS_C2_67
	Speech Pathology Charges.	044X and 047X	Speech Pathology	C_1_C5_68	C_1_C7_67 C_1_C6_68	D3_HOS_C2_68
Inhalation Therapy	Inhalation Therapy Charges.	041X and 046X	Respiratory Therapy	C_1_C5_65	C_1_C7_68 C_1_C6_65	D3_HOS_C2_65
Operating Room	Operating Room Charges.	036X	Operating Room	C_1_C5_50	C_1_C7_65 C_1_C6_50	D3_HOS_C2_50
		071X	Recovery Room	C_1_C5_51	C_1_C7_50 C_1_C6_51	D3_HOS_C2_51
Labor & Delivery	Operating Room Charges.	072X	Delivery Room and Labor Room.	C_1_C5_52	C_1_C7_51 C_1_C6_52	D3_HOS_C2_52
Anesthesia	Anesthesia Charges	037X	Anesthesiology	C_1_C5_53	C_1_C7_52 C_1_C6_53	D3_HOS_C2_53
Cardiology	Cardiology Charges	048X and 073X	Electrocardiology	C_1_C5_69	C_1_C7_53 C_1_C6_69	D3_HOS_C2_69
Cardiac Catheterization.		0481	Cardiac Catheterization.	C_1_C5_59	C_1_C7_69 C_1_C6_59	D3_HOS_C2_59
Laboratory	Laboratory Charges	030X, 031X, and 075X.	Laboratory	C_1_C5_60	C_1_C7_59 C_1_C6_60	D3_HOS_C2_60
			PBP Clinic Laboratory Services.	C_1_C5_61	C_1_C7_60 C_1_C6_61	D3_HOS_C2_61
		074X, 086X	Electro-Encephalography.	C_1_C5_70	C_1_C7_61 C_1_C6_70	D3_HOS_C2_70
Radiology	Radiology Charges	032X, 040X	Radiology–Diagnostic.	C_1_C5_54	C_1_C7_70 C_1_C6_54	D3_HOS_C2_54
		028x, 0331, 0332, 0333, 0335, 0339, 0342.	Radiology–Therapeutic.	C_1_C5_55	C_1_C7_54 C_1_C6_55	D3_HOS_C2_55
		0343 and 344	Radioisotope	C_1_C5_56	C_1_C6_56 C_1_C7_56	D3_HOS_C2_56
Computed Tomography (CT) Scan.	CT Scan Charges	035X	Computed Tomography (CT) Scan.	C_1_C5_57	C_1_C6_57 C_1_C7_57	D3_HOS_C2_57
Magnetic Resonance Imaging (MRI).	MRI Charges	061X	Magnetic Resonance Imaging (MRI).	C_1_C5_58	C_1_C6_58 C_1_C7_58	D3_HOS_C2_58

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS–2552–10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS–2552–10	Medicare Charges from HCRIS (Worksheet D–3, Column & line number) Form CMS–2552–10
Emergency Room ...	Emergency Room Charges.	045x	Emergency	C_1_C5_91	C_1_C6_91 C_1_C7_91	D3_HOS_C2_91
Blood and Blood Products.	Blood Charges	038x	Whole Blood & Packed Red Blood Cells.	C_1_C5_62	C_1_C6_62 C_1_C7_62	D3_HOS_C2_62
	Blood Storage/Processing.	039x	Blood Storing, Processing, & Transfusing.	C_1_C5_63	C_1_C6_63 C_1_C7_63	D3_HOS_C2_63
Other Services	Other Service Charge.	0002–0099, 022X, 023X, 024X, 052X, 053X. 055X–060X, 064X–070X, 076X–078X, 090X–095X and 099X.				
	Renal Dialysis	0800X	Renal Dialysis	C_1_C5_74	C_1_C6_74 C_1_C7_74	D3_HOS_C2_74
	ESRD Revenue Setting Charges.	080X and 082X–088X.				
			Home Program Dialysis.	C_1_C5_94	C_1_C6_94 C_1_C7_94	D3_HOS_C2_94
	Outpatient Service Charges.	049X	ASC (Non Distinct Part).	C_1_C5_75	C_1_C6_75 C_1_C7_75	D3_HOS_C2_75
	Lithotripsy Charge ...	079X				
			Other Ancillary	C_1_C5_76	C_1_C6_76 C_1_C7_76	D3_HOS_C2_76
	Clinic Visit Charges	051X	Clinic	C_1_C5_90	C_1_C6_90 C_1_C7_90	D3_HOS_C2_90
			Observation beds	C_1_C5_92.01	C_1_C6_92.01 C_1_C7_92.01	D3_HOS_C2_92.01
	Professional Fees Charges.	096X, 097X, and 098X.	Other Outpatient Services.	C_1_C5_93	C_1_C6_93 C_1_C7_93	D3_HOS_C2_93
	Ambulance Charges	054X	Ambulance	C_1_C5_95	C_1_C6_95 C_1_C7_95	D3_HOS_C2_95
			Rural Health Clinic ..	C_1_C5_88	C_1_C6_88 C_1_C7_88	D3_HOS_C2_88
			FQHC	C_1_C5_89	C_1_C6_89 C_1_C7_89	D3_HOS_C2_89

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2014 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. We then created CCRs for each provider for each cost center (see prior table for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. We then took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost

per case to determine the relative weight.

The FY 2017 cost-based relative weights were then normalized by an adjustment factor of 1.691521 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The 19 national average CCRs for FY 2017 are as follows:

Group	CCR
Routine Days	0.457
Intensive Days	0.375
Drugs	0.194
Supplies & Equipment	0.297
Implantable Devices	0.331
Therapy Services	0.321
Laboratory	0.120
Operating Room	0.191
Cardiology	0.112
Cardiac Catheterization	0.118
Radiology	0.153
MRIs	0.079
CT Scans	0.038
Emergency Room	0.171
Blood and Blood Products	0.323
Other Services	0.365
Labor & Delivery	0.410
Inhalation Therapy	0.170
Anesthesia	0.089

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. As we proposed, we use that same case threshold in recalibrating the MS–DRG relative weights for FY 2017. Using data from the FY 2015 MedPAR file, there were 8 MS–DRGs that contain fewer than 10 cases. Under the MS–DRGs, we have fewer low-volume DRGs than under the CMS DRGs because we no longer have separate DRGs for patients aged 0 to 17 years. With the exception of newborns, we previously separated some DRGs based on whether the patient was age 0 to 17 years or age 17 years and older. Other than the age split, cases grouping to these DRGs are identical. The DRGs for patients aged 0 to 17 years generally have very low volumes because children are typically ineligible for Medicare. In the past, we have found that the low volume of cases for the pediatric DRGs could lead to significant year-to-year instability in their relative weights. Although we have always encouraged non-Medicare payers to develop weights applicable to their own patient populations, we have received frequent complaints from providers about the use of the Medicare relative weights in the pediatric population. We believe that eliminating this age split in the MS–DRGs will provide more stable payment for pediatric cases by determining their payment using adult cases that are much higher in total volume. Newborns are unique and require separate MS–DRGs that are not mirrored in the adult population. Therefore, it remains necessary to retain separate MS–DRGs for newborns. All of the low-volume MS–DRGs listed are for newborns. For FY 2017, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, as we proposed, we compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2016 relative weights by the percentage change in the average weight of the cases in other MS–DRGs. The crosswalk table is shown:

Low–volume MS–DRG	MS–DRG Title	Crosswalk to MS–DRG
768	Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C.	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
789	Neonates, Died or Transferred to Another Acute Care Facility.	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate.	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
793	Full-Term Neonate with Major Problems	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS DRGs).
795	Normal Newborn	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

We did not receive any public comments on our proposals for establishing the relative weights for FY 2017 and are finalizing them as proposed.

H. Add-On Payments for New Services and Technologies for FY 2017

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. We note that, beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs.

The regulations at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the

service or technology must demonstrate a substantial clinical improvement over existing services or technologies. Below we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For a complete discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574).

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will be considered ''new'' for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to a technology that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352), and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to the discharge involving the new medical services or technologies must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed certain threshold amounts. Table 10 that was released with the FY 2016 IPPS/LTCH PPS final rule contains the final thresholds that we used to evaluate applications for new medical service and new technology add-on payments for FY 2017. We refer readers to the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Tables.html* to download and view Table 10.

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service and new technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

Under the third criterion, § 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available. (We refer readers to the September 7, 2001 final rule for a more detailed discussion of this criterion (66 FR 46902).)

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. Under § 412.88, if the costs of the discharge (determined by applying cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology or medical service (if the estimated costs for the case including the new technology or medical service exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology or new medical service.

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We amended § 412.87(c) to specify that all applicants for new technology add-on payments must have FDA approval or clearance for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered.

The Council on Technology and Innovation (CTI) at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies and medical services between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Center for Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local claims-payment contractors (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an ''Innovator's Guide'' to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS Web site, in a user-friendly format. This guide was published in 2010 and is available on the CMS Web site at: *http://www.cms.gov/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf*.

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any product developers or manufacturers of new medical services or technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov*.

We note that applicants for add-on payments for new medical services or technologies for FY 2018 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*. To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2018, the CMS Web site also will post the tracking forms completed by each applicant.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2017 prior to publication of the FY 2017 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 30, 2015 (80 FR 74774), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 16, 2016. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for each of the FY 2017 new medical service and technology add-on payment applications before the publication of the FY 2017 IPPS/LTCH PPS proposed rule.

Approximately 76 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. We also live-streamed the town hall meeting and posted the town hall on the CMS YouTube Web page at: *https://www.youtube.com/watch?v=dn-R5KGQu-M.* We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the due date of February 26, 2016, in our evaluation of the new technology add-on payment applications for FY 2017 presented in the FY 2017IPPS/LTCH PPS proposed rule.

As indicated earlier in this section, CMS is required to provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS. In recent years, CMS has live-streamed the town hall meeting through the CMS YouTube Web page and later posted the recorded version of the town hall meeting, in addition to maintaining an open telephone line. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25033), we proposed to conduct future town hall meetings entirely via teleconference and Webcast using the same technologies. Under that proposal, we would continue to publish a notice informing the public of the date of the meeting, as well as requirements for the submission of presentations. We also would continue to maintain an open telephone line, with an option for participation in the Webcast. The recording of the town hall meeting would continue to be available on the CMS You Tube Web page or other CMS

Web site following the meeting. This recording would include closed captioning of all presentations and comments. In addition to submitting materials for discussion at the town hall meeting, individuals would continue to be able to submit other written comments after the town hall meeting on whether the service or technology represents a substantial clinical improvement. We invited public comments on this proposal in the proposed rule.

Comment: One commenter expressed appreciation for CMS' efforts to organize and host the new technology town hall meetings entirely via teleconference and Webcast, while continuing to maintain an open telephone line with an option for participation through the Webcast and making the recording of the town hall meeting available on the CMS You Tube Web page or other CMS Web site following the meeting. However, the commenter requested that the option for an open face-to-face meeting be maintained in addition to the teleconference and Webcast participation options. The commenter noted that the opportunity to be able to present in an actual face-to-face forum allows attendees and presenters to gauge reaction and foster added awareness of the use of new technologies.

Several commenters disagreed with the proposal to conduct the new technology town hall meetings via phone and video conference only, and to discontinue in-person meetings. The commenters stated that there is considerable value in face-to-face meetings and presentations on new technologies.

Response: We appreciate the commenter's support and have taken into consideration the commenters' concerns. Therefore, in the interim, we will continue to host the new technology town hall meetings in person. However, we encourage the public to utilize the teleconference and Webcast participation options in order to become familiar with the advancing technological options. We will continue to gauge the public's interest in CMS hosting the new technology town hall meetings entirely via teleconference and Webcast in subsequent fiscal years.

In response to the published notice and the February 16, 2016 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2017 new technology add-on payments. We summarized in the proposed rule a general comment that did not relate to a specific application for FY 2017 new technology add-on payments. We also summarized comments regarding individual applications, or, if applicable, indicated that there were no comments received in section II.H.5. of the preamble of the proposed rule at the end of each applicable discussion of the individual applications. We note that we did receive public comments unrelated to the substantial clinical improvement criterion. As stated earlier, the purpose of the new technology town hall meeting is specifically to discuss the substantial clinical improvement criterion in regard to pending new technology add-on payment applications for FY 2017. Therefore, we did not summarize these additional comments in the proposed rule. However, we did invite the commenter to resubmit its comments in response to proposals presented in the proposed rule.

Comment: Commenters provided additional comments during the 60-day comment period for the proposed rule with regard to the newness, cost, and substantial clinical improvement criteria. Some commenters reiterated comments presented at the town hall meeting, including a recommendation that CMS broaden the criteria applied in making substantial clinical improvement determinations to require, in addition to existing criteria, consideration of whether the new technology or medical service meets one or more of the following additional suggested criteria: (1) Results in a reduction of the length of a hospital stay; (2) improves patient quality of life; (3) creates long-term clinical efficiencies in treatment; (4) addresses patient-centered objectives as defined by the Secretary; or (5) meets such other criteria as the Secretary may specify; and a suggestion that an entity submitting an application for new technology add-on payments be entitled to administrative review of an adverse determination made by the Secretary.

Response: We did not propose any policy changes to the criteria applied to new technology applications in the FY 2016 IPPS/LTCH PPS proposed rule. Therefore, we are not addressing these additional comments in this final rule. Similar to our response in the proposed rule, we will take the commenters' recommendation and suggestion into consideration in future rulemaking.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html,* including guidelines for ICD–10–PCS ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

Comment: One commenter supported the implementation of Section ''X'' codes, but recommended that CMS, in order to avoid confusion, make it mandatory that requestors of these new Section ''X'' codes also request the creation of new procedure codes in the body of ICD–10–PCS to accommodate the new medical service or technology. Other commenters also supported the creation and implementation of the Section ''X'' codes, but noted the need to gain better understanding of how the new section ''X'' codes will be used and applied. These commenters encouraged CMS to continue to remain transparent in how the agency develops and applies these new codes.

Response: We appreciate the commenters' support of the new ICD–10–PCS codes. These Section ''X'' codes are included in Table 6B associated with this final rule (which is available via the Internet on the CMS Web site). Section ''X'' codes are standalone codes. They are not supplemental codes. Section ''X'' codes fully represent the specific procedure described in the code title and do not require any additional codes from other sections of ICD–10–PCS. When a section ''X'' code contains a code title that describes a specific new technology procedure, only that section ''X'' code is reported for the procedure. There is no need to report a broader, nonspecific code in another section of ICD–10–PCS. Section X of the ICD–10–PCS structure does not introduce any new coding concepts or unusual guidelines for correct coding. We encourage individuals interested in the creation of ICD–10–PCS codes (including Section ''X'' codes) and any recommendations as to whether or not there should be a mandatory requirement that new code requests

include both codes in Section X as well as in other sections of ICD–10–PCS to make this suggestion at future meetings of the ICD–10 Coordination and Maintenance Committee. We encourage participation at these future meetings as well as the presentation of comments during the comment period regarding proposals and approvals for creating and implementing new codes. We refer commenters to the CMS Web site at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html* for complete details.

4. FY 2017 Status of Technologies Approved for FY 2016 Add-On Payments

a. Kcentra™

CSL Behring submitted an application for new technology add-on payments for Kcentra™ for FY 2014. Kcentra™ is a replacement therapy for fresh frozen plasma (FFP) for patients with an acquired coagulation factor deficiency due to warfarin and who are experiencing a severe bleed. Kcentra™ contains the Vitamin K dependent coagulation factors II, VII, IX and X, together known as the prothrombin complex, and antithrombotic proteins C and S. Factor IX is the lead factor for the potency of the preparation. The product is a heat-treated, non-activated, virus filtered and lyophilized plasma protein concentrate made from pooled human plasma. Kcentra™ is available as a lyophilized powder that needs to be reconstituted with sterile water prior to administration via intravenous infusion. The product is dosed based on Factor IX units. Concurrent Vitamin K treatment is recommended to maintain blood clotting factor levels once the effects of Kcentra™ have diminished.

Kcentra™ was approved by the FDA on April 29, 2013. Under the ICD–10 coding system, Kcentra™ is uniquely identified by ICD–10–CM procedure code 30283B1 (Transfusion of nonautologous 4-factor prothrombin complex concentrate into vein, percutaneous approach).

After evaluation of the newness, cost, and substantial clinical improvement criteria for new technology add-on payments for Kcentra™ and consideration of the public comments we received in response to the FY 2014 IPPS/LTCH PPS proposed rule, we approved Kcentra™ for new technology add-on payments for FY 2014 (78 FR 50575 through 50580). In the application, the applicant estimated that the average Medicare beneficiary would require an average dosage of 2500 International Units (IU). Vials contain 500 IU at a cost of $635 per vial. Therefore, cases of Kcentra™ would incur an average cost per case of $3,175 ($635 × 5). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum add-on payment for a case of Kcentra™ was $1,587.50 for FY 2014. We refer the reader to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50579) for complete details on the new technology add-on payments for Kcentra™.

As stated above, the new technology add-on payment regulations provide that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (§ 412.87(b)(2)). Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend add-on payments for an additional year only if the 3-year anniversary date of the product's entry on the market occurs in the latter half of the fiscal year (70 FR 47362).

With regard to the newness criterion for Kcentra™, we considered the beginning of the newness period to commence when Kcentra™ was approved by the FDA on April 29, 2013. Because the 3-year anniversary date for Kcentra™ would occur in the latter half of FY 2016 (April 29, 2016), in the FY 2016 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2016 (80 FR 49437). However, for FY 2017, the 3-year anniversary date of the entry of Kcentra™ on the U.S. market (April 29, 2016) occurred prior to the beginning of FY 2017. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25034), we proposed to discontinue new technology add-on payments for this technology for FY 2017. We invited public comments on this proposal in the proposed rule.

We did not receive any public comments on our proposal. Therefore, as we proposed, we are discontinuing new technology add-on payments for Kcentra™ for FY 2017. The 3-year anniversary date of the product's entry onto the U.S. market occurred prior to the beginning of FY 2017. Therefore, the technology is not eligible for new technology add-on payments for FY 2017 because the technology will no longer meet the ''newness'' criterion.

b. Argus® II Retinal Prosthesis System

Second Sight Medical Products, Inc. submitted an application for new technology add-on payments for the Argus® II Retinal Prosthesis System (Argus® II System) for FY 2014. The Argus® II System is an active implantable medical device that is intended to provide electrical stimulation of the retina to induce visual perception in patients who are profoundly blind due to retinitis pigmentosa (RP). These patients have bare or no light perception in both eyes. The system employs electrical signals to bypass dead photo-receptor cells and stimulate the overlying neurons according to a real-time video signal that is wirelessly transmitted from an externally worn video camera. The Argus® II implant is intended to be implanted in a single eye, typically the worse-seeing eye. Currently, bilateral implants are not intended for this technology. According to the applicant, the surgical implant procedure takes approximately 4 hours and is performed under general anesthesia.

With regard to the newness criterion, the applicant received a Humanitarian Device Exemption (HDE) approval from the FDA on February 13, 2013. However, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49924 through 49925), we discussed comments we had received informing CMS that the Argus® II System was not available on the U.S. market until December 20, 2013. The applicant explained that, as part of the lengthy approval process, it was required to submit a request to the Federal Communications Commission (FCC) for a waiver of section 15.209(a) of the FCC rules that would allow the applicant to apply for FCC authorization to utilize this specific RF band. The FCC approved the applicant's waiver request on November 30, 2011. After receiving the FCC waiver of the section 15.209(a) rules, the applicant requested and obtained a required Grant of Equipment Authorization to utilize the specific RF band, which the FCC issued on December 20, 2013. Therefore, the applicant stated that the date the Argus® II System first became available for commercial sale in the United States was December 20, 2013. We agreed with the applicant that, due to the delay, the date of newness for the Argus® II System was December 20, 2013, instead of February 13, 2013.

After evaluation of the new technology add-on payment application and consideration of public comments received, we concluded that the Argus®

II System met all of the new technology add-on payment policy criteria. Therefore, we approved the Argus® II System for new technology add-on payments in FY 2014 (78 FR 50580 through 50583). Cases involving the Argus® II System that are eligible for new technology add-on payments currently are identified when one of the following ICD–10–PCS procedure codes is reported: 08H005Z (Insertion of epiretinal visual prosthesis into right eye, open approach); or 08H105Z (Insertion of epiretinal visual prosthesis into left eye, open approach). In the application, the applicant provided a breakdown of the costs of the Argus® II System. The total operating cost of the Argus® II System is $144,057.50. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum add-on payment for a case involving the Argus® II System for FY 2014 was $72,028.75.

With regard to the newness criterion for the Argus® II System, we considered the beginning of the newness period to commence when the Argus® II System became available on the U.S. market on December 20, 2013. Because the 3-year anniversary date for the Argus® II System will occur after FY 2016 (December 20, 2016), in the FY 2016 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2016 (80 FR 49439). However, for FY 2017, the 3-year anniversary date of the entry of the Argus® II System on the U.S. market (December 20, 2016) will occur in the first half of FY 2017. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry on to the U.S. market occurs in the latter half of the fiscal year. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25034 and 25035), we proposed to discontinue new technology add-on payments for this technology for FY 2017. We invited public comments on this proposal in the proposed rule.

We did not receive any public comments on our proposal. Therefore, as we proposed, we are discontinuing new technology add-on payments for the Argus® II System for FY 2017. The 3-year anniversary date of the product's entry onto the U.S. market occurs in the first half of FY 2017. Therefore, the technology is not eligible for new technology add-on payments for FY 2017 because the technology will no longer meet the ''newness'' criterion.

c. CardioMEMS™ HF (Heart Failure) Monitoring System

CardioMEMS, Inc. submitted an application for new technology add-on payment for FY 2015 for the CardioMEMS™ HF (Heart Failure) Monitoring System, which is an implantable hemodynamic monitoring system comprised of an implantable sensor/monitor placed in the distal pulmonary artery. Pulmonary artery hemodynamic monitoring is used in the management of heart failure. The CardioMEMS™ HF Monitoring System measures multiple pulmonary artery pressure parameters for an ambulatory patient to measure and transmit data via a wireless sensor to a secure Web site.

The CardioMEMS™ HF Monitoring System utilizes radiofrequency (RF) energy to power the sensor and to measure pulmonary artery (PA) pressure and consists of three components: An Implantable Sensor with Delivery Catheter, an External Electronics Unit, and a Pulmonary Artery Pressure Database. The system provides the physician with the patient's PA pressure waveform (including systolic, diastolic, and mean pressures) as well as heart rate. The sensor is permanently implanted in the distal pulmonary artery using transcatheter techniques in the catheterization laboratory where it is calibrated using a Swan-Ganz catheter. PA pressures are transmitted by the patient at home in a supine position on a padded antenna, pushing one button which records an 18-second continuous waveform. The data also can be recorded from the hospital, physician's office or clinic.

The hemodynamic data, including a detailed waveform, are transmitted to a secure Web site that serves as the Pulmonary Artery Pressure Database, so that information regarding PA pressure is available to the physician or nurse at any time via the Internet. Interpretation of trend data allows the clinician to make adjustments to therapy and can be used along with heart failure signs and symptoms to adjust medications.

The applicant received FDA approval on May 28, 2014. After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the CardioMEMS™ HF Monitoring System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the CardioMEMS™ HF Monitoring System for new technology add-on payments for FY 2015 (79 FR 49940). Cases involving the CardioMEMS™ HF Monitoring System that are eligible for new technology add-on payments are identified by either ICD–10–PCS procedure code 02HQ30Z (Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous approach) or ICD–10–PCS procedure code 02HR30Z (Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous approach). With the new technology add-on payment application, the applicant stated that the total operating cost of the CardioMEMS™ HF Monitoring System is $17,750. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the CardioMEMS™ HF Monitoring System is $8,875.

With regard to the newness criterion for the CardioMEMS™ HF Monitoring System, we considered the beginning of the newness period to commence when the CardioMEMS™ HF Monitoring System was approved by the FDA on May 28, 2014. Because the 3-year anniversary date of the entry of the CardioMEMS™ HF Monitoring System on the U.S. market will occur in the latter half of FY 2017 (May 28, 2017), in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25035 and 25036), we proposed to continue new technology add-on payments for this technology for FY 2017. We proposed that the maximum payment for a case involving the CardioMEMS™ HF Monitoring System would remain at $8,875 for FY 2017. We invited public comments on our proposal in the proposed rule.

Comment: One commenter, the manufacturer, supported the continuation of new technology add-on payments for the CardioMEMS™ HF Monitoring System in FY 2017. The commenter requested that CMS provide further and more detailed guidance to the various stakeholders, including hospitals, physicians, MACs, and other manufacturers, on the purpose for the additional payment and how the new technology add-on payment is calculated thereafter. The commenter added that when new technology add-on payments are approved, it is ultimately the responsibility of the applicable provider to charge and bill appropriately. The commenter further explained that it is most often the manufacturer that developed the new technology that researches and provides guidance and expertise to the adopting facilities regarding the technology's use. However, the commenter believed that, given the few new medical services or technologies approved for new

technology add-on payments, hospitals often lack the resources or experience to research and understand the payment calculations. The commenter recommended that CMS provide examples or sample calculations of the new technology add-on payment in a similar fashion that CMS has published examples of other payment methodologies, for example, DSH payments.

Response: We appreciate the commenter's support. We note that after the development and publication of each final rule, CMS issues instructions to the MACs informing them of important changes for the upcoming fiscal year. In addition, CMS issues a Medicare Learning Matters (MLN) article for the public in order to provide information regarding changes for the upcoming fiscal year. The instructions for the MACs and the MLN article for the public always include which new technologies are eligible for new technology add-on payments for in the upcoming fiscal year. We refer readers to the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2015-Transmittals-Items/R3431CP.html* to view the MAC instructions and MLN article issued in conjunction with the FY 2016 IPPS/LTCH final rule. For information regarding how to receive MLN articles, we refer readers to the CMS Web site at: *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/What_Is_MLNMatters.pdf*. Also, the regulations at 42 CFR 412.88 explain how the new technology add-on payment is made. Further, on December 13, 2002, we issued Change Request 2301, which provides examples of how the new technology add-on payment is made. Change Request 2301 is available for download via the Internet from the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/A02124.pdf*. We also educate the public through our conference calls via open door forums. For information on CMS' open door forums, we refer readers to the CMS Web site at: *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html*.

After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for the CardioMEMS™ HF Monitoring System for FY 2017. The maximum new technology add-on payment for a case involving the CardioMEMS™ HF Monitoring System will remain at $8,875 for FY 2017.

d. MitraClip® System

Abbott Vascular submitted an application for new technology add-on payments for the MitraClip® System for FY 2015. The MitraClip® System is a transcatheter mitral valve repair system that includes a MitraClip® device implant, a Steerable Guide Catheter, and a Clip Delivery System. It is designed to perform reconstruction of the insufficient mitral valve for high-risk patients who are not candidates for conventional open mitral valve repair surgery.

With regard to the newness criterion, the MitraClip® System received a premarket approval from the FDA on October 24, 2013. The MitraClip® System is indicated ''for the percutaneous reduction of significant symptomatic mitral regurgitation (MR >= 3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.'' The MitraClip® System became immediately available on the U.S. market following FDA approval. The MitraClip® System is a Class III device, and has an investigational device exemption (IDE) for the EVEREST study (Endovascular Valve Edge-to-Edge Repair Study)—IDE G030061, and for the COAPT study (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Health Failure Patients with Functional Mitral Regurgitation)—IDE G120024. Cases involving the MitraClip® System are identified using ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach).

On August 7, 2014, CMS issued a National Coverage Decision (NCD) concerning Transcatheter Mitral Valve Repair procedures. We refer readers to the CMS Web site at: *http://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=273* for information related to this NCD.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the MitraClip® System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the MitraClip® System for new technology add-on payments for FY 2015 (79 FR 49946). As discussed in the FY 2015 IPPS/LTCH PPS final rule, this approval is on the basis of using the MitraClip® consistent with the NCD. The average cost of the MitraClip® System is reported as $30,000. Under section 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the MitraClip® System is $15,000 for FY 2015.

With regard to the newness criterion for the MitraClip® System, we considered the beginning of the newness period to commence when the MitraClip® System was approved by the FDA on October 24, 2013. Because the 3-year anniversary date of the entry of the MitraClip® System on the U.S. market (October 24, 2016) will occur after FY 2016, in the FY 2016 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2016 (80 FR 49442). However, for FY 2017, the 3-year anniversary date of the entry of MitraClip® System on the U.S. market (October 24, 2016) will occur in the first half of FY 2017. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry on to the U.S. market occurs in the latter half of the fiscal year. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25036), we proposed to discontinue new technology add-on payments for this technology for FY 2017. We invited public comments on this proposal in the proposed rule.

We did not receive any public comments on our proposal. Therefore, as we proposed, we are discontinuing new technology add-on payments for the MitraClip® System for FY 2017. The 3-year anniversary of the product's entry onto the U.S. market occurs in the first half of FY 2017. Therefore, the technology is not eligible for new technology add-on payments for FY 2017 because the technology will no longer meet the ''newness'' criterion.

e. Responsive Neurostimulator (RNS®) System

NeuroPace, Inc. submitted an application for new technology add-on payments for FY 2015 for the use of the RNS® System. (We note that the applicant submitted an application for new technology add-on payments for FY 2014, but failed to receive FDA approval prior to the July 1 deadline.) Seizures

occur when brain function is disrupted by abnormal electrical activity. Epilepsy is a brain disorder characterized by recurrent, unprovoked seizures. According to the applicant, the RNS® System is the first implantable medical device (developed by NeuroPace, Inc.) for treating persons diagnosed with epilepsy whose partial onset seizures have not been adequately controlled with antiepileptic medications. The applicant further stated that, the RNS® System is the first closed-loop, responsive system to treat partial onset seizures. Responsive electrical stimulation is delivered directly to the seizure focus in the brain when abnormal brain activity is detected. A cranially implanted programmable neurostimulator senses and records brain activity through one or two electrode-containing leads that are placed at the patient's seizure focus/foci. The neurostimulator detects electrographic patterns previously identified by the physician as abnormal, and then provides brief pulses of electrical stimulation through the leads to interrupt those patterns. Stimulation is delivered only when abnormal electrocorticographic activity is detected. The typical patient is treated with a total of 5 minutes of stimulation a day. The RNS® System incorporates remote monitoring, which allows patients to share information with their physicians remotely.

With regard to the newness criterion, the applicant stated that some patients diagnosed with partial onset seizures that cannot be controlled with antiepileptic medications may be candidates for the vagus nerve stimulator (VNS) or for surgical removal of the seizure focus. According to the applicant, these treatments are not appropriate for, or helpful to, all patients. Therefore, the applicant believed that there is an unmet clinical need for additional therapies for partial onset seizures. The applicant further stated that the RNS® System addresses this unmet clinical need by providing a novel treatment option for treating persons diagnosed with medically intractable partial onset seizures. The applicant received FDA premarket approval on November 14, 2013.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the RNS® System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the RNS® System for new technology add-on payments for FY 2015 (79 FR 49950). Cases involving the RNS® System that are eligible for new technology add-on payments are identified using the following ICD–10–PCS procedure code combination: 0NH00NZ (Insertion of neurostimulator generator into skull, open approach) in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach). According to the applicant, cases using the RNS® System would incur an anticipated cost per case of $36,950. Under § 412.88(a)(2) of the regulations, we limit new technology add-on payments to the lesser of 50 percent of the average costs of the device or 50 percent of the costs in excess of the MS–DRG payment rate for the case. As a result, the maximum new technology add-on payment for cases involving the RNS® System is $18,475.

With regard to the newness criterion for the RNS® System, we considered the beginning of the newness period to commence when the RNS® System was approved by the FDA on November 14, 2013. Because the 3-year anniversary date of the entry of the RNS® System on the U.S. market (November 14, 2016) will occur after FY 2016, in the FY 2016 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2016 (80 FR 49443). However, for FY 2017, the 3-year anniversary date of the entry of RNS® System on the U.S. market (November 14, 2016) will occur in the first half of FY 2017. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry on to the U.S. market occurs in the latter half of the fiscal year. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25036 and 25037), we proposed to discontinue new technology add-on payments for this technology for FY 2017. We invited public comments on this proposal in the proposed rule.

Comment: One commenter, the manufacturer, submitted a comment and requested that CMS continue to make new technology add-on payments for the RNS® System in FY 2017. The commenter stated that it recognized that the 3-year anniversary date of the RNS® System's entry onto the U.S. market technically occurs in the first half of FY 2017. However, the commenter believed that CMS should continue to consider the device ''new'' in FY 2017 for purposes of new technology add-on payments because numerous obstacles were encountered before the product began to be sold, resulting in a significant delay in the product's availability on the U.S. market. As a result of these obstacles, the commenter believed that the data used to analyze and compare cost for the limited number of cases reported in the first half of FY 2014 were also hindering and skewed the comparisons. The commenter provided the following reasons why it believed CMS should continue new technology add-on payments for the RNS® System for FY 2017:

- Because of delays encountered during the FDA approval process for the RNS® System, FDA approval for the use of the new technology was not received by July 1, 2013, which disqualified the approval of the FY 2014 new technology add-on payment application for the RNS® System in FY 2014. Although the RNS® System received FDA approval on November 14, 2013, a 30-day notice to replace a component supplier was required to be submitted to FDA following the approval. According to the manufacturer, the delays significantly impacted the product's availability on the U.S. market; prohibiting the ability to market or make the product available on the U.S. market until December 18, 2013.
- As a condition of approval by the FDA, the RNS® System can only be sold to Comprehensive Epilepsy Centers (CECs) that meet specific requirements related to physician expertise and center experience. The FDA does not grant approval for the CECs to purchase and implant the RNS® System. Rather, the manufacturer (NeuroPace) has to verify that the CEC meets certain requirements before it allows the CEC to procure the device. After that verification is completed, the CEC then has to comply with its own internal approval processes, which are quite extensive, before the actual acquisition or purchase of the device and commencing use of the device. The approval process typically involves several different groups within the CEC and occurs in a series of sequential steps. According to the manufacturer, as a result, many CECs were unwilling to adopt the use of the technology initially because they would incur a significant financial loss for each Medicare patient treated in FY 2014 because new technology add-on payments for the RNS® System were not available. In addition, the manufacturer stated that further complications and delays were presented and encountered because a number of CECs were unwilling to proceed with acquisition and use of the new technology until CMS announced approval of new technology add-on payments for the RNS® System in the FY 2015 IPPS/LTCH PPS final rule.
- According to the manufacturer, because the RNS® System can only be sold to CECs, by March 30, 2014 (that

is, during the first half of FY 2014), only six RNS® System commercial implant procedures were performed (which occurred at previous clinical trial sites that allowed the internal approval process to proceed more quickly). Of these cases, only two represented the treatment of Medicare beneficiaries. As a result, the market activity was extremely limited in the first half of that fiscal year. In addition, the manufacturer stated that hospitals incorrectly reported cases involving ICD–9–CM procedure codes 01.20 and 02.93 for non-RNS® System procedures. The manufacturer asserted that, as a result, CMS may have reviewed MedPAR data and may have believed that there were many more RNS® System cases than what actually occurred (including during the first 6 months of FY 2014), which may have negatively impacted how CMS views and applies the criteria regarding continuing new technology add-on payments for the RNS® System for a third year because the MedPAR data does not accurately reflect cases involving treatment using the RNS® System.

• Without the approval for new technology add-on payments in FY 2017, CECs currently offering treatment involving the RNS® System would face the difficult challenge of continuing to provide treatment using the device to Medicare beneficiaries in the face of substantial losses because of an inadequate applicable MS–DRG payment rate.

Response: With regard to the technology's newness, the timeframe that a new technology can be eligible to receive new technology add-on payments ends when data documenting the use and cost of the procedures become available. Section 412.87(b)(2) states that, a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). Section 412.87(b)(2) also states, after CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the applicable criteria. Therefore, as discussed in the FY 2005 IPPS final rule (69 FR 49003), if the costs of the technology are included in the charge data, and the MS–DRGs have been recalibrated using that data, the technology can no longer be considered ''new'' for the purposes of this provision. We further stated in the FY 2005 IPPS final rule that the period of newness does not necessarily start with the FDA approval date for the medical service or technology or the issuance of a distinct procedure code. Instead, the newness period begins with the date of availability of the product on the U.S. market, which is when data become available. We have consistently applied this standard, and believe that it is most consistent with the purpose of new technology add-on payments.

With regard to the RNS® System, while there may have been issues with some CECs meeting specific requirements and delays prohibiting the use of the device, as the commenter noted, the RNS® System was available for acquisition on the U.S. market on or after December 18, 2013. We agree that the newness period for the RNS® System should begin on December 18, 2013. However, because the 3-year anniversary date of the entry of the RNS® System on the U.S. market (December 18, 2016) will still occur in the first half of FY 2017, the RNS® System continues to be ineligible for new technology add-on payments in FY 2017. As noted previously, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry on to the U.S. market occurs in the latter half of the fiscal year.

In addition, similar to our discussion in the FY 2006 IPPS final rule (70 FR 47349), we do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new.'' Consistent with the statute and our implementing regulations, a technology no longer qualifies as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently it has been used in the Medicare population. Therefore, if a product is more than 2 to 3 years old, we consider its costs to be included in the MS–DRG relative weights, whether its use in the Medicare population has been frequent or infrequent.

Therefore, based on all of the reasons stated above, the RNS® System is no longer considered ''new'' for purposes of new technology add-on payments for FY 2017. We are finalizing our proposal to discontinue making new technology add-on payments for the RNS® System for FY 2017.

Comment: Several commenters that had experienced the effects of the correlating illnesses explained the clinical effectiveness of the device and requested the continuation of new technology add-on payments for the RNS® System for FY 2017.

Response: We thank the commenters for their input. However, as stated above, the RNS® System is no longer considered ''new'' for FY 2017 and, therefore, is no longer eligible for new technology add-on payments.

f. Blinatumomab (BLINCYTO®Trade Brand)

Amgen, Inc. submitted an application for new technology add-on payments for FY 2016 for Blinatumomab (BLINCYTO®), a bi-specific T-cell engager (BiTE) used for the treatment of Philadelphia chromosome-negative (Ph-) relapsed or refractory (R/R) B-cell precursor acute-lymphoblastic leukemia (ALL), which is a rare aggressive cancer of the blood and bone marrow. Approximately 6,050 individuals are diagnosed with Ph- R/R B-cell precursor ALL in the United States each year, and approximately 2,400 individuals, representing 30 percent of all new cases, are adults. Ph- R/R B-cell precursor ALL occurs when there are malignant transformations of B-cell or T-cell progenitor cells, causing an accumulation of lymphoblasts in the blood, bone marrow, and occasionally throughout the body. As a bi-specific T-cell engager, the BLINCYTO® technology attaches to a molecule on the surface of the tumorous cell, as well as to a molecule on the surface of normal T-cells, bringing the two into closer proximity and allowing the normal T-cell to destroy the tumorous cell. Specifically, the BLINCYTO® technology attaches to a cell identified as CD19, which is present on all of the cells of the malignant transformations that cause Ph- R/R B-cell precursor ALL and helps attract the cell into close proximity of the T-cell CD3 with the intent of getting close enough to allow the T-cell to inject toxins that destroy the cancerous cell. According to the applicant, the BLINCYTO® technology is the first, and the only, bi-specific CD19-directed CD3 T-cell engager single-agent immunotherapy approved by the FDA.

BLINCYTO® is administered as a continuous IV infusion delivered at a constant flow rate using an infusion pump. A single cycle of treatment consists of 28 days of continuous infusion, and each treatment cycle is followed by 2 weeks without treatment prior to administering any further treatments. A course of treatment would consist of two phases. Phase 1 consists of initial inductions or treatments intended to achieve remission followed by additional inductions and treatments to maintain consolidation; or treatments

given after remission has been achieved to prolong the duration. During phase 1 of a single treatment course, up to two cycles of BLINCYTO® are administered, and up to three additional cycles are administered during consolidation. The recommended dosage of BLINCYTO® administered during the first cycle of treatment is 9 mcg per day for the first 7 days of treatment. The dosage is then increased to 28 mcg per day for 3 weeks until completion. During phase 2 of the treatment course, all subsequent doses are administered as 28 mcg per day throughout the entire duration of the 28-day treatment period.

With regard to the newness criterion, the BLINCYTO® technology received FDA approval on December 3, 2014, for the treatment of patients diagnosed with Ph- R/R B-cell precursor ALL, and the product gained entry onto the U.S. market on December 17, 2014.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for BLINCYTO® and consideration of the public comments we received in response to the FY 2016 IPPS/LTCH PPS proposed rule, we approved BLINCYTO® for new technology add-on payments for FY 2016 (80 FR 49449). Cases involving BLINCYTO® that are eligible for new technology add-on payments are identified using one of the following ICD–10–PCS procedure codes: XW03351 (Introduction of Blinatumomab antineoplastic immunotherapy into peripheral vein, percutaneous approach, new technology group 1) or XW04351 (Introduction of Blinatumomab antineoplastic immunotherapy into central vein, percutaneous approach, new technology group 1).

As discussed in the FY 2016 IPPS/LTCH final rule (80 FR 49449), the applicant recommended that CMS consider and use the cost of the full 28-day inpatient treatment cycle as the expected length of treatment when determining the maximum new technology add-on payment for cases involving the BLINCYTO® rather than the average cost of lesser number of days used as other variables. For the reasons discussed, we disagreed with the applicant and established the maximum new technology add-on payment amount for a case involving the BLINCYTO® technology for FY 2016 using the weighted average of the cycle 1 and cycle 2 observed treatment length. Specifically, in the Phase II trial, the most recent data available, 92 patients received cycle 1 for an average length of 21.2 days, and 52 patients received cycle 2 for an average length of 10.2 days. The weighted average of cycle 1 and 2 treatment length is 17 days. We noted that a small number of patients also received 3 to 5 treatment cycles. However, based on the data provided, these cases do not appear to be typical at this point and we excluded them from this calculation. We noted that, if we included all treatment cycles in this calculation, the weighted average number of days of treatment is much lower, 10 days. Using the clinical data provided by the applicant, we stated that we believe that setting the maximum new technology add-on payment amount for a case involving the BLINCYTO® technology for FY 2016 based on a 17-day length of treatment cycle is representative of historical and current practice. We also stated that, for FY 2017, if new data on length of treatment are available, we would consider any such data in evaluating the maximum new technology add-on payment amount. However, we did not receive any new data from the applicant to evaluate for FY 2017.

In the application, the applicant estimated that the average Medicare beneficiary would require a dosage of 9mcg/day for the first 7 days under the first treatment cycle, followed by a dosage of 28mcg/day for the duration of the treatment cycle, as well as all days included in subsequent cycles. All vials contain 35mcg at a cost of $3,178.57 per vial. The applicant noted that all vials are single-use. Therefore, we determined that cases involving the use of the BLINCYTO® technology would incur an average cost per case of $54,035.69 (1 vial/day × 17 days × $3,178.57/vial). Under 42 CFR 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of the BLINCYTO® is $27,017.85 for FY 2016.

With regard to the newness criterion for BLINCYTO®, we considered the beginning of the newness period to commence when the product gained entry onto the U.S. market on December 17, 2014. Because the 3-year anniversary date of the entry of the BLINCYTO® on the U.S. market will occur after FY 2017 (December 17, 2017), in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25038), we proposed to continue new technology add-on payments for this technology for FY 2017. We proposed that the maximum payment for a case involving BLINCYTO® would remain at $27,017.85 for FY 2017. We invited public comments on this proposal in the proposed rule.

Comment: Commenters supported CMS' proposal to continue new technology add-on payments for BLINCYTO® for FY 2017. The manufacturer submitted a comment with regard to the substantial clinical improvement of the BLINCYTO® and stated that recently released results from a randomized, open-label, Phase 3 confirmatory study (the TOWER study) show significant improvements in overall survival (primary endpoint), complete remission, and event-free survival with BLINCYTO® compared to standard of care chemotherapy in adult patients diagnosed with Ph- R/R B-cell precursor ALL. According to the manufacturer, in this study, 405 patients were randomized in a 2:1 ratio to receive BLINCYTO® or one of four standard of care chemotherapeutic regimens chosen by the investigator. The manufacturer noted that the study was ended early based on a prespecified interim analysis from an independent data monitoring committee (DMC), which found a significant overall survival improvement in the BLINCYTO® arm over standard of care chemotherapy. According to the manufacturer, results from the DMC analysis demonstrated a median overall survival (OS) of 7.8 months.

Response: We appreciate the commenters' support for our proposal.

After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for BLINCYTO® for FY 2017. The maximum new technology add-on payment for a case involving BLINCYTO® will remain at $27,017.85 for FY 2017.

g. Lutonix® Drug Coated Balloon PTA Catheter and In.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

Two manufacturers, CR Bard Inc. and Medtronic, submitted applications for new technology add-on payments for FY 2016 for LUTONIX® Drug-Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) Catheter (LUTONIX®) and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter (IN.PACT™ Admiral™), respectively. Both of these technologies are drug-coated balloon angioplasty treatments for patients diagnosed with peripheral artery disease (PAD). Typical treatments for patients with PAD include angioplasty, stenting, atherectomy and vascular bypass surgery. PAD most commonly occurs in the femoropopliteal segment of the

peripheral arteries, is associated with significant levels of morbidity and impairment in quality of life, and requires treatment to reduce symptoms and prevent or treat ischemic events.[2] Treatment options for symptomatic PAD include noninvasive treatment such as medication and life-style modification (for example, exercise programs, diet, and smoking cessation) and invasive options which include endovascular treatment and surgical bypass. The 2013 American College of Cardiology and American Heart Association (ACC/AHA) guidelines for the management of PAD recommend endovascular therapy as the first-line treatment for femoropopliteal artery lesions in patients suffering from claudication (Class I, Level A recommendation).[3]

According to both applicants, LUTONIX® and IN.PACT™ Admiral™ are the first drug coated balloons that can be used for treatment of patients who are diagnosed with PAD. In the FY 2016 IPPS/LTCH final rule, we stated that because cases eligible for the two devices would group to the same MS–DRGs and we believe that these devices are substantially similar to each other (that is, they are intended to treat the same or similar disease in the same or similar patient population and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action), we evaluated both technologies as one application for new technology add-on payment under the IPPS. The applicants submitted separate cost and clinical data, and we reviewed and discussed each set of data separately. However, we made one determination regarding new technology add-on payments that applied to both devices. We believe that this is consistent with our policy statements in the past regarding substantial similarity. Specifically, we have noted that approval of new technology add-on payments would extend to all technologies that are substantially similar (66 FR 46915), and that we believe that continuing our current practice of extending a new technology add-on payment without a further application from the manufacturer of the competing product or a specific finding on cost and clinical improvement if we make a finding of substantial similarity among two products is the better policy because we avoid—

- Creating manufacturer-specific codes for substantially similar products;
- Requiring different manufacturers of substantially similar products from having to submit separate new technology applications;
- Having to compare the merits of competing technologies on the basis of substantial clinical improvement; and
- Bestowing an advantage to the first applicant representing a particular new technology to receive approval (70 FR 47351).

CR Bard, Inc. received FDA approval for LUTONIX® on October 9, 2014. Commercial sales in the U.S. market began on October 10, 2014. Medtronic received FDA approval for IN.PACT™ Admiral™ on December 30, 2014. Commercial sales in the U.S. market began on January 29, 2015.

In accordance with our policy, we stated in the FY 2016 IPPS\LTCH final rule (80 FR 49463) that we believe it is appropriate to use the earliest market availability date submitted as the beginning of the newness period. Accordingly, for both devices, we stated that the beginning of the newness period will be October 10, 2014.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the LUTONIX® and IN.PACT™ Admiral™ technologies and consideration of the public comments we received in response to the FY 2016 IPPS/LTCH PPS proposed rule, we approved the LUTONIX® and IN.PACT™ Admiral™ technologies for new technology add-on payments for FY 2016 (80 FR 49469). Cases involving the LUTONIX® and IN.PACT™ Admiral™ technologies that are eligible for new technology add-on payments are identified using one of the ICD–10–PCS procedure codes in the following table:

ICD–10–PCS code	Code description
047K041	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047K0D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, open approach.
047K0Z1	Dilation of right femoral artery using drug-coated balloon, open approach.
047K341	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047K3D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047K3Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous approach.
047K441	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047L041	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047L0D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, open approach.
047L0Z1	Dilation of left femoral artery using drug-coated balloon, open approach.
047L341	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047L3D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047L3Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous approach.
047L441	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047M041	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047M0D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, open approach.
047M0Z1	Dilation of right popliteal artery using drug-coated balloon, open approach.
047M341	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047M3D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.

[2] Tepe G, Zeller T, Albrecht T, Heller S, Schwarzwalder U, Beregi JP, Claussen CD, Oldenburg A, Scheller B, Speck U.: Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. N Engl J Med 2008; 358: 689–99.

[3] Anderson JL, Halperin JL, Albert NM, Bozkurt B, Brindis RG, Curtis LH, DeMets D, Guyton RA, Hochman JS, Kovacs RJ, Ohman EM, Pressler SJ, Sellke FW, Shen WK.: Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013; 61:1555–70. Available at: *http://dx.doi.org/10.1016/j.jacc.2013.01.004.*

ICD–10–PCS code	Code description
047M3Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous approach.
047M441	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous endoscopic approach.
047N041	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047N0D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, open approach.
047N0Z1	Dilation of left popliteal artery using drug-coated balloon, open approach.
047N341	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047N3D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047N3Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous approach.
047N441	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous endoscopic approach.

As discussed in the FY 2016 IPPS/LTCH final rule (80 FR 49469), each of the applicants submitted operating costs for its DCB. The manufacturer of the LUTONIX® stated that a mean of 1.37 drug-coated balloons was used during the LEVANT 2 clinical trial. The acquisition price for the hospital will be $1,900 per drug-coated balloon, or $2,603 per case (1.37 × $1,900). The applicant projected that approximately 8,875 cases will involve use of the LUTONIX® for FY 2016. The manufacturer for the IN.PACT™ Admiral™ stated that a mean of 1.4 drug-coated balloons was used during the IN.PACT™ Admiral™ DCB arm. The acquisition price for the hospital will be $1,350 per drug-coated balloon, or $1,890 per case (1.4 × $1,350). The applicant projected that approximately 26,000 cases will involve use of the IN.PACT™ Admiral™ for FY 2016.

For FY 2016, we based the new technology add-on payment for cases involving these technologies on the weighted average cost of the two DCBs described by the ICD–10–PCS procedure codes listed above (which are not manufacturer specific). Because ICD–10 codes are not manufacturer specific, we cannot set one new technology add-on payment amount for IN.PACT™ Admiral™ and a different new technology add-on payment amount for LUTONIX®; both technologies will be captured by using the same ICD–10–PCS procedure code. As such, we stated that we believe that the use of a weighted average of the cost of the standard DCBs based on the projected number of cases involving each technology to determine the maximum new technology add-on payment would be most appropriate. To compute the weighted cost average, we summed the total number of projected cases for each of the applicants, which equaled 34,875 cases (26,000 plus 8,875). We then divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 25 percent for the LUTONIX® and 75 percent for the IN.PACT™ Admiral™. We then multiplied the cost per case for the manufacturer specific DCB by the case-weighted percentage (0.25 * $2,603 = $662.41 for LUTONIX® and 0.75 * $1,890 = $1,409.03 for the IN.PACT™ Admiral™). This resulted in a case-weighted average cost of $2,071.45 for DCBs. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum payment for a case involving the LUTONIX® or IN.PACT™ Admiral™ DCBs is $1,035.72.

With regard to the newness criterion for LUTONIX® and IN.PACT™ Admiral™ technologies, we considered the beginning of the newness period to commence when LUTONIX® gained entry onto the U.S. market on October 10, 2014. Because the 3-year anniversary date of the entry of LUTONIX® on the U.S. market will occur after FY 2017 (October 10, 2017), in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25039 and 25040), we proposed to continue new technology add-on payments for both the LUTONIX® and IN.PACT™ Admiral™ technologies for FY 2017. We proposed that the maximum add-on payment for a case involving LUTONIX® and IN.PACT™ Admiral™ would remain at $1,035.72 for FY 2017. We invited public comments on this proposal in the proposed rule.

Comment: Commenters supported CMS' proposal to continue new technology add-on payments for the LUTONIX® and IN PACT™ Admiral™ for FY 2017.

Response: We appreciate the commenters' support for our proposal.

After consideration of the public comments we received, we are finalizing our proposal and continuing new technology add-on payments for both the LUTONIX® and IN PACT™ Admiral™ for FY 2017. The maximum add-on payment for a case involving LUTONIX® and IN.PACT™ Admiral™ remains at $1,035.72 for FY 2017.

5. FY 2017 Applications for New Technology Add-On Payments

We received nine applications for new technology add-on payments for FY 2017. One applicant withdrew its application prior to the issuance of the FY 2017 IPPS/LTCH PPS proposed rule. Another applicant, Andexanet Alfa, withdrew its application prior to the issuance of the FY 2017 IPPS/LTCH PPS final rule.

In addition, in accordance with the regulations under § 412.87(c), applicants for new technology add-on payments must have FDA approval or clearance by July 1 of each year prior to the beginning of the fiscal year that the application is being considered. One applicant, the EDWARDS INTUITY Elite™ Valve System, did not receive FDA approval for their technology by July 1, 2016, and, therefore, it is ineligible for consideration for new technology add-on payments for FY 2017. We are not including the descriptions and discussions of these two applications that were included in the FY 2017 proposed rule in this final rule. We note that we did receive public comments on these two applications. However, because Andexanet Alfa withdrew its application and the EDWARDS INTUITY Elite™ Valve System is ineligible for new technology add-on payments for FY 2017 because it did not receive FDA approval by July 1, 2016, we are not summarizing or responding to public comments on these applications in this final rule. A

discussion of the seven remaining applications is presented below.

a. MAGEC® Spinal Bracing and Distraction System (MAGEC® Spine)

Ellipse Technologies, Inc. submitted an application for new technology add-on payments for FY 2017 for the MAGEC® Spine. According to the applicant, the MAGEC® Spine has been developed for use in the treatment of children diagnosed with severe spinal deformities, such as scoliosis. The system can be used in the treatment of skeletally immature patients less than 10 years of age who have been diagnosed with severe progressive spinal deformities associated with or at risk of Thoracic Insufficiency Syndrome (TIS). The MAGEC® Spine consists of a (spinal growth) rod that can be lengthened through the use of magnets that are controlled by an external remote controller (ERC). The rod(s) can be implanted into children as young as 2 years of age. According to the applicant, use of the MAGEC® Spine has proven to be successfully used in the treatment of patients diagnosed with scoliosis who have not been responsive to other treatments.

The MAGEC® Spine initially received FDA clearance for use of the predicate device, which used a Harrington Rod on February 27, 2014. The applicant verified that, due to manufacturing delays, the MAGEC® Spine was not available for implant until April 1, 2014. Specifically, the complete MAGEC® Spine system was produced and available for shipment for the first implant on April 1, 2014. Therefore, the newness period for the MAGEC® Spine begins on April 1, 2014. Subsequent FDA clearance was granted for use of the modified device, which uses a shorter 70 mm rod on September 18, 2014. After minor modification of the product, the MAGEC® Spine received FDA clearances on March 24, 2015, and May 29, 2015, respectively.

The applicant submitted a request for a unique ICD–10–PCS procedure code and was granted approval for the following procedure codes under New Technology Group 2: XNS0032 (Reposition of lumbar vertebra using magnetically controlled growth rod(s), open approach); XNS0432 (Reposition of lumbar vertebra using magnetically controlled growth rod(s), percutaneous endoscopic approach); XNS3032 (Reposition of cervical vertebra using magnetically controlled growth rod(s), open approach); XNS3432 (Reposition of cervical vertebra using magnetically controlled growth rod(s), percutaneous endoscopic approach); XNS4032 (Reposition of thoracic vertebra using magnetically controlled growth rod(s), open approach); and XNS4432 (Reposition of thoracic vertebra using magnetically controlled growth rod(s), percutaneous endoscopic approach). These new ICD–10–PCS procedure codes are effective on October 1, 2016.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352), and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

With regard to the first criterion, the applicant stated that the MAGEC® Spine's mechanism of action is dependent upon growing rods used for the treatment of patients diagnosed with early onset scoliosis (EOS), and is unique because the technique uses magnetic distraction (lengthening), which does not require the patients to be subjected to the potential and adverse effects of additional surgeries.

The applicant explained that treatment of patients diagnosed with EOS involves the implantation of traditional growth rods (TGRs) followed by surgery every 6 months to distract the rods to accommodate the growing spine until the patient reaches a level of spinal maturity when the spine can then be fused. The average number of distraction surgeries per patient is 12 over the course of 6 years. Once spinal alignment and maturity is reached, the TGRs are surgically and permanently removed. The applicant stated that, while the most recent modification to the MAGEC® Spine's rods accomplish the same goal as the predicate device, Harrington rods, MAGEC® Spine rods achieve the predetermined goal with minimally invasive techniques after implantation, which prevents the patients from being subjected to the potential and adverse effects of numerous lengthening surgeries. The applicant further noted that after the MAGEC® Spine's rod has been implanted, the ERC is placed externally over the patient's spine at the location of the magnet in the MAGEC® Spine's rod. Periodic, noninvasive distraction of the rod is performed to lengthen the spine and to provide adequate bracing during growth. Routine X-ray or ultrasound procedures are used to confirm the position and amount of distraction. The frequency of distraction sessions is customized to the needs of the individual patient by the treating surgeon.

With regard to the first criterion, in the proposed rule (81 FR 25040), we stated that we were concerned that the MAGEC® Spine uses the same mechanism of action, spinal rod distraction, to achieve the same therapeutic outcome of spinal alignment as other currently available technologies and treatment options for Medicare beneficiaries. Specifically, TGRs are implanted and affixed to the immature spine in order to correct spinal deformities. As a child grows, the TGRs must be distracted to accommodate spinal growth. The common denominator between TGRs and the MAGEC® Spine is that they both are devices (rods) that use the same mechanism of action to perform and achieve spinal distraction, the implantation of rods that are later lengthened. While we acknowledged that the applicant noted that the MAGEC® Spine does not require the patient to endure the potential and adverse effects of additional surgeries, we stated that this assertion seems to be a component of substantial clinical improvement rather than a basis to distinguish the mechanism of action.

In consideration of the applicant's statements that the mechanism of action of the MAGEC® Spine, which uses growing rods in the treatment of patients diagnosed with EOS, is unique because the technique of using magnetic distraction (lengthening) does not require patients to endure the potential and adverse effects of additional surgeries, in the proposed rule, we stated that there are other technologies and products currently available that achieve spinal growth without the need to subject patients to potential and adverse effects of additional surgeries. For example, the Shilla growth guidance system, which received FDA clearance in 2014, uses a non-locking set screw at the proximal and distal portions of the construct's rods. This specific feature is designed to allow the rod to slide through the screw heads as a child's spine grows, while still providing correction of the spinal deformity. The Shilla technique also eliminates the

need for scheduled distraction surgeries, as the applicant pointed out are needed with the use of TGRs. Therefore, in the proposed rule, we stated that we believe that the MAGEC® Spine's mechanism of action may be similar to the mechanism of action employed by the Shilla growth guidance system because both technologies achieve the same therapeutic outcome and do not require the patient to endure the potential and adverse effects of additional surgeries.

With regard to the second criterion, cases that may be eligible for treatment involving the MAGEC® Spine map to the following MS–DRGs: 456 (Spinal Fusion Except Cervical With Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC); 457 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with CC); and 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions without CC/MCC). All cases involving procedures describing spinal distraction devices, including those that use TGRs and the Shilla growth guidance system, currently map to the same MS–DRGs.

With regard to the third criterion, we believe that the MAGEC® Spine technology involves the treatment of the same or similar type of disease and the same or similar patient population. Although the applicant stated that the MAGEC® Spine was developed for the use in the treatment of children diagnosed with severe spinal deformities, the MAGEC® Spine treats the same patient population as other currently available spinal distraction devices and technologies, including those that use TGRs and the Shilla growth guidance system. Because it appears that the MAGEC® Spine is substantially similar to these other currently available devices used to treat the same or similar types of diseases and the same or similar patient populations, in the proposed rule we stated that we were concerned that the technology may not be considered ''new'' for the purposes of new technology add-on payments (81 FR 25041). We also invited public comments on whether the MAGEC® Spine meets the newness criterion.

Comment: The applicant submitted public comments that responded to CMS' concerns presented in the proposed rule with regard to newness. The applicant provided a working definition of ''mechanism of action'' of spinal distraction systems as: The combined device-technique interaction with tissues that produces a therapeutic effect. The combined device-technique interaction includes the following elements: Initial fusion; device mechanism; spinal growth control; and spinal curvature control.

The applicant distinguished MAGEC® Spine's mechanism of action as distinct from the Shilla system's tissue interaction because the Shilla system provides passive growth guidance and the MAGEC® Spine provides active distraction by noninvasive magnetically controlled lengthening. Furthermore, MAGEC® Spine enables a surgeon to customize or adjust a patient's therapy with more frequent, noninvasive, magnetic external remote controlled sessions. The applicant described the MAGEC® Spine's device mechanism as distinct from the Shilla system in that the MAGEC® Spine system's initial fusion is the cephalad and caudad ends of the spine whereas the Shilla system's initial fusion is at the apex of the spinal curve. The MAGEC® Spine system drives growth with active noninvasive rod distractions whereas the Shilla system provides passive growth guidance with sliding anchors and limited stability.

The applicant further described the MAGEC® Spine's device mechanism as distinct from TGRs in that the MAGEC® Spine system consists of magnetically controlled growing rods and actuators and an external remote, whereas, TGRs device mechanism consists of growing rods and tandem connectors which must be surgically removed and replaced with longer rods to achieve the desired lengthening. The applicant further compared the MAGEC® Spine system's tissue interaction as frequent noninvasive lengthening in an awake patient to control and adapt spine growth to a child's development, with low complication rates and few repeated surgeries. TGRs tissue interactions include manual surgical lengthening under general anesthesia at 6-month intervals.

Response: We appreciate the details and input provided by the applicant in response to our concerns. As the commenter has described above, we agree that the MAGEC® Spine's mechanism of action is distinct from the TGR and the Shilla system. Specifically, the MAGEC® Spine's noninvasive method of distraction is distinct from TGRs surgical distraction and the MAGEC® Spine's active distraction is distinct from the Shilla system's passive distraction. After considering the additional information submitted by the applicant in response to our concerns, which supported the technology's uniqueness in achieving spinal rod distraction, we agree with the applicant that the MAGEC® Spine meets the newness criterion, and we consider the technology to be ''new'' as of April 1, 2014.

With regard to the cost criterion, the applicant maintained that there is an insufficient number of cases in the Medicare claims data to evaluate because of the small number of potential cases and cases reflecting patients who were actually diagnosed with or who experience early onset scoliosis (EOS) requiring the implantation of growing rods. Specifically, the applicant stated that the majority of the Medicare population is 65 years of age and older, while individuals who may be eligible for the MAGEC® Spine are typically less than 10 years of age. Therefore, the applicant estimated the number of EOS cases using internal estimates for de novo cases (<10 year of age), as well as cases that could potentially convert to using the MAGEC® Spine without searching the MedPAR data file or any other data source. The applicant estimated that a total of 2,500 EOS cases may be eligible for treatment using the MAGEC® Spine in FY 2016. According to the applicant, 580 cases would map to MS–DRG 456, 870 cases would map to MS–DRG 457, and 1,050 cases would map to MS–DRG 458. The applicant based the distribution of cases on data from its medical advisors, customers, and reimbursement support team.

The applicant used Medicare and non-Medicare data for six providers that used the MAGEC® Spine during CY 2016. This resulted in an average unstandardized case-weighted charge per case of $243,999. The applicant then removed charges related to the predicate technology. Using the Impact File published with the FY 2016 IPPS/LTCH PPS final rule, the applicant standardized the charges and applied an inflation factor of 10 percent. The applicant computed an average CCR of the six hospitals based on the overall hospitals CCRs in the FY 2016 IPPS/LTCH final rule Impact File. The applicant then computed the charges for the device by dividing the costs of the device by the average CCR and added these charges to determine the inflated average standardized case-weighted charge per case. The applicant noted that the cost of the technology was proprietary information. Based on the FY 2016 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $105,909. The applicant computed an inflated average standardized case-weighted charge per case of $248,037. Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25041), we stated that we have the following concerns regarding the applicant's cost analysis:

- The applicant did not specify how many cases were the basis for the average standardized case-weighted charges per case. Therefore, we cannot determine if the charges per case represent a statistical sample relative to the projected cases eligible for the MAGEC® Spine for the upcoming fiscal year.
- The applicant did not specify how many cases included in the analysis were Medicare and non-Medicare cases. We typically rely on Medicare data and understand the limitations of this patient population in the Medicare data (as the applicant explained above). However, CMS would still like the details regarding the numerical representation of Medicare and non-Medicare cases the applicant used in its analysis.
- The applicant did not explain the methodology it used to remove the charges for the predicate technology, as well as the type of technology that the charges replaced. Therefore, in the proposed rule, we stated that we were unable to validate the accuracy of the applicant's methodology.
- The applicant did not explain the basis of using a 10-percent inflation factor. Specifically, the applicant used cases from CY 2016 and inflated the costs to FY 2017 using a 10-percent inflation factor. However, the 1-year inflation factor in the FY 2016 IPPS/LTCH final rule (80 FR 49784) is 3.7 percent. Therefore, we do not believe that a 10-percent inflation factor is appropriate.

The applicant used the average overall CCR of the six hospitals to convert the costs of the MAGEC® Spine to charges. However, rather than using an average CCR, to increase the precision of determining the charges of the MAGEC® Spine, the applicant could have instead used each hospital's individual CCR or the implantable device CCR of 0.337 as reported in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49429).

We invited public comments on whether the MAGEC® Spine meets the cost criterion, particularly with regard to the concerns we raised in the proposed rule.

Comment: In response to our concerns, the applicant reported that it had conducted a new cost analysis using the FY 2015 MedPAR data set. Specifically, the applicant searched for cases with patients less than 25 years of age that had the following ICD–9–CM diagnosis codes (737.30, 737.32, 737.34, 737.39, 737.43 or 754.2) that map to MS–DRGs 456, 457, and 458. This resulted in fewer than 11 cases in each of the applicable MS–DRGs (456, 457 and 458); therefore, the applicant suppressed the exact number of cases to protect patient privacy. The applicant stated that the total number of cases across all three MS–DRGs was between 11 and 20. This resulted in average case weighted charge per case of $329,370. The applicant then removed charges for the prior technology (traditional growth rods) and standardized the charges which resulted in a case-weighted standardized charge per case of $228,627. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $170,061 (all calculations above were performed using unrounded numbers). Without inflating the charges and adding charges for the device to the standardized case-weighted charge per case, the applicant determined that the standardized case-weighted charge per case exceeds the average case-weighted threshold amount.

Because the MedPAR analysis identified only a few cases, the applicant provided additional charge data to demonstrate it would meet the cost criterion. The applicant explained that patients who receive the MAGEC® Spine technology have an average length of stay of 5 days in the hospital. To compute the average implantation procedure costs for the MAGEC® Spine, the applicant used FY 2015 MedPAR data and determined average implantation procedure costs for MS–DRGs 456, 457, and 458 of $40.932. The applicant noted that 20 percent of cases use a single rod while 80 percent of cases use a dual rod. The applicant then computed an average weighted cost of $43,049 for single and dual rod construct of the device (which includes costs for pedicle and rod screws and hooks as well as some connectors). This resulted in a subtotal of total costs of $83,981 ($40.932 + $43,049). The applicant then deducted $13,845 for total costs related to the previous technology (costs for TGR). This resulted in total costs of $70,136 related to the MAGEC® Spine ($83,981 − $13,845). To convert the total costs to charges, the applicant applied divided the total costs of $70,136 by the national average implantable device CCR of 0.337 from the FY 2016 IPPS/LTCH PPS final rule (80 FR 49429) which resulted in total charges of $208,119. Because the total charges for the MAGEC® Spine technology of $208,119 exceed the average case-weighted threshold amount of $170,061, the applicant maintained that the MAGEC® Spine technology meets the cost criterion.

Response: We thank the applicant for providing these further analyses. We agree that the applicant has demonstrated that the MAGEC® Spine technology meets the cost criterion.

With regard to substantial clinical improvement, the applicant stated that use of the MAGEC® Spinal Bracing and Distraction System significantly improves clinical outcomes for the pediatric patient population with spinal deformities when compared to technologies and treatment options that employ TGRs by decreasing the number of subsequent surgeries and potential adverse effects following implantation. The applicant provided results from a study,[4] which demonstrated that patients receiving treatment using the magnetically controlled growth rods (MCGR) system had 57 fewer surgeries as a whole than those patients receiving treatment options using TGRs. According to the applicant, the results further projected decreased rates of infection and attendant costs because the need for additional distraction (lengthening) surgeries is eliminated. In addition, the applicant stated that 1,500 patients located around the world have been successfully treated with the use of this technology. The applicant indicated that the results from another study [5] cited the following qualitative outcomes: minimal surgical scarring, decreased psychological distress and improved quality of life, improved pulmonary function tests (PFTs), and capabilities to continuously monitor neurological behaviors because the patient is not exposed to anesthesia during follow-up distractions.

We stated in the proposed rule (81 FR 25042) that we were concerned that the applicant's assertions that the MAGEC® Spine technology leads to significantly better clinical outcomes; specifically, decreased rates of infection, when compared to treatment options that use TGRs has not been shown by the results of the studies provided. The results of the studies provided did not compare rates of infection for patients receiving treatment using the MAGEC® Spine versus patients receiving treatment using TGRs or other spinal growth rods. Also, as previously mentioned, there are

[4] Akbarnia BA, Cheung K, Noordeen H et al. Traditional rods versus magnetically controlled growing rods in early onset scoliosis: a case-matched two year study. 2013.

[5] Cheng, KMC, Cheung JPY, Damartzis, D, Mak, KC, Wong, WYC, Akbaria, BA, Luk KDK. Magnetically controlled growing rods for sever spinal curvature in young children. A prospective study. Lancet 379 (830) 26 May–1 June 2012, pp. 1967–1974.

other currently available technologies and devices such as the Shilla growth guidance system that also achieve the same therapeutic outcome and do not require the patient to be subjected to the potential and adverse effects of additional surgery. Therefore, we stated that we were concerned that the MAGEC® Spine may not represent a substantial clinical improvement over existing technologies. We also invited public comments on whether the MAGEC® Spine meets the substantial clinical improvement criterion.

Comment: The applicant submitted public comments that responded to our concerns presented in the proposed rule with regard to substantial clinical improvement. The applicant provided studies which showed frequency of spinal lengthening improves thoracic-sacral spinal growth. The applicant also provided studies which showed improved spinal curve correction, increased spinal height, and decreased complications with the MAGEC® Spine when compared to traditional growth rods.

The applicant maintained that treatment goals for Early Onset Scoliosis (EOS) are not limited to controlling curvature and increasing height, but also include the avoidance of surgical and nonsurgical complications. Specifically, these additional goals include minimizing complications, procedures, hospitalizations, and family burden. The applicant asserted that the use of the MAGEC® Spine system achieves curve correction, increases patient height, results in fewer surgeries/hospitalizations (as compared to TGRs) which leads to fewer complications and better outcomes in a fragile and vulnerable patient population through reduced exposure to anesthesia,[6] reduced exposure to radiation, reduced negative psychosocial outcomes,[7] reduced infections risk due to fewer surgeries,[8] and improved lung development and weight gain.

Several commenters indicated improvements in clinical outcomes and decreased morbidity in this patient population. Other commenters who were parents with children who have converted to the MAGEC® rods from traditional growth rods and body casts considered the MAGEC® rods the best option to eliminate pain and hospitalization. Several other commenters supported approval of new technology add-on payment for the MAGEC® Spine System.

Response: We appreciate the commenters' support and comments addressing our concerns. We agree that the MAGEC® Spine represents a substantial clinical improvement over existing technologies because it avoids surgical complications. Specifically, the MAGEC® Spine rods can be nonsurgically lengthened, eliminating the need for subsequent surgical intervention for revision.

After consideration of the public comments we received, we have determined that the MAGEC® Spinal Bracing Distraction system meets all of the criteria for approval of new technology add-on payments for FY 2017. Cases involving the MAGEC® Spinal Bracing Distraction system that are eligible for new technology add-on payments will be identified by the ICD–10–PCS procedure codes XNS0032, XNS0432, XNS3032, XNS3432, XNS4032, and XNS4432. With the new technology add-on payment application, the applicant stated that the total operating cost of the MAGEC® Spine is $17,500 for a single rod and $35,000 for a dual rod. It is historical practice for CMS to make the new technology add-on payment based on the average cost of the technology and not the maximum. For example, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53358), we approved new technology add-on payments for DIFICID™ based on the average dosage of 6.2 days rather than the maximum 10 day dosage. As noted above, 20 percent of cases use a single rod while 80 percent of cases use a dual rod. As a result, the weighted average cost for a single and dual MAGEC® Spine is $31,500 (((0.2 * $17,500) + (0.8 * $35,000))). We note that the costs for pedicle and rod screws and hooks as well as some connectors are not unique to the MAGEC® Spine as these components are generic to TGR. Therefore, they are not considered new and are not included in the costs above. Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of the MAGEC® Spinal Bracing Distraction system is $15,750 for FY 2017.

b. MIRODERM Biologic Wound Matrix (MIRODERM)

Miromatrix Medical, Inc. submitted an application for new technology add-on payments for FY 2017 for MIRODERM. MIRODERM is a non-crosslinked acellular wound matrix that is derived from the porcine liver and is processed and stored in a phosphate buffered aqueous solution. MIRODERM is clinically indicated for the management of wounds, including: Partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds, drainage wounds, and surgical wounds. Typical decellularization where tissues are immersed in a decellularization solution is a diffusion-based process, and thereby limits the ability to fully decellularize thick, complex tissues such as the liver. MIRODERM uses a perfusion decellularization process that rapidly removes cellular material while maintaining the native architecture, vasculature and tissue structure. Following decellularization, MIRODERM is isolated from partial thickness liver sections following slight compression of the liver. This allows for the retention of the native liver structure, including the vasculature, within MIRODERM. The applicant noted that the MIRODERM is the only acellular skin substitute product that is derived from the liver.

According to the applicant, MIRODERM is positioned to completely contact the entire surface of the wound bed and extend slightly beyond all wound margins. As required, it is securely anchored to the wound site with a physician's preferred fixation method. An appropriate, primary non-adherent wound dressing is then applied over the MIRODERM matrix. A secondary dressing (multi-layer compression bandage system), total contact cast, or other appropriate dressing that will manage the wound exudate should be applied in order to keep the MIRODERM matrix moist and keep all layers securely in place. Additional applications of MIRODERM are applied as needed until the wound closes.

MIRODERM received FDA clearance for its use on January 27, 2015. The applicant submitted a request for an unique ICD–10–PCS procedure code and was granted approval for the following code: XLRPXL2 (Replacement of Skin using Porcine Liver Derived Skin Substitute, External Approach, New Technology Group 2). The new

[6] Matsumoto, W.E., Abnormal psychological scores are observed in patients with EOS. The at-risk patients are younger at the time of their initial scoliosis surgery and the number of repetitive surgeries. *Journal of Pediatric Orthopedics,* 2014, pp. 172–182.

[7] Flynn, E., Psychological Dysfunction in Children Who Require Repetitive Surgery for Early Onset Scoliosis. *Journal of Pediatric Orthopedics,* 2014, pp. 594–599.

[8] Kabirian, et al., Deep Surgical Site Infection Following 2344 Growing-Rod Procedures for Early-Onset Scoliosis: Rick Factors and Clinical Consequences, *Journal of Bone and Joint Surgery,* 2014, pp. 2739–2744.

code is effective on October 1, 2016 (FY 2017).

Comment: One commenter asserted that an unique ICD–10–PCS procedure code for procedures involving the use of the MIRODERM is not necessary because the use of this product should coincide with the same coding used for all cellular and/or tissue-based products (CTPs).

Response: As noted above, an unique ICD–10–PCS procedure code was created for procedures involving the use of the MIRODERM in Section ''X'' of the ICD–10–PCS codes. As discussed in the FY 2016 IPPS/LTCH final rule (80 FR 49434), Section ''X'' of the ICD–10–PCS was created to identify and describe new technologies and medical services for purposes of new technology, or that capture other new technologies that are not currently classified within the ICD–10–PCS. The Section ''X'' codes identify new medical services and technologies that are not usually captured by coders, or that do not usually have the desired specificity within the current ICD–10–PCS structure required to capture the use of these new services and technologies. We believe that the issuance of a unique ICD–10–PCS procedure code in Section ''X'' of the ICD–10–PCS for procedures involving the use of the MIRODERM is an example of why we created Section ''X.''

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first substantial similarity criterion, whether the product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant stated in its application that current wound healing therapies are provided in several different modalities, which include hyperbaric oxygen treatment, negative wound pressure therapy, and treatment with other bioengineered skin substitute products. The applicant noted that other products that have been commonly used for similar procedures are Oasis Wound Matrix, Primatrix Dermal Repair, and Theraskin. The applicant asserted that MIRODERM is different from these other products because it is the only product sourced from porcine liver and undergoes a unique, patented process of perfusion decellularization that rapidly removes cellular material, while maintaining the native architecture, vasculature and tissue structure. The applicant explained that MIRODERM is isolated from partial thickness liver sections following slight compression of the liver, which allows for the retention of the native liver structure, including the vasculature, within MIRODERM. The applicant stated that partial thickness allows for one surface of MIRODERM to retain the native liver capsule (an epithelial basement membrane) and the other opposite surface to be comprised of open liver matrix. The applicant further stated that case studies of the MIRODERM demonstrated accelerated healing, which is likely the result of the unique perfusion decellularization technology that retains a 3-dimensional extracellular matrix that includes the vasculature.

With regard to the first criterion, similar to other current wound matrix treatments, the MIRODERM uses a collagen matrix for tissue repair and regeneration. Therefore, we stated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25042) that we were concerned that MIRODERM employs the same mechanism of action as other wound matrix treatments. Although the applicant had described how the MIRODERM differs from other wound matrix treatments due to the perfusion decellularization process, and is the first product that is derived from the porcine liver, we stated that we believe that the mechanism of action of MIRODERM may be substantially similar or the same as those employed by other wound treatment matrixes. With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, cases that may be eligible for treatment using MIRODERM map to the same MS–DRGs as other currently approved or cleared wound treatment matrixes. With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, MIRODERM is used to treat the same patient population as other currently approved or cleared wound treatment matrixes. Because it appeared that the MIRODERM may be substantially similar to currently approved or cleared wound treatment matrixes, we stated that we were concerned the technology may not be considered ''new'' for the purposes of new technology add-on payments. We also invited public comments on whether MIRODERM meets the newness criterion in the proposed rule.

Comment: The applicant commented that, by definition, the native tissue reaction to liver tissue compressed into a biologic mesh will be different than other highly processed tissue sources. According to the applicant, the ''gentleness'' of the unique and patent-protected perfusion decellularization process results in a fully intact decellularized liver matrix, complete with a mix of proteins not contained in matrices decellularized by other means. The applicant further stated that the remaining large vascular structures in the perfusion decellularized liver matrix provide an entirely new and enhanced conduit for revascularization and remodeling.

The applicant noted that MIRODERM is the only wound matrix derived from the porcine liver utilizing perfusion decellularization technology, which has been highly published by numerous leading academic institutions for its ability to decellularize the whole liver while retaining the native architecture and vasculature. The applicant stated that preclinical studies have demonstrated the importance of the preexisting vasculature in cellular migration into the matrix and subsequent revascularization. The vascular density within liver tissue far exceeds that of other tissues that are used to derive acellular skin substitutes including dermis, urinary bladder, pericardial sac and small intestine submucosa. For these reasons, the applicant believed that MIRODERM is unique compared to other currently approved wound treatment matrixes.

One commenter stated that MIRODERM is substantially similar to existing wound matrix treatments because it supplies the wound bed an extracellular matrix (ECM). According to the commenter, treatments using an acellular matrix closely resemble native ECM. The commenter explained the following with regard to wound matrix treatments: While the ECM may act as a scaffold for matrix metalloproteinase (MMPs) to bind to and break down collagen in the product, epithelial cells, fibroblasts and vascular endothelial cells will migrate into the wound and proliferate; having reduced levels of MMPs to be released back into the wound as the collagen matrix breaks down, the ECM rebalances the protease and growth factor levels in the wound, thus allowing wound to heal.

The commenter stated that the source of skin wound matrix treatments is collagen and the only difference between MIRODERM and other wound matrix treatments is the source of the ECM. The commenter noted that recent skin wound matrix products such as Kerecis, an intact fish skin that is rich in naturally occurring Omega3 polyunsaturatedfatty acids and is used to regenerate damaged human tissue, have been approved for use in the treatment of chronic wounds. According to the commenter, when grafted onto

damaged human tissue, such as a diabetic ulcer, the acellular material recruits the body's cells from the wound perimeter and these cells are then incorporated into the fish skin, which is ultimately converted into functional, living tissue. The commenter explained that fish skin structure resembles the native structure of human skin and studies have shown that cells and stem cells proliferate faster in this structure than in other materials such amnion-membrane and other mammalian-sourced materials.

Response: After consideration of the public comments we received, we believe that MIRODERM's mechanism of action is similar to other acellular skin substitutes currently available for wound healing. We note that MIRODERM provides a scaffold of collagen with a mix of matrix proteins, both of which are similar to other acellular skin substitutes. Therefore, although the applicant asserted that MIRODERM's matrix proteins are different from the proteins found in other acellular skin substitutes, the mechanism of wound healing carried out by the body in the presence of the acellular substitutes is the same. We note that the applicant also indicated that the remaining large vascular structures in the perfusion decellularized liver matrix provide an entirely new and enhanced conduit for revascularization and remodeling. However, the applicant did not provide any data illustrating that MIRODERM's acellular porcine liver skin substitute is a conduit for revascularization and remodeling. Therefore, we are unable to verify the applicant's assertion.

We believe that the MIRODERM is substantially similar to currently approved or cleared wound treatment matrixes because it meets all three of the criteria identified above and, therefore, does not meet the newness criterion. Therefore, because the MIRODERM is not considered ''new,'' it is not eligible for new technology add-on payments for FY 2017.

With regard to the cost criterion, the applicant conducted the following analysis. The applicant began by researching the 2014 Medicare Inpatient Hospital Standard Analytical File (SAF) file for cases primarily associated with dermal regenerative grafts that may be eligible for treatment using MIRODERM. The applicant searched for claims that reported ICD–9–CM procedure code 86.67 (Dermal regenerative graft) that mapped to one of the following MS–DRGs: 463, 464, and 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders with MCC, with CC, or without CC/MCC, respectively); 573, 574, and 575 (Skin Graft for Skin Ulcer or Cellulitis with MCC, with CC, or without CC/MCC, respectively); 576, 577, and 578 (Skin Graft Except for Skin Ulcer or Cellulitis with MCC, with CC, or without CC/MCC, respectively); 622, 623, and 624 (Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Diseases with MCC, with CC or without CC/MCC, respectively); and 904 and 905 (Skin Grafts for Injuries with CC/MCC or without CC/MCC, respectively). As a result, the applicant identified 1,130 cases across the MS–DRGs listed, which resulted in an average case-weighted charge per case of $83,059.

Included in the average case-weighted charge per case were charges for other previously used dermal regenerative grafts. According to the applicant, the MIRODERM would replace the need for other dermal regenerative grafts and, therefore, the applicant removed charges related to the use of other currently used dermal regenerative grafts from the average case-weighted charge per case. Specifically, using the January 2016 CMS Part B Drug Pricing File, the applicant first computed an average cost per square centimeter for currently used dermal regenerative grafts (Apligraf $31.207/cm^2, Oasis $10.676/cm^2, Integra DRT $21.585/cm^2, Dermagraft $32.858/cm^2, Integra skin substitute $35.627/cm^2, Primatrix $37.590/cm^2, and Theraskin $38.474/cm^2), which equaled $29.72/cm^2. To determine the average amount of square centimeters of the other dermal regenerative grafts used for each case within the MS–DRG, given the vast complexity and variation in wounds, the applicant used clinical judgment based on experience, observation and typical sizes and depths of wounds that would present on different parts of the body. For an example, wounds on the hand would typically be smaller than those located on the lower extremities. The applicant also assumed that other dermal regenerative grafts would require three applications to close a wound as opposed to treatment using MIRODERM, which requires only two applications. Based on this assumption, the applicant noted that it assumed that the first application required 100 percent of the amount of skin substitute required to treat the original wound area, the second application required 70 percent, and the third application required 40 percent, totaling 210 percent. To compute the total amount of square centimeters used for each case within the MS–DRG, the applicant multiplied this percentage (210 percent) by the amount of square centimeters used for the first application for each case within the MS–DRG. The applicant then multiplied the average cost of the other previously used dermal regenerative grafts ($29.72/cm^2) by the average amount of centimeters used for each case within the MS–DRG to determine the average cost of the other previously used dermal regenerative grafts for each case within the MS–DRG. To convert the costs to charges, the applicant computed an average CCR for each MS–DRG using CCRs from the FY 2014 Standardizing File of the hospitals indicated on each of the claims for each case within the MS–DRG. The applicant then divided the average cost of the other previously used dermal regenerative grafts for each MS–DRG by the average CCR for each MS–DRG to determine the average charges of the other previously used dermal regenerative grafts for each MS–DRG. The applicant also reduced the charges for the number of days of hospitalization by 30 percent because the applicant believed that MIRODERM heals patients faster than the other currently used dermal regenerative grafts, resulting in a reduction in the average lengths of stay. The applicant then deducted the charges related to the other previously used dermal regenerative grafts and the charges for the reduction in the average lengths of stay from the average case-weighted charge per case and then standardized the charges, which resulted in an average standardized case-weighted charge per case of $34,279. The applicant then inflated the average standardized case-weighted charge per case by 7.7 percent, the same inflation factor used by CMS to update the FY 2016 outlier threshold (80 FR 49784).

After inflating the charges, it was necessary to add the associated charges for the use of MIRODERM. The applicant conducted a similar calculation to compute the charges for MIRODERM. Specifically, the applicant used clinical judgment based on experience, observation, and typical sizes and depths of wounds that would be present on different parts of the body. The applicant stated that because MIRODERM has shown greater efficacy in wound closure based on their case series, the applicant modeled for only two applications with 50 percent closure of the wound after the first application and full closure of the wound after the second application. Based on this assumption, the applicant noted that it assumed that the first application required 100 percent of the

amount of skin substitute required to treat the original wound area and the second application required 50 percent, totaling 150 percent. To compute the total amount of square centimeters used for each MS–DRG, the applicant multiplied this percentage (150 percent) by the amount of square centimeters used for the first application for each MS–DRG. The applicant then multiplied the cost per square centimeter for MIRODERM by the average amount of centimeters used for each case within the MS–DRG to determine the average cost of MIRODERM grafts used for each MS–DRG. Similar to above, to convert the costs to charges, the applicant used the same average CCRs for each MS–DRG and divided the average cost of MIRODERM for each MS–DRG by the average CCR for each MS–DRG to determine the average charges of MIRODERM for each MS–DRG. The applicant then added charges related to the use of MIRODERM to the inflated average standardized charges and determined a final inflated average standardized case-weighted charge per case of $94,009. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $67,559 (all calculations above were performed using unrounded numbers). Because the final inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We invited public comments on whether the MIRODERM technology meets the cost criterion in the proposed rule.

Comment: One commenter stated that the evaluation of the cost criterion using the average standardized case-weighted threshold amount to determine cost savings is not unique to the MIRODERM.

Response: We are not certain what the commenter is referring to with regard to the evaluation of the cost criterion for this technology because the criterion measures and determines whether a new technology is inadequately paid, but does not measure or determine cost savings. Based on the applicant's analysis, it appears that the MIRODERM meets the cost criterion. However, because we believe that the MIRODERM is substantially similar to other wound treatment matrixes for the reasons discussed earlier and, therefore, does not meet the newness criterion, it is not eligible for new technology add-on payments.

With regard to substantial clinical improvement, the applicant believed that the technology represents a substantial clinical improvement over existing technologies because patients treated with the MIRODERM for complicated wounds heal quicker and avoid additional surgeries. To demonstrate that the technology meets the substantial clinical improvement criterion, the applicant submitted the results of two actual case studies of a complicated wound from necrotizing fasciitis that was treated with the MIRODERM. According to the applicant, one case study involved a complicated wound that would typically be treated with a diverting colostomy. The applicant noted that that the patient was discharged with intact anoplasty and good sphincter control after 35 days and four applications for MIRODERM. The applicant further stated that the use of MIRODERM demonstrated rapid healing and likely avoided at least two major debilitating surgeries, as well as the emotional and physical impact of a colostomy for 3 to 6 months. In the second case study, according to the applicant, the attending physician estimated the wound would likely take greater than 90 days to close using traditional wound care matrixes. The applicant stated that after 12 days and two applications of MIRODERM the patient was discharged and after 21 days the wound was sutured closed.

The applicant noted that additional patients have been treated with MIRODERM. According to the applicant, given the recent product launch, the case studies have not been completed, but similar results have been communicated to the applicant.

We stated in the proposed rule (81 FR 25044) that we were concerned that the clinical data the applicant submitted is from a very small sample with no comparisons to other currently approved wound treatment matrixes. Specifically, the applicant submitted data from only two case studies. Also, the applicant compared the use of MIRODERM to the use of other treatments, such as diverting colostomy. While MIRODERM may represent an improvement in treatment options compared to the other treatment options such as diverting colostomy, we stated that we were unable to determine if use of MIRODERM represents a substantial clinical improvement when compared to other wound treatment matrixes of other currently approved treatments. We invited public comments on whether MIRODERM meets the substantial clinical improvement criterion in the proposed rule.

Comment: The applicant submitted additional clinical data, including a case series of seven additional cases that were selected to receive MIRODERM as a treatment for diabetic foot ulcers (DFU). The commenter noted the following: the duration of the preexisting chronic wound prior to MIRODERM treatment ranged from 5 to 48 months and 3 of the 6 patients in the evaluation healed after treatment with MIRODERM within the 12-week study duration. The applicant stated that the results obtained by case series demonstrated a 50-percent closure rate of hard to heal DFUs that had previously failed advanced biologic wound care treatment.

The commenter also submitted one additional case study that had been submitted for presentation at a national wound conference. The patient was a 54-year old male that sustained a myocardial infarction in November 2015. This necessitated a coronary artery bypass graft surgical procedure. A major postoperative complication of the CABG procedure was bilateral pulmonary embolism with respiratory failure. The patient also developed bilateral lower extremity deep venous thrombosis and initiated Heparin therapy. This triggered a Heparin induced thrombocytopenia resulting in bilateral forefoot gangrene and bilateral lower extremity compartment syndrome.

The commenter noted the following: The patient underwent an open transmetatarsal (TMA) of the left forefoot and extensive skin and deep tissue of the plantar foot extending to the distal heel; the wound remained open due to a lack of appropriate plantar soft tissue coverage with exposed muscle and bone; local wound care consisted of negative pressure wound therapy (NPWT) initially which was discontinued due to severe pain; enzymatic debridement with local wound care continued until the initial application of a perfusion decellularized porcine hepatic wound matrix. The patient was healed to a functional outcome.

The commenter further stated that, with regard to perfusion decellularization technology, the MIRODERM encompasses a method to decellularize and recellularize whole or partial organs and tissues. The commenter explained that the technology is based on a proprietary method for removing all cells, while maintaining a non-cellular (called extracellular) matrix or scaffold with its original architecture, mechanical properties, and a vascular network capable of maintaining physiological pressures. The commenter noted that the most widely recognized method of removing cells in use today is ''immersion decellularization,'' in which an organ is soaked in a vat of

harsh detergent, which migrates from the outer surface inward and then back out once the cells are dissolved. The commenter stated that this method damages the organ capsule through mechanical or enzymatic methods, and the cells within the organ begin to break down before being exposed to the detergent, releasing various enzymes that also degrade the surrounding scaffold with the end result a partially degraded scaffold with a compromised vascular network and an outer organ capsule that will not maintain physiological pressures when tested. The commenter further stated that cells will no longer recognize this degraded scaffold as the appropriate environment in which to become functional.

The commenter added that perfusion decellularization technology is in contrast to immersion decellularization and overcomes the hurdles of immersion by facilitating rapid access to the whole organ through the native vasculature by cannulating the vasculature and perfusing (running) a mild detergent solution through the native blood vessels, as opposed to immersing the organ. The commenter stated that scaffolds created with this technology are capable of receiving and incorporating a variety of cell types, depending on the organ scaffold utilized. Moreover, the commenter believed that as cell type discovery continues to grow, the fact that scaffolds created with this technology are of a natural biological design make them an ideal template to support the growth and differentiation of stem cells into functional tissues, organs and bioidentical test beds.

One commenter stated that there are other CTPs with substantiated evidence of a randomized clinical trial that also demonstrate healing in one or two applications (GraftJacket and DermACELL). Additionally, the commenter stated there has been no published randomized clinical trial regarding the use of the MIRODERM in the treatment of chronic wound applications. The commenter concluded that citing two case studies, one involving a diverting colostomy, is not sufficient evidence.

Response: We appreciate the commenters' input. However, because we believe that the MIRODERM is substantially similar to other wound treatment matrixes for the reasons discussed earlier and, therefore, does not meet the newness criterion, it is not eligible for new technology add-on payments.

c. Idarucizumab

Boehringer Ingelheim Pharmaceuticals, Inc. submitted an application for new technology add-on payments for FY 2017 for Idarucizumab; a product developed as an antidote to reverse the effects of PRADAXA® (Dabigatran), which is also manufactured by Boehringer Ingelheim Pharmaceuticals, Inc. (We note that the applicant submitted an application for new technology add-on payments for FY 2016, but failed to obtain FDA approval prior to the July 1 deadline.) Dabigatran is an oral direct thrombin inhibitor currently indicated to: (1) Reduce the risk of stroke and systemic embolism in patients who have been diagnosed with nonvalvular atrial fibrillation (NVAF); (2) treat deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been administered a parenteral anticoagulant for 5 to 10 days; and (3) reduce the risk of recurrence of DVT and PE in patients who have been previously diagnosed with NVAF. Currently, unlike the anticoagulant Warfarin, there is no specific way to reverse the anticoagulant effect of Dabigatran in the event of a major bleeding episode.

Idarucizumab is a humanized fragment antigen binding (Fab) molecule, which specifically binds to Dabigatran to deactivate the anticoagulant effect, thereby allowing thrombin to act in blood clot formation. The applicant stated that Idarucizumab represents a new pharmacologic approach to neutralizing the specific anticoagulant effect of Dabigatran in emergency situations. Idarucizumab was approved by the FDA on October 16, 2015. The applicant noted that Idarucizumab is the only FDA-approved therapy available to neutralize the anticoagulant effect of Dabigatran. Before the FDA approval of Idarucizumab, the approach for the management of the anticoagulant effect of Dabigatran prior to an invasive procedure was to withhold administration of Dabigatran, when possible, for a certain duration of time prior to the procedure to allow sufficient time for the patient's kidneys to flush out the medication. The duration of time needed to flush out the medication prior to the surgical procedure is based on the patient's kidney function. According to the applicant, if surgery cannot be delayed to allow the kidneys the necessary time to flush out the traces of Dabigatran, there is an increased risk of bleeding.

Based on the FDA indication for Idarucizumab, the product can be used in the treatment of patients who have been diagnosed with NVAF and administered Dabigatran to reverse life-threatening bleeding events, or who require emergency surgery or medical procedures and rapid reversal of the anticoagulant effects of Dabigatran is necessary and desired. The applicant received a unique ICD–10–PCS procedure code that became effective October 1, 2015. The approved procedure code is XW03331 (Introduction of Idarucizumab, Dabigatran reversal agent into central vein, percutaneous approach, New Technology Group 1). We invited public comments on whether Idarucizumab meets the newness criterion in the proposed rule.

Comment: Several commenters stated that there is currently no other reversal agent on the U.S. market for patients who are being treated with Dabigatran and experience severe bleeding.

The applicant submitted public comments reiterating its assertion that Idarucizumab satisfies the newness criterion. The applicant emphasized that Idarucizumab was developed as a specific reversal agent to Dabigatran, an anticoagulant that works by directly inhibiting thrombin, thereby blocking the final step of the coagulation cascade. The applicant further defined the potential adverse effects of anticoagulant therapy and the increased risk of bleeding that may be life-threatening or fatal which may require emergent medical and surgical procedures and the need for rapid reversal of an anticoagulation to perform the procedure in a timely manner. The applicant reiterated that Idarucizumab was developed as a specific reversal agent to Dabigatran, and that Idarucizumab was granted FDA approval on October 16, 2015.

Response: We appreciate the details and input provided by the commenters and the applicant on whether Idarucizumab meets the newness criterion. After review of the information provided by the applicant and consideration of the public comments we received, we believe that Idarucizumab meets the newness criterion and we consider the technology to be ''new'' as of October 16, 2015, when the technology received FDA approval.

With regard to the cost criterion, in the proposed rule, we noted that the applicant conducted two analyses. The applicant began by researching claims data in the FY 2014 MedPAR file for cases that may be eligible for Idarucizumab using a combination of ICD–9–CM diagnosis and procedure codes. Specifically, the applicant searched the database for cases

reporting anticoagulant therapy diagnosis code E934.2 (Agents primarily affecting blood constituents, anticoagulants) or V58.61 (Long-term (current) use of anticoagulants) in combination with either current standard of care procedure code 99.03 (Other transfusion of whole blood), 99.04 (Transfusion of packed cells), 99.05 (Transfusion of platelets), 99.06 (Transfusion of coagulation factors), 99.07 (Transfusion of other serum), or 39.95 (Hemodialysis), and Dabigatran indication diagnosis code 427.31 (Atrial fibrillation), 453.40 (Acute venous embolism and thrombosis of unspecified deep vessels of lower extremity), 453.41 (Acute venous embolism and thrombosis of deep vessels of proximal lower extremity), 453.42 (Acute venous embolism and thrombosis of deep vessels of distal lower extremity), 453.50 (Chronic venous embolism and thrombosis of unspecified deep vessels of lower extremity), 453.51 (Chronic venous embolism and thrombosis of deep vessels of proximal lower extremity), 453.52 (Chronic venous embolism and thrombosis of deep vessels of distal lower extremity), 415.11 (Iatrogenic pulmonary embolism and infarction), 415.12 (Septic pulmonary embolism), 415.13 (Saddle embolus of pulmonary artery), 415.19 (Other pulmonary embolism and infarction), 416.2 (Chronic pulmonary embolism), V12.51 (Personal history of venous thrombosis and embolism), or V12.55 (Personal history of pulmonary embolism).

To further target potential cases that may be eligible for Idarucizumab, the applicant also excluded specific cases based on Dabigatran contraindications, including all cases representing patients who have been diagnosed with chronic kidney disease (CKD) stage V (diagnosis code 585.5), end-stage renal disease (diagnosis code 585.6), prosthetic heart valves (diagnosis code V43.3), and cases representing patients who have been diagnosed with both CKD stage IV (diagnosis code 585.4) and either DVT or PE (using the same ICD–9–CM diagnosis codes listed above). As a result, the applicant identified 84,224 cases that mapped to 684 MS–DRGs. The applicant standardized the charges and computed an average standardized case-weighted charge per case of $60,089.

The applicant then identified hospital charges potentially associated with the current treatments to reverse anticoagulation, specifically charges associated with pharmacy services, dialysis services, and laboratory services for blood work. Due to limitations associated with the claims data, the applicant was unable to determine the specific drugs used to reverse anticoagulation and if these cases represented patients who required laboratory services for blood work or dialysis services unrelated to the reversal of anticoagulation. Therefore, the applicant subtracted 40 percent of the charges related to these three categories from the standardized charge per case, based on the estimation that the full amount of charges associated with these services would not be incurred by hospitals when Idarucizumab is administered for use in the treatment of patients who have been diagnosed with NVAF and Dabigatran is administered during treatment. The applicant then inflated the standardized charge per case by 7.665 percent, the same inflation factor used by CMS to update the FY 2016 outlier threshold (80 FR 49784) and added charges for Idarucizumab. This resulted in an inflated average standardized case-weighted charge per case of $67,617. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount across all 684 MS–DRGs is $55,586 (all calculations above were performed using unrounded numbers). Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion under this analysis.

Further, the applicant conducted an additional analysis using the same data from the FY 2014 MedPAR file and variables used in the previous analysis. However, instead of using potentially eligible cases that mapped to 100 percent of the 684 MS–DRGs identified, the applicant used potentially eligible cases that mapped to the top 75 percent of the 684 MS–DRGs identified. By applying this limitation, the applicant identified 63,033 cases that mapped to 87 MS–DRGs. The applicant computed an inflated average standardized case-weighted charge per case of $55,872. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount across all 87 MS–DRGs is $63,323 (all calculations above were performed using unrounded numbers). Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology also meets the cost criterion under this analysis. We invited public comments regarding the applicant's analyses with regard to the cost criterion in the proposed rule.

Comment: The applicant submitted public comments reiterating its costs analysis results. According to the applicant, the standardized case-weighted charge per case exceeds the average case-weighted threshold for Idarucizumab. The applicant stated that CMS' summary in the proposed rule did not accurately reflect the analysis submitted by the applicant with its application. Specifically, the applicant stated that, with regard to the analysis cases that mapped to the top 75 percent of the 684 MS–DRGs identified, CMS listed the inflated average standardized case-weighted charge per case as $55,872 and the average case-weighted threshold amount across all 87 MS–DRGs as $63,323. The commenter stated that the inflated average standardized case-weighted charge per case should have been $63,323 and the average case-weighted threshold amount across all 87 MS–DRGs should have been $52,753.

Response: We agree with the applicant that we inadvertently listed the wrong amounts in the proposed rule. The amounts listed above by the applicant are indeed the correct amounts. Under both analyses provided by the applicant, the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount. Therefore, we agree that Idarucizumab meets the cost criterion.

With regard to substantial clinical improvement, according to the applicant, aside from Idarucizumab, there are no other FDA-approved antidotes to reverse the anticoagulant effects of Dabigatran. Management of the treatment of patients who have been diagnosed with NVAF and administered Dabigatran and experience bleeding may often include supportive care such as Hemodialysis and the use of fresh frozen plasma, blood factor products such as prothrombin complex concentrates (PCC), activated prothrombin complex concentrates, and recombinant factor VIIa or delayed intervention. Protamine sulfate and Vitamin K are typically used to reverse the effects of Heparin and Warfarin, respectively. However, due to the mechanism of action in Dabigatran, the applicant maintained that the use of protamine sulfate and Vitamin K may not be effective to reverse the anticoagulant effect of Dabigatran.

The applicant provided information regarding the management of major bleeding events experienced by patients who were administered Dabigatran and Warfarin during the RE–LY trial.[9]

[9] Healy, et al.: Periprocedural bleeding and thromboembolic events with dabigatran compared with Warfarin: results from the randomized evaluation of long-term anticoagulation therapy

During this study, most major bleeding events were only managed by supportive care. Patients who were administered 150 mg of Dabigatran were transfused with pack red blood cells more often when compared to patients who were administered Warfarin (61.4 percent versus 49.9 percent, respectively). However, patients who were administered Warfarin were transfused with plasma more often when compared to patients who were administered 150 mg of Dabigatran (30.2 percent versus 21.6 percent, respectively). In addition, the use of Vitamin K in the treatment of patients who were administered Warfarin was more frequent when compared to the frequency of use in the treatment of patients who were administered 150 mg of Dabigatran (27.3 percent versus 10.3 percent, respectively). The use of PCCs, recombinant factor VIIa and other coagulation factor replacements in the treatment of patients who were administered both Warfarin and 150 mg of Dabigatran was minimal, and did not significantly differ in frequency when compared among patients assigned to either group. Hemodialysis was used in a single case.

The applicant reported that, currently, it is recommended that the administration of Dabigatran be discontinued 1 to 2 days (CrCl ≥ 50 ml/min) or 3 to 5 days (CrCl < 50 ml/min), if possible, before invasive or surgical procedures because of the increased risk of bleeding.[10] A longer period of discontinuation time should be considered for patients undergoing major surgery, spinal puncture, or placement of a spinal or epidural catheter or port, if complete hemostasis is required. The applicant stated that delaying emergency medical or surgical procedures can cause urgent conditions to become more severe if intervention is not initiated. The applicant further maintained that delaying emergency medical or surgical procedures for an extended period of time can ultimately lead to negative healthcare outcomes and increased healthcare costs. The applicant asserted that rapidly reversing the anticoagulant effect of Dabigatran administered to patients that require an urgent medical procedure or surgery allows the medical procedure or surgery to be performed in a timely manner, which in turn may decrease complications and minimize the need for more costly therapies.

The applicant also provided interim data from an ongoing Phase III trial [11] [12] in patients who may have life-threatening bleeding, or require emergency procedures. The applicant noted that published results of the interim data based on 90 patients suggested the following: Reversal of the Dabigatran anticoagulant effect, which was evident immediately after administration; reversal was 100 percent in the first 4 hours and greater than 89 percent of patients achieved complete reversal; hemostasis in 35 patients in Group A was restored at a median of 11.4 hours. Also, the 5 gram dose of Idarucizumab was calculated to reverse the total body load of Dabigatran that was associated with the 99th percentile of the Dabigatran levels measured in the RE–LY trial.

The applicant provided safety data from three Phase I studies and interim data from the Phase III study. In the Phase I study, 110 healthy male patients enrolled in the study were administered dosages of Idarucizumab that ranged from 20 mg to 8 grams. In this study, 135 patients received placebo. The applicant reported that adverse events were generally mild in intensity and nonspecific. Healthy human volunteers enrolled in the Phase I study were administered Idarucizumab in dosages of 2 and 4 grams, which resulted in immediate and complete reversal of the anticoagulant effect of Dabigatran that was sustained for several hours. In the Phase III study, five thrombotic events occurred. One occurred 2 days after treatment and the remainder occurred 7, 9, 13, and 26 days after treatment. These patients were not receiving antithrombotic therapy when the events occurred, and complications or adverse effects can be attributed to patients' underlying medical conditions. Twenty-one patients (13 in Group A and 8 in Group B) had a serious adverse event. The most frequently reported adverse reactions in greater than or equal to 5 percent of the patients treated with Idarucizumab were hypokalemia, delirium, constipation, pyrexia, and pneumonia. The applicant concluded that the data from these studies demonstrated that Idarucizumab effectively, safely, and potently reverses the anticoagulant effect of Dabigatran. We invited public comments on whether Idarucizumab meets the substantial clinical improvement criterion in the proposed rule.

Comment: Several commenters supported the substantial clinical improvement criterion for Idarucizumab. Several commenters stated that, aside from Idarucizumab, the only alternative for anticoagulation reversal in patients being treated with Dabigatran is withholding the drug and observing the patient for bleeding. The commenters noted that this approach is not ideal in the case of severe bleeding when rapid reversal is needed for emergent surgical procedures. The applicant also reiterated its assertion that Idarucizumab satisfies the clinical improvement criterion, citing that prior to the approval of Idarucizumab, patients treated with Dabigatran who experienced severe bleeding were often managed by supportive care alone, such as fluid administration and blood transfusions. The applicant stated that Idarucizumab has been shown to reverse the anticoagulant effect of Dabigatran immediately in patients needing rapid reversal of anticoagulation in emergency situations.

Response: We appreciate the comments supporting the substantial clinical improvement criterion for Idarucizumab. We agree that Idarucizumab meets the substantial clinical improvement criterion.

After consideration of the public comments we received, we have determined that Idarucizumab meets all of the criteria for approval of new technology add-on payments. Therefore, we are approving new technology add-on payments for Idarucizumab for FY 2017. Cases involving Idarucizumab that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XW03331.

In its application, the applicant estimated that the average Medicare beneficiary would require a dosage of 5 grams for Idarucizumab. According to the applicant, the wholesale acquisition cost for one dose is $3,500. Under 42 CFR 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of Idarucizumab is $1,750 for FY 2017.

d. Titan Spine (Titan Spine Endoskeleton® nanoLOCK™ Interbody Device)

Titan Spine submitted an application for new technology add-on payments for the Titan Spine Endoskeleton® nanoLOCK™ Interbody Device (the Titan Spine nanoLOCK™) for FY 2017. The Titan Spine nanoLOCK™ is a

(RE–LY) randomized trial, Circulation, 2012; 126:343–348.

[10] Pradaxa® (Dabigatran Etexilate Mesylate) prescribing information. Ridgefield, CT: Boehringer Ingelheim; 2014.

[11] Pollack C, et al. Design and rationale for RE–VERSE AD: A phase 3 study of idarucizumab, a specific reversal agent for dabigatran. Thromb Haemost. 2015 Jul; 114(1):198–205.

[12] Pollack C, et al. Idarucizumab for Dabigatran Reversal. N Engl J Med. 2015 Aug 6; 373(6):511–20.

nanotechnology-based interbody medical device with a dual acid-etched titanium interbody system used to treat patients diagnosed with degenerative disc disease (DDD). One of the key distinguishing features of the device is the surface manufacturing technique and materials, which produce macro, micro, and nano surface textures. According to the applicant, the combination of surface topographies enables initial implant fixation, mimics an osteoclastic pit for bone growth, and produces the nano-scale features that interface with the integrins on the outside of the cellular membrane. Further, the applicant noted that these features generate better osteogenic and angiogenic responses that enhance bone growth, fusion, and stability. The applicant asserted that the Titan Spine nanoLOCK™'s clinical features also reduce pain, improve recovery time, and produce lower rates of device complications such as debris and inflammation.

On October 27, 2014, the Titan Spine nanoLOCK™ received FDA clearance for the use of five lumbar interbody devices and one cervical interbody device: The nanoLOCK™ TA-Sterile Packaged Lumbar ALIF Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy; the nanoLOCK™ TAS-Sterile Packaged Lumbar ALIF Stand Alone Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy; the nanoLOCK™ TL-Sterile Packaged Lumbar Lateral Approach Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy; the nanoLOCK™ TO-Sterile Packaged Lumbar Oblique/PLIF Approach Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy; the nanoLOCK™ TT-Sterile Packaged Lumbar TLIF Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy and the nanoLOCK™ TC-Sterile Packaged Cervical Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy. The applicant received FDA clearance on December 14, 2015, for the nanoLOCK™ TCS-Sterile Package Cervical Stand Alone Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy. The applicant indicated that, due to manufacturing delays, all of the devices above were not available on the market until July 8, 2016. Therefore, the applicant believes that all of the devices above are new as of July 8, 2016.

The applicant submitted a request for a unique ICD–10–PCS procedure code and was granted approval for the following procedure codes under New Technology Group 2: XRG0092 (Fusion of occipital-cervical joint using nanotextured surface interbody fusion device, open approach); XRG1092 (Fusion of cervical vertebral joint using nanotextured surface interbody fusion device, open approach); XRG2092 (Fusion of 2 or more cervical vertebral joints using nanotextured surface interbody fusion device, open approach); XRG4092 (Fusion of cervicothoracic vertebral joint using nanotextured surface interbody fusion device, open approach); XRG6092 (Fusion of thoracic vertebral joint using nanotextured surface interbody fusion device, open approach); XRG7092 (Fusion of 2 to 7 thoracic vertebral joints using nanotextured surface interbody fusion device, open approach); XRG8092 (Fusion of 8 or more thoracic vertebral joints using nanotextured surface interbody fusion device, open approach); XRGA092 (Fusion of thoracolumbar vertebral joint using nanotextured surface interbody fusion device, open approach); XRGB092 (Fusion of lumbar vertebral joint using nanotextured surface interbody fusion device, open approach); XRGC092 (Fusion of 2 or more lumbar vertebral joints using nanotextured surface interbody fusion device, open approach); and XRGD092 (Fusion of lumbosacral joint using nanotextured surface interbody fusion device, open approach). These new ICD–10–PCS procedure codes are effective on October 1, 2016.

We note that cases reporting procedures involving lumbar and cervical interbody devices map to different MS–DRGs. As discussed in the Inpatient New Technology Add-On Payment Final Rule (66 FR 46915), two separate reviews and evaluations of the technologies are necessary in this instance because cases representing patients receiving treatment for diagnoses associated with lumbar procedures that may be eligible for use of the technology under the first indication are not expected to be assigned to the same MS–DRGs as patients receiving treatment for diagnoses associated with cervical procedures using the technology under the second indication. Specifically, cases representing patients who have been diagnosed with lumbar DDD and received treatment that involved implanting a lumbar device map to MS–DRGs 028 (Spinal Procedures with MCC), 029 (Spinal Procedures with CC or Spinal Neurostimulators), 030 (Spinal Procedures without CC/MCC), 453 (Combined Anterior/Posterior Spinal Fusion with MCC), 454 (Combined Anterior/Posterior Spinal Fusion with CC), 455 (Combined Anterior/Posterior Spinal Fusion without CC/MCC), 456 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC), 457 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusion without MCC), 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions without CC/MCC), 459 (Spinal Fusion Except Cervical with MCC), and 460 (Spinal Fusion Except Cervical without MCC), while cases representing patients who have been diagnosed with cervical DDD and received treatment that involved implanting a cervical interbody device map to MS–DRGs 471 (Cervical Spinal Fusion with MCC), 472 (Cervical Spinal Fusion with CC), and 473 (Cervical Spinal Fusion without CC/MCC). Procedures involving the lumbar and cervical interbody devices are assigned to separate MS–DRGs. Therefore, the devices categorized as lumbar devices and the devices categorized as cervical devices must distinctively (each category) meet the cost criterion and the substantial clinical improvement criterion in order to be eligible for new technology add-on payments beginning in FY 2017. We discuss application of these criteria following discussion of the newness criterion.

As discussed previously in this section, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments. We note that the substantial similarity discussion is applicable to both the lumbar and the cervical devices because all of the devices use the Titan Spine nanoLOCK™ technology.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant stated that, for both interbody devices (the lumbar and the cervical interbody device), the Titan Spine nanoLOCK™'s surface stimulates osteogenic cellular response to assist in bone formation during fusion. During the manufacturing process, the surface produces macro, micro, and nano-surface textures. The applicant believed that this unique

combination and use of these surface topographies represents a new approach to stimulating osteogenic cellular response. The applicant asserted that the macro-scale textured features are important for initial implant fixation. The micro-scale textured features mimic an osteoclastic pit for supporting bone growth. The nano-scale textured features interface with the integrins on the outside of the cellular membrane, which generates the osteogenic and angiogenic (mRNA) responses necessary to promote healthy bone growth and fusion. The applicant provided the results from *in vitro* studies, using human mesenchymal cells (MSCs), which showed positive effects on bone growth related to cellular signaling achieved by using the device's surface, and osteoblasts exhibited a more differentiated phenotype and increased bone morphogenetic protein (BMP) production using titanium alloy substrates as opposed to poly-ether-ether-ketone (PEEK) substrates. The applicant stated that Titan Spine's proprietary and unique surface technology, the Titan Spine nanoLOCK™ interbody devices, contain optimized nano-surface characteristics, which generate the distinct cellular responses necessary for improved bone growth, fusion, and stability. The applicant further stated that the Titan Spine nanoLOCK™'s surface engages with the strongest portion of the endplate, which enables better resistance to subsidence because a unique dual acid-etched titanium surface promotes earlier bone in-growth. The Titan Spine nanoLOCK™'s surface is created by using a reductive process of the titanium itself. The applicant asserted that use of the Titan Spine nanoLOCK™ significantly reduces the potential for debris generated during impaction when compared to treatments using PEEK-based implants coated with titanium. According to the results of an *in vitro* study [13] provided by the applicant, which compared angiogenic factor production using PEEK-based versus titanium alloy surfaces, osteogenic production levels were greater with the use of rough titanium alloy surfaces than the levels produced using smooth titanium alloy surfaces. The results of an additional study [14] provided by the applicant examined whether inflammatory microenvironment generated by cells as a result of use of titanium aluminum-vanadium (Ti-alloy, TiAlV) surfaces is effected by surface microtexture, and whether it differs from the effects generated by PEEK-based substrates. The applicant noted that the use of microtextured surfaces has demonstrated greater promotion of osteoblast differentiation when compared to use of PEEK-based surfaces.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, cases that may be eligible for treatment involving the Titan Spine nanoLOCK™ map to the same MS–DRGs as other (lumbar and cervical) interbody devices currently available to Medicare beneficiaries and also are used for the treatment of patients who have been diagnosed with DDD (lumbar or cervical).

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that the Titan Spine nanoLOCK™ can be used in the treatment of patients diagnosed with similar types of diseases, such as DDD, and for a similar patient population receiving treatment involving both lumbar and cervical interbody devices.

In summary, the applicant maintained that the Titan Spine nanoLOCK™ technology has a different mechanism of action when compared to other spinal fusion devices. Therefore, the applicant did not believe that the Titan Spine nanoLOCK™ technology is substantially similar to existing technologies.

After reviewing the applicant's statements regarding nonsubstantial similarity of its technology with other existing technologies, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25047), we stated that we were still concerned that there are other titanium surfaced devices currently available on the U.S. market. While these devices do not use the Titan Spine nanoLOCK™ technology, their surfaces also are made of titanium. Therefore, we stated that we believe that the Titan Spine nanoLOCK™ interbody devices may be substantially similar to currently available titanium interbody devices.

We invited public comments on whether the Titan Spine Endoskeleton® nanoLOCK™ Interbody Devices are substantially similar to existing technologies and whether these devices meet the newness criterion in the proposed rule.

Comment: One commenter stated the Titan Spine nanoLOCK's rough topography is not unique to Titan Spine's nanoLOCK™ interbody devices. The commenter listed other titanium devices with micro and macro surfaces which also stimulate bone growth. According to the commenter, the studies provided by the Titan Spine applicant show that any roughened surface topography is associated with an increase in the apha2-beta1 integrin mRNA expression, which is favorable to osteogenesis.

Response: We appreciate the commenter's comments regarding the Titan Spine Endoskeleton® nanoLOCK™ Interbody Devices. In the proposed rule, we stated concerns that Titan Spine Endoskeleton® nanoLOCK™ Interbody Devices may be substantially similar to currently available titanium interbody devices. Although Titan Spine Endoskeleton® nanoLOCK™ Interbody Devices employ nanotechnology in their surface manufacturing technique to produce macro, micro, and nano surfaces, there are other titanium devices that also produce porous surfaces which promote an osteogenic response.

After consideration of the public comments we received, we remain concerned that the Titan Spine Endoskeleton® nanoLOCK™ Interbody Devices are substantially similar to other titanium spinal implants and, therefore, as to whether the Titan Spine Endoskeleton® nanoLOCK™ Interbody Devices meet the newness criterion.

(1) Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Lumbar DDD

As previously mentioned, the Titan Spine nanoLOCK™ received FDA clearance for the use of five lumbar interbody devices on October 27, 2014. To demonstrate that the Titan Spine nanoLOCK™ for Lumbar DDD technology meets the cost criterion, the applicant researched claims data in the FY 2014 MedPAR file for cases assigned to MS–DRGs 028, 029, 030, 453, 454, and 455 reporting any of the ICD–9–CM procedure codes within the code series 81.xx (Repair and plastic operations on joint structures) or code series 084.6x (Replacement of spinal disk), excluding cases reporting the following ICD–9–CM procedure codes describing cervical fusion: 81.01 (Atlas-axis spinal fusion), 81.02 (Other cervical fusion, anterior technique), 81.03 (Other cervical fusion, posterior technique), 81.31 (Refusion of atlas-axis spine), 81.32 (Refusion of other cervical spine, anterior technique), or 81.33 (Refusion of other cervical spine, posterior technique). As a result, the applicant found that all cases potentially eligible for treatment using

[13] Olivares-Navarrete R, Hyzy S, Gittens R. Titanium Alloys Regulate Osteoblast Production of Angiogenic Factors. The Spine Journal, 2013, ep.13. 1563–1570.

[14] Olivares-Navrrete R, Hyzy s, Slosar P, et al. Implant Materials Generate Different Peri-implant Inflammatory Factors. SPINE. 2015: 40:6:339–404.

the technology mapped to MS–DRGs 456, 457, 458, 459, and 460. However, the applicant focused its analyses on MS–DRGs 028 through 030, 453 through 455, and 456 through 460 because these are the MS–DRGs to which cases treated with interbody fusion devices for degenerative disc disease would most likely be assigned. The applicant applied CMS' relative weight filtering process as described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49424) to ensure the correct claim types were used and the charge details across the cost centers were appropriate.

According to the applicant, 78.03 percent of the 96,281 cases found in the FY 2014 MedPAR file mapped to MS–DRG 460, while the remaining 21.97 percent of cases mapped to MS–DRGs 028 through 030, 453 through 455, and 456 through 459. This resulted in an average case-weighted charge per case of $127,082. The applicant then removed $15,766 for associated charges for other previously used spinal devices. The applicant determined the associated charges to be removed for other previously used devices based on current Titan Spine sales data for the Titan Spine nanolock™ for Lumbar DDD various sizes. The applicant computed the associated charges by multiplying the weighted sales mix by the average sales price for each product in the Titan Spine nanoLOCK™ for Lumbar DDD product line. After the charges for other previously used technologies were removed, the applicant standardized the charges for all cases using the FY 2014 standardizing file posted on the CMS Web site. The applicant excluded all cases without standardized charges, resulting in a total of 96,281 cases. The applicant then inflated the average standardized case-weighted charges from 2014 to 2016 by applying a 2-year rate of inflation factor of 7.7 percent, which is the same inflation factor used by CMS to update the FY 2016 outlier threshold (80 FR 49784).

To calculate the appropriate charges for the Titan Spine nanoLOCK™ for Lumbar DDD, the applicant used a case-weighted charge because the devices implanted are produced and made available in different sizes. To calculate the case-weighted charge for different lumbar device sizes, the applicant determined the average cost to the hospital per device and divided that amount by the national average CCR for implantable devices (0.337) published in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49429). Based on sales data, the applicant then applied a factor of 1.5 per patient to the case-weighted charge by dividing the total number of products sold in the United States by the total invoices generated; with one invoice being the equivalent to one patient and a single surgery. The applicant then added the device-related charges to the inflated average standardized charge per case, which resulted in an inflated average standardized case-weighted charge per case of $167,197. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $112,825 (all calculations above were performed using unrounded numbers). Because the final inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We invited public comments on whether the Titan Spine nanoLOCK™ for Lumbar DDD meets the cost criterion, particularly with regard to the assumptions and methodology used in the applicant's analyses in the proposed rule. We did not receive any public comments concerning costs for Titan Spine nanoLOCK™ for Lumbar DDD. We believe Titan Spine nanoLOCK™ for Lumbar DDD meets the cost criterion.

(2) Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Cervical DDD

As previously mentioned, Titan Spine received FDA clearance for the use of the nanoLOCK™ TC-Sterile Packaged Cervical Interbody Fusion Device with nanoLOCK™ surface on October 27, 2014, and the nanoLOCK™ TCS-Sterile Package Cervical Interbody Fusion Device with nanoLOCK™ surface on December 14, 2015. To demonstrate that the Titan Spine nanoLOCK™ for Cervical DDD meets the cost criterion, the applicant researched claims data in the FY 2014 MedPAR file for cases assigned to MS–DRGs 028, 029, 030, 453, 454, and 455 reporting any of the following ICD–9–CM cervical fusion procedure codes: 81.01, 81.02, 81.03, 81.32, 81.33. The applicant found that all of the cases mapped to MS–DRGs 471, 472, and 473. However, the applicant focused its analysis on MS–DRGs 028 through 030, 453 through 455, and 471 through 473 because these are the MS–DRGs to which cases treated with the implantation of cervical spinal devices for degenerative disc disease would most likely be assigned. Similar to the sensitivity analysis submitted for the Titan Spine nanoLOCK™ for Lumbar DDD, the applicant applied CMS' relative weight filtering process as described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49424) to ensure the correct claim types were used and the charge details across the cost centers were appropriate.

According to the applicant, 59.47 percent of the 48,187 cases mapped to MS–DRG 473 and 25.65 percent of the cases mapped to MS–DRG 472, while the remaining 14.88 percent of the cases mapped to MS–DRGs 028 through 030, 453 through 455, and 471. This resulted in an average case-weighted charge per case of $83,841. Using the same methodology described above, the applicant removed $4,423 for associated charges for other previously used technologies from the average case-weighted charge per case using current Titan Spine sales data for cervical device sizes and then standardized the charges. The applicant then inflated the average standardized case-weighted charges from 2014 to 2016 by applying the same 2-year rate of inflation factor used above (7.7 percent). Similar to the methodology described above, the applicant calculated $36,023 for associated device related charges for the Titan Spine nanoLOCK™ for Cervical DDD and added this amount to the inflated average standardized case-weighted charge per case, which resulted in a final inflated average standardized case-weighted charge per case of $114,472. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $79,827 (all calculations above were performed using unrounded numbers). Because the final inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We invited public comments on whether the Titan Spine nanoLOCK™ for Cervical DDD meets the cost criterion in the proposed rule. We did not receive any public comments concerning costs for Titan Spine nanoLOCK™ for Cervical DDD. We believe Titan Spine nanoLOCK™ for Cervical DDD meets the cost criterion.

With regard to the substantial clinical improvement criterion for the Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Lumbar and Cervical DDD, the applicant asserted that the Titan Spine nanoLOCK™ substantially improves the treatment of Medicare beneficiaries who have been diagnosed with and receive treatment for serious spinal pathologies, such as DDD, compared to the currently available technologies and treatment options, especially in terms of improved fusion, decreased pain, greater stability, faster recovery times, and lower rates of interbody device related complications, such as debris and inflammation.

The applicant noted that the cellular process that occurs after implantation of the Titan Spine nanoLOCK™ induces the body to produce and regulate its own bone morphogenetic proteins (BMP), which help stimulate bone growth naturally in the human body. According to the applicant, this result supports new bone growth without requiring use of exogenous BMP. The applicant explained that exogenous rhBMPs trigger a significant cytokine related anti-inflammatory reaction that has resulted in adverse side effects. The applicant stated that the Titan Spine nanoLOCK™'s proprietary surface and use promotes endogenous production of osteogenic growth factors, such as BMP–2, BMP–4, BMP–7, and TGF–β1.2, which produce only the physiologic amounts necessary for bone production without the concomitant cytokine related to anti-inflammatory reaction.

The applicant also stated that the unique surface of the TitanSpine nanoLOCK™ differentiates the technology from existing interbody devices, which use materials such as PEEK-based or ceramic surfaces. The applicant explained that these materials cause stem cells to flatten on the surface of the implant and primarily differentiate into fibroblasts (fiber-producing cells). This result is avoided by using the Titan Spine nanoLOCK™ because the nano-textured surface promotes differentiation of osteoblasts (bone-forming cells), which increases bone production around the implant site and increases the potential for a faster and more robust fusion. The applicant further stated that use of titanium and titanium alloy surfaces with rough microtopography demonstrate greater bone apposition, but use of macrotextured titanium and titanium alloy surfaces, such as the Titan Spine nanoLOCK™, promotes osteoblast differentiation and productions of factors that favor bone formation, whereas PEEK-based surfaces do not.

As previously noted, the applicant provided results from *in vitro* studies, using human MSCs, which showed positive effects on bone growth related to cellular signaling achieved from use of the device's surface, and osteoblasts exhibited a more differentiated phenotype and increased bone morphogenetic protein BMP production using titanium alloy substrates as opposed to PEEK-based substrates. The applicant believed that the Titan Spine nanoLOCK™ substantially improves the treatment of Medicare beneficiaries diagnosed with and receiving treatment for serious spinal pathologies, such as DDD, compared to currently available technologies and treatment options for Medicare beneficiaries, especially in terms of improved fusion, decreased pain, greater stability, faster recovery times, and lower rates of interbody device related complications, such as debris and inflammation.

We stated in the proposed rule (81 FR 25049) that we were concerned that the results of the *in vitro* studies may not necessarily correlate with the clinical results specified by the applicant. Specifically, because the applicant has only conducted *in vitro* studies without obtaining any clinical data from live subjects during a specific clinical trial, we further stated that we were unable to substantiate the clinical results that the applicant believed the technology achieved from a clinical standpoint based on the results of the studies provided. As a result, we stated that we were concerned that the results of the studies provided by the applicant do not demonstrate that the Titan Spine nanoLOCK™ technologies meet the substantial clinical improvement criterion. We invited public comments on whether the Titan Spine nanoLOCK™ technologies meet the substantial clinical improvement criterion in the proposed rule.

Comment: Several commenters supported that Titan Spine Endoskeleton® nanoLOCK™ Interbody Devices for Lumbar DDD and Cervical DDD represent a substantial clinical improvement over existing technologies. The commenters cited enhanced clinical outcomes with Titan Spine's predicate devices. Commenters cited the success of bench studies which show improved bone growth with nano-textured titanium surfaces. Several commenters have used Titan Spine's predicate devices and stated satisfaction with these predicate devices.

Response: We appreciate the commenters' statements concerning Titan Spine's predicate devices. However, none of the commenters cited actual clinical data that used the Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Lumbar DDD and Cervical DDD. As mentioned above, the commenters cited data with regard to Titan Spine's predicate devices. Therefore, our concerns stated in the proposed rule are still the same. Due to the lack of actual clinical data using the Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Lumbar DDD and Cervical DDD, we are unable to determine if Titan Spine Endoskeleton® meets the substantial clinical improvement criterion. Therefore, we are not approving new technology add-on payments for the Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Lumbar DDD and Cervical DDD for FY 2017. The applicant can reapply in FY 2018 and provide additional clinical data supporting substantial clinical improvement.

e. Defitelio® (Defibrotide)

Jazz Pharmaceuticals submitted an application for new technology add-on payments for FY 2017 for defibrotide (Defitelio®), a treatment for patients diagnosed with hepatic veno-occlusive disease (VOD) with evidence of multi-organ dysfunction. VOD, also known as sinusoidal obstruction syndrome (SOS), is a potentially life-threatening complication of hematopoietic stem cell transplantation (HSCT), with an incidence rate of 8 percent to 15 percent. Diagnoses of VOD range in severity from what has been classically defined as a disease limited to the liver (mild) and reversible, to a severe syndrome associated with multi-organ dysfunction or failure and death. Patients treated with HSCT who develop VOD with multi-organ failure face an immediate risk of death, with a mortality rate of more than 80 percent when only supportive care is used. The applicant asserts that Defitelio® improves the survival rate of patients with VOD with multi-organ failure by 23 percent.

VOD is believed to be the result of endothelial cell damage and hepatocellular injury from high-dose conditioning regimens administered prior to receiving treatment with HSCT. Preclinical data suggest that Defitelio® stabilizes endothelial cells by reducing endothelial cell activation and by protecting endothelial cells from further damage. Defitelio® is administered as a 2-hour intravenous infusion every 6 hours for a minimum of 21 days. The recommended dosage is 6.25 mg/kg body weight (25mg/kg/day). If after 21 days the signs and symptoms associated with hepatic VOD are not resolved, the administration of Defitelio® should be continued until clinical resolution.

In the proposed rule, we noted that the applicant had applied for a unique ICD–10–PCS procedure code to identify the use of Defitelio®. In this final rule, we note that the new ICD–10–PCS procedure codes XW03392 (Introduction of defibrotide sodium anticoagulant into peripheral vein, percutaneous approach) and XW04392 (Introduction of defibrotide sodium anticoagulant into central vein, percutaneous approach) were established in New Technology Group 2 as shown in Table 6B (New Procedure Codes) and will uniquely identify procedures involving the Defitelio® technology. More information on this

request and the approval can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-MeetingMaterials.html* and the FY 2016 New ICD–10–PCS Codes can be found at the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html*.

As stated in the proposed rule, with regard to the newness criterion, according to the manufacturer, Defitelio® received FDA approval on March 30, 2016. We subsequently learned that Defitelio® was granted Orphan Drug Designation for the treatment of VOD in 2003 and for the prevention of VOD in 2007. It has been available to patients as an investigational drug through an expanded access program since 2007. The applicant's New Drug Application (NDA) for Defitelio® received FDA approval on March 30, 2016.

After the proposed rule was issued and after further analysis, we recognized that Defitelio® may no longer be considered ''new'' due to the drug's prior Orphan Drug Designation and availability through an expanded access program. The regulations at § 412.87(b)(2) state that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of this section. As we have indicated in the past, we generally believe that the newness period begins on the date that FDA approval is granted. The FDA approval date is typically the date when new technologies are available on the market and as a result begin to be reflected within the MS–DRGs cost data. As noted above, Defitelio® was first granted Orphan Drug Designation by the FDA in 2003.

The applicant verified that it did not recover the costs of making Defitelio® available under its 2003 Orphan Drug Designation or through its 2007 FDA grant of expanded access. Therefore, the applicant asserted that because cost recovery did not occur until after the NDA approval on March 30, 2016, the drug was not included in the data used to calculate the DRG relative weights, and it is inappropriate to consider prior availability of the drug as constituting an FDA approval in the context of the newness criterion. As we discuss in section II.H.4. and in our discussion of Voraxaze included in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53348), the period of newness does not necessarily start with the FDA approval date for the medical service or technology or the issuance of a distinct procedure code. Instead, the newness period begins with the date of availability of the product on the U.S. market, which is when data become available. The applicant confirmed that Defitelio® was not available on the U.S. market as of the FDA NDA approval date of March 30, 2016, which we believed to be the start of the newness period in the proposed rule. According to the applicant, commercial packaging could not be completed until the label for Defitelio® was finalized with FDA approval, and that commercial shipments of Defitelio® to hospitals and treatment centers began on April 4, 2016. We agree that, based on this information, the newness period for Defitelio® begins on April 4, 2016, the date of its first commercial availability.

As discussed earlier, if a technology meets all three of the criteria for substantial similarity, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether the product uses the same or similar mechanism of action to achieve a therapeutic outcome, in the proposed rule, we stated that the applicant maintained that Defitelio® has a unique mechanism of action that is not shared by any other drug on the market used to treat patients diagnosed with VOD with multi-organ failure. According to the applicant, there are no FDA-approved treatments for VOD other than supportive care. Anticoagulants such as heparin, antithrombin, and tissue plasminogen factor have been used to treat patients diagnosed with VOD, but there is a lack of conclusive evidence that these treatments are effective and they also present a high risk of bleeding. The applicant maintained that Defitelio® addresses the underlying pathology of VOD with evidence of multi-organ failure and its use is effective as a treatment for this form of the disease. According to the applicant, it is speculated that the mechanism of action of the Defitelio® revolves around the stabilization of endothelial cells because endothelial cell damage is believed to be a major contributing factor to the development of VOD. However, we stated in the proposed rule that we were concerned that this mechanism of action is not well understood by the manufacturer and we are unable to determine whether Defitelio® is substantially similar to the other drugs on the market without full understanding of its distinct mechanism of action.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, in the proposed rule, we stated that the applicant maintained that cases potentially eligible for treatment using Defitelio® and representing the target patient population mainly group to two MS–DRGs: MS–DRG 014 (Allogeneic Bone Marrow Transplant) and MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC). We believe that these are the same MS–DRGs that identify cases of patients treated with supportive care for VOD with multi-organ failure.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, in the proposed rule, we stated that the applicant asserted that there are no FDA-approved treatments for VOD other than supportive care, such as dialysis or ventilation. In addition, the applicant stated that poor outcomes have been reported for patients treated with non-approved pharmacological treatments for VOD. These treatments have largely been discontinued because of the high incidence of hemorrhagic complications, particularly among patients diagnosed with multi-organ failure. According to the applicant, Defitelio® would be the first and only FDA-approved treatment for VOD with evidence of multi-organ failure. However, we stated our concern that the applicant did not include in its application data comparing the outcomes of patients treated with Defitelio® to outcomes of patients treated only for supportive care. We also stated in the proposed rule that we were concerned that Defitelio® may not produce outcomes that are significantly different than the outcomes of patients treated with supportive care.

We invited public comments on whether Defitelio® is substantially similar to existing technologies and whether it meets the newness criterion.

Comment: With regard to our concern that we cannot determine whether Defitelio® is substantially similar to other technologies without a full understanding of its mechanism of action, the applicant provided additional information about the

pathophysiology of VOD and how it is addressed by Defitelio®'s dual mechanism of action consisting of: (1) Endothelial cell protection and stabilization, and (2) enhancement of plasmin enzymatic activity to restore thrombo-fibrinolytic balance. According to the applicant, this two-pronged mechanism of action sets Defitelio® apart from supportive care agents available to treat VOD with multi-organ failure.

The applicant described the damage, detachment, and death of endothelial cells as triggered first by conditioning chemotherapy and/or radiotherapy, a necessary part of the HSCT conditioning regimen, and then by complications related to the HSCT procedure itself. The applicant asserted that progressive deterioration of endothelial cells results in tissue damage characteristic of VOD with multi-organ failure. In particular, clots form at the site of endothelial cell damage and obstruct small veins in the liver. The hepatocellular necrosis and vascular occlusion resulting from endothelial cell damage ultimately leads to liver, pulmonary, and renal failure which can culminate in death.

The applicant provided additional information from numerous clinical studies that demonstrate Defitelo®'s robust and reproducible ability to protect endothelial cells from cell damage, particularly from chemotherapy-induced cell death, as well as its ability to restore the thrombo-fibrinolytic balance, improving blood circulation. The applicant reiterated that Defitelio® is the only FDA-approved treatment for VOD with multi-organ failure and that, prior to this approval, patients only received supportive care. While supportive care agents with anti-coagulant activity are available, they do not have the unique dual mechanism of action that Defitelio® possesses, nor have they been proven to be effective in the treatment of VOD with multi-organ failure.

With regard to our concern that cases eligible for Defitelio® would be assigned to the same MS–DRGs that identify cases of patients treated with supportive care for VOD with multi-organ failure, the applicant noted that, prior to NDA approval of Defitelio®, patients with VOD with multi-organ failure would have received supportive care alone because there were no FDA-approved treatments for VOD. As a result, there are no charges for VOD treatment in MS–DRG 014, MS–DRG 016, or any other MS–DRG to which cases eligible for Defitelio® would map.

With regard to our concern that the applicant did not include in its application data comparing the outcomes of patients treated with Defitelio® to outcomes of patients treated only with supportive care and that Defitelio® may not produce outcomes that are significantly different than the outcomes of patients treated with supportive care, the applicant clarified that it did include such studies, including the Phase 3 Study #2005–01, which enabled a comparison of Defitelio® versus supportive care alone and demonstrated the statistically and clinically significant benefit of Defitelio® over supportive care. The results of Study #2005–01 are described below in our discussion of whether Defitelio® meets the substantial clinical improvement criterion.

Response: We appreciate the applicant's input and the detailed explanation of Defitelio®'s mechanism of action and the pathophysiology of VOD with multi-organ failure. We acknowledge that, as the only FDA-approved treatment for VOD with multi-organ failure, the applicant believed there are no charges for VOD treatment in the MS–DRGs claims data. We also acknowledge that the applicant submitted data from the Phase 3 Study #2005–01 to demonstrate that the improved outcomes among patients treated with Defitelio® compared to patients treated only with supportive care are statistically significant and valid. After considering the additional information submitted by the applicant, we have determined that Defitelio® is not substantially similar to any other technologies currently on the U.S. market for the treatment of VOD with multi-organ failure, and we agree that Defitelio® meets the newness criterion.

With regard to the cost criterion, in the proposed rule, we stated that the applicant conducted sensitivity analyses using claims data from 2012 through 2014 and determined the results in aggregate and by year. The applicant researched 100 percent of the 2012 through 2014 Inpatient Standard Analytic Files (SAFs) for cases eligible for Defitelio®. Because an ICD–9–CM code specific to treatment for VOD does not exist, the applicant used an algorithm to identify cases to use in its sensitivity analyses. The most appropriate ICD–9–CM diagnosis codes were identified based on clinical criteria used to diagnose VOD and were used to identify cohorts of patients diagnosed with VOD and VOD with multi-organ dysfunction. The applicant first identified claims with an ICD–9–CM procedure code indicating an HSCT (Group A) within a 30-day window; VOD most commonly occurs after receipt of HSCT. The applicant then looked for cases with ICD–9–CM diagnosis codes related to liver injury (Group B) or clinical evidence of suspected VOD symptoms based on at least two relevant ICD–9 diagnosis codes (Group C). Lastly, the applicant filtered out cases that did not show clinical evidence of multi-organ dysfunction based on at least one relevant ICD–9–CM code (Group D).

The applicant submitted the following table indicating the ICD–9–CM codes used for each category of the algorithm.

TABLE SUBMITTED BY APPLICANT: ICD–9 CODES USED FOR THE PREMIER VOD ALGORITHM

Group	Title	ICD–9–CM code	Description
A	Hematopoietic Stem Cell Transplant (HSCT) (at least one code).	41.00	Bone marrow transplant, not otherwise specified.
		41.01	Autologous bone marrow transplant without purging.
		41.02	Allogeneic bone marrow transplant with purging.
		41.03	Allogeneic bone marrow transplant without purging.
		41.04	Autologous hematopoietic stem cell transplant without purging.
		41.05	Allogeneic hematopoietic stem cell transplant without purging.
		41.06	Cord blood stem cell transplant.
		41.07	Autologous hematopoietic stem cell transplant with purging.
		41.08	Allogeneic hematopoietic stem cell transplant.
		41.09	Autologous bone marrow transplant with purging.

TABLE SUBMITTED BY APPLICANT: ICD–9 CODES USED FOR THE PREMIER VOD ALGORITHM—Continued

Group	Title	ICD–9–CM code	Description
B	Liver Injury (at least one code)	453.xx	Other venous embolism and thrombosis.
		570.xx	Acute and subacute necrosis of liver.
		573.8	Other specified disorders of liver.
		573.9	Unspecified disorder of liver.
		459.89	Other specified disorders of the circulatory system.
		277.4	Disorders of bilirubin excretion.
C	VOD Symptoms (at least two codes)	782.4	Hyperbilirubinemia.
		789.1	Hepatomegaly.
		783.1	Abnormal weight gain.
		789.5	Ascites.
D	Multi-Organ Dysfunction (at least one code).	518.8x	Acute/Chronic Respiratory Failure.
		786.09	Other respiratory abnormalities (respiratory distress, except that associated with trauma/surgery in adults, or with RDS in newborns).
		799.02	Hypoxemia.
		518.81	Acute respiratory failure.
		V46.2	Other dependence on machines, supplemental oxygen.
		96.7x	Other continuous invasive mechanical ventilation.
		93.90, 93.91, 93.93, 93.99.	Non-invasive mechanical ventilation.
		584.X	Acute renal failure.
		586.X	Renal failure unspecified.
		593.9	Renal Failure.
		39.27, 39.42, 39.95, 54.98.	Dialysis, including hemodialysis, peritoneal dialysis, hemofiltration.

Using the above algorithm, the applicant identified a total of 267 patient cases of VOD with multi-organ dysfunction in the 2012–2014 Inpatient SAFs, with 78 patient cases in 2012, 102 patient cases in 2013, and 87 patient cases in 2014, or an average annual patient case volume of 89. The applicant determined that these cases grouped mainly into two MS–DRGs: 014 and 016. The applicant noted that there were no cases in the data from MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC). The applicant further noted that there were no cases from MS–DRG 017 because the ICD–9–CM codes identifying VOD with multi-organ dysfunction include serious medical conditions that are listed on the MCC and CC lists. In total, 38 MS–DRGs were represented in the patient cohort, with 27 percent of cases mapping to MS–DRG 014 and 42 percent of cases mapping to MS–DRG 016. The remaining cases mapped to 1 of the 36 remaining MS–DRGs with fewer than 11 cases.

For results in the aggregate, the applicant calculated an average case-weighted charge per case of $427,440 across 267 cases representing diagnoses of VOD with multi-organ dysfunction from 2012 through 2014. The applicant assumed there would be a reduction in the use of selected drugs as a result of using Defitelio® and removed 50 percent of the estimated charges for heparin, furosemide, and spironolactone. The charges for these drugs were estimated based on pricing taken from the Medispan PriceRx database, whose costs were marked up according to the inverse of CCRs from cost center 07300 (Drugs Charged to Patients) obtained from providers' 2012, 2013, and 2014 cost reports. The applicant matched these CCRs with the provider numbers on each claim. The applicant removed an average of $2,631 in charges for these drugs from the overall unstandardized charges for Defitelio®.

The applicant then standardized the charges and calculated an average standardized case-weighted charge per case of $310,651. To update the charge data to the current fiscal year, the applicant inflated the charges based on the charge inflation factor of 1.048116 in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49779). The 1-year inflation factor was applied four times to FY 2012 claims, three times to FY 2013 claims, and twice to FY 2014 claims to inflate all charges to 2016. The applicant computed an inflated average standardized case-weighted charge per case of $356,015. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $157,951 (all calculations above were performed using unrounded numbers). Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion. The applicant noted that it did not include charges for Defitelio® in the inflated average standardized case-weighted charge per case because the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold amount without charges for Defitelio®.

The applicant provided a similar analysis for each individual year of the SAF data rather than combining all the data from all 3 years into one analysis. Under the other three analyses, the applicant noted that the average standardized case-weighted charge per case exceeded the average case-weighted threshold amount (as shown in the table below) without inflating the charges and without adding any charges for Defitelio®.

SAF Year	Average case-weighted threshold amount	Average standardized case-weighted charge per case
2012	$161,469	$347,910
2013	150,585	326,445

SAF Year	Average case-weighted threshold amount	Average standardized case-weighted charge per case
2014	163,434	404,883

We invited public comments on whether Defitelio® meets the cost criterion in the proposed rule.

Comment: The applicant submitted a technical correction to update its cost criterion analysis. According to the applicant, the 1-year inflation factor from the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24632) was used in the sensitivity analysis included in its application instead of the 1-year inflation factor from the FY 2016 IPPS/LTCH PPS final rule (80 FR 49784). The applicant maintained that, in the revised sensitivity analysis with the updated inflation factor, the average standardized case-weighted charge per case for the applicable MS–DRGs exceeded the average case-weighted threshold amount without adding any charges for Defitelio®. In the applicant's initial analysis using the 1-year inflation factor of 1.048116 from the proposed rule, the average standardized case-weighted charges exceeded the average case-weighted MS–DRG thresholds by an average of $200,323. After applying the updated inflation factor of 1.037616, the average standardized case-weighted charges exceeded the average case-weighted MS–DRG thresholds by an average of $187,776 before adding charges for Defitelio®. The 1-year inflation factor was applied four times for 2012 claims, three times for 2013 claims, and two times for 2014 claims in order to compare 2012 through 2014 claims data to the FY 2016 IPPS/LTCH PPS final rule thresholds.

Response: We appreciate the applicant submitting the additional information. After reviewing the sensitivity analysis included in the original application and subsequent analysis included in the applicant's public comment, we have determined that the Defitelio® meets the cost criterion.

With regard to the substantial clinical improvement criterion, in the proposed rule, we stated that the applicant maintained that Defitelio® is an effective treatment for VOD as an early onset cause of mortality following HSCT. According to the applicant, patients treated with Defitelio® have improved survival and efficacy rates compared to patients who were not treated with Defitelio®. In increasing the chances of post-HSCT survival, Defitelio® affords the transplant patient the opportunity for engraftment, which could be a potential cure for the underlying disease that required HSCT.

The applicant supported these assertions with clinical evidence from pivotal trial 2005–01, a Phase III historical control study in which patients with VOD with multi-organ failure were given Defitelio® in doses of 25/mg/kg/day for the recommended minimum treatment duration of 21 days. Patients in the historical control group were selected by an independent medical review committee (MRC) from a pool of 6,867 medical charts of patients receiving HSCT that were hospitalized from January 1995 through November 2007. The trial consisted of 102 patients in the Defitelio® treated group and 32 patients in the historical control group. The trial used the survival rate and rate of Complete Response (CR) at Day+100 as clinical endpoints. The observed survival rate at Day+100 in the Defitelio® treated group was 38.2 percent compared to 25 percent in the historical control group. Moreover, the rate of CR by Day+100 post-HSCT for the Defitelio® treated group was 25.5 percent compared to 12.5 percent in the historical control group. The applicant conducted additional analyses that showed improvements in survival outcomes among subgroups of patients with baseline prognostic factors related to worse outcomes.

According to the applicant, running a controlled, blinded, and randomized trial in a patient population with high mortality rates would be unethical. We stated in the proposed rule that we are concerned that there are limitations to the historical control group used in pivotal trial 2005–01. We stated that we believe that the discrepancy between the size of the treatment group (N=102) and the historical control group (N=32) may skew the trial results in favor of the treatment group. We also were uncertain, given the small sample size and historical data used, whether the historical control group is representative of patients with VOD with multi-organ failure. According to the applicant, patients in the historical control group were hospitalized between January 1995 and November 2007. Because of advancements in medicine within this timeframe, we were concerned that the patients in the historical control group cannot be appropriately compared to patients in the treatment group. Moreover, we stated that we believe that it is difficult to attribute improved survival and CR rates only to Defitelio® treatment.

We invited public comments on whether Defitelio® meets the substantial clinical improvement criterion in the proposed rule.

Comment: The applicant submitted public comments in response to CMS' concerns presented in the proposed rule, which asserted that the small sample size and nonrandomized trial design of Study #2005–01 is due to the rarity of conditions that require HSCT and the low incidence of severe VOD in patients who have undergone HSCT. In addition to the difficulty of enrolling large numbers of patients in any study of VOD, the high overall mortality rate among patients who develop VOD with multi-organ failure would make a randomized controlled trial that did not allow use of Defitelio® unethical. For these reasons, the applicant chose a study design with a Historical Control group. The applicant ensured that the Defitelio® treatment (n=102) and Historical Control (n=32) groups were comparable in baseline prognostic variables and disease characteristics using a propensity score adjustment based on baseline prognostic factors of survival. The applicant also ensured that the rate of VOD with multi-organ failure observed among patients screened for the Historical Control group in Study #2005–01 was consistent with overall incidence expected and validated from other sources. According to the applicant, the overall incidence of severe VOD in the screened population is estimated to be 1.5 percent, which was comparable to the incidence of 1.3 percent in an independent registry. Overall, the applicant stated that the incidence of VOD with multi-organ failure remains similar across diverse populations, indicating not only a consistently low incidence, but also that the Historical Control group for Study #2005–01 was representative of VOD with multi-organ failure.

With regard to our concern that patients in the Historical Control group cannot be appropriately compared to treatment group patients because of advancements in medicine within the timeframe of the patients in the

historical control group, the applicant asserted that medical advances have only lowered the incidence of VOD with multi-organ failure but have not improved the highly lethal outcome of the disease once it develops. The applicant asserted that increasing utilization of reduced-intensity conditioning regimens have led to a reduction in the incidence of VOD over time; however, they do not improve outcomes for those patients who develop VOD with multi-organ failure. The clinical pattern of VOD following HSCT and its high mortality rate of over 80 percent are the same, regardless of the conditioning regimen the patient receives. The applicant reported that during the period of Study #2005–01, there were no improvements in the treatment of VOD once multi-organ failure developed. Although Defitelio® was available as an orphan drug beginning in 2003, it did not have enough distribution to impact mortality. The Historical Control patients were treated in a functionally similar timeframe to the Defitelio® treatment patients and received similar care with the key exception of the availability of Defitelio® for the treatment group.

Finally, the applicant cited a recently published study describing Study #2005–01, which concluded that Defitelio® use in patients with VOD with multi-organ failure post-HSCT is associated with a 23 percent improvement in survival at Day+100 post-HSCT, as well as a clinically meaningful improvement in the rate of Complete Response by Day+100 compared with the Historical Control.[15] In this respect, the applicant maintained that Defitelio® provides a promising treatment option for patients with a high unmet medical need.

Response: We appreciate the applicant's submittal of the additional information and the explanation of the reasons behind the study design that was chosen. We acknowledge the limitations due to the small population of patients with VOD with multi-organ failure and the high mortality rate of patients who develop the disease and that a Historical Control group is appropriate for purposes of the Phase III trial. We also acknowledge the appropriateness of using propensity scoring to ensure a balanced patient population between the Defitelio® treatment group and Historical Control group and the statistically and clinically significant results of Study #2005–01, which demonstrate that the Defitelio® treated group experienced better survival and complete response rates compared to patients in the Historical Control group.

Comment: One commenter concurred with the applicant that Defitelio® meets the substantial clinical improvement criterion. The commenter cited the pivotal trial for Study #2005–01, which demonstrates that treatment with Defitelio® is associated with higher incidence of VOD resolution and survival than what was observed in a historically controlled cohort of patients with VOD with multi-organ failure.[16] The commenter asserted that, over the past two decades, many supportive care agents have been used to treat VOD with multi-organ failure but that none have been successful in demonstrating superior survival. The commenter reported that, given that supportive care agents have led to disappointing results and that there are no other FDA-approved treatments for VOD with multi-organ failure, Defitelio® is now universally accepted as the only treatment for VOD currently available and should therefore be made available for patients who need it.

Response: We agree with the commenter that Defitelio® represents a substantial clinical improvement over existing technologies in a patient population diagnosed with VOD with multi-organ failure. In particular, we concur with the applicant and the commenter that, because Defitelio® is the only FDA-approved treatment for VOD with multi-organ failure, it represents a substantial clinical improvement for patients afflicted with this disease, whose alternatives include supportive care agents that have not demonstrated improved survival or complete response rates.

After consideration of the public comments we received, we have determined that the Defitelio® meets all of the criteria for approval of new technology add-on payments. Therefore, we are approving new technology add-on payments for Defitelio® for FY 2017. Cases involving Defitelio® that are eligible for new technology add-on payments will be identifiable by ICD–10–PCS procedure codes XW03392 and XW04392.

In its application, the applicant estimated that the average Medicare beneficiary would require a dosage of 25 mg/kg/day for a minimum of 21 days of treatment. The recommended dose is 6.25 mg/kg given as a 2-hour intravenous infusion every 6 hours. Dosing should be based on a patient's baseline body weight, which is assumed to be 70 kg for an average adult patient. All vials contain 200 mg at a cost of $825 per vial. Therefore, we have determined that cases involving the use of the Defitelio® technology would incur an average cost per case of $151,800 (70 kg adult × 25 mg/kg/day × 21 days = 36,750 mg per patient/200 mg vial = 184 vials per patient × $825 per vial = $151,800). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of Defitelio® is $75,900 for FY 2017.

f. GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE)

W. L. Gore and Associates, Inc. submitted an application for new technology add-on payments for the GORE® EXCLUDER® Iliac Branch Endoprosthesis (GORE IBE device) for FY 2017. The device consists of two components: The Iliac Branch Component (IBC) and the Internal Iliac Component (IIC). The applicant indicated that each endoprosthesis is pre-mounted on a customized delivery and deployment system allowing for controlled endovascular delivery via bilateral femoral access. According to the applicant, the device is designed to be used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis for the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. When deployed, the GORE IBE device excludes the common iliac aneurysm from systemic blood flow, while preserving blood flow in the external and internal iliac arteries.

With regard to the newness criterion, the applicant received pre-market FDA approval of the GORE IBE device on February 29, 2016. The applicant submitted a request for a unique ICD–10–PCS procedure code and was granted approval for the following procedure codes: 04VC0EZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, open approach); 04VC0FZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, three or more arteries, open approach); 04VC3EZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach); 04VC3FZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, three or more

[15] Richardson PG, Riches M, Kernan NA, Brochstein JA, Mineishi S, Termuhlen AM, Phase 3 trial of defibrotide for the treatment of severe veno-occlusive disease and multi-organ failure. Blood. 2016 Mar 31;127(13)1656–65.

[16] Richardson et al. 2016.

arteries, percutaneous approach); 04VC4EZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach); 04VC4FZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, three or more arteries, percutaneous endoscopic approach); 04VD0EZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, one or two arteries, open approach); 04VD0FZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, three or more arteries, open approach); 04VD3EZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach); 04VD3FZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, three or more arteries, percutaneous approach); 04VD4EZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous endoscopic approach); and 04VD4FZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, three or more arteries, percutaneous endoscopic approach). These new ICD–10–PCS procedure codes are effective on October 1, 2016.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant indicated that the GORE IBE device is based on the same design principles as other endovascular repair devices, and its use differs because of the specific target site for implantation. Consequently, it has a different shape and method of delivery from other endovascular devices. The GORE IBE device is similar to the GORE® EXCLUDER® AAA Endoprosthesis, primarily differing in device dimensions to fit within the iliac artery anatomy. With regard to the first criterion, we expressed concern in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25058) that the GORE IBE device has a similar mechanism of action to other stenting grafts used to treat patients with abdominal aortic aneurysms (AAAs) because it repairs the abdominal aortoiliac aneurysm from the inside and is inserted in a similar manner to other abdominal aortoiliac endovascular aneurysm repair devices.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant indicated that cases using the GORE IBE device would map to the same MS–DRGs as cases involving other stent-grafts used to treat patients with AAAs. Specifically, similar to cases involving other stent-grafts used to treat AAAs, cases involving the GORE IBE device would be assigned to MS–DRG 268 (Aortic and Heart Assist Procedures except Pulsation Balloon with MCC) and MS–DRG 269 (Aortic and Heart Assist Procedures except Pulsation Balloon without MCC).

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant indicated that the GORE IBE device is intended to be used in the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. The applicant stated that this device, if approved, would be the first purpose-built endovascular device for patients whose conditions (common iliac or aortoiliac aneurysm) put them at risk for negative clinical outcomes due to limitations of current treatment methods, which may not preserve internal iliac artery perfusion. The applicant described current repair options for these patients as: (a) Intentional occlusion and coverage of the internal iliac artery; (b) undergoing a more extensive surgical operation to place a bypass graft; or (c) use of combinations of devices in a nonindicated, variable, and inconsistent manner. With regard to the third criterion, we expressed concern that this device appears to treat a similar type of disease to existing stent grafts.

Based on the statements above, the applicant maintained that the GORE IBE device is not substantially similar to other stent-grafts used to treat patients with AAAs. In the FY 2017 IPPS/LTCH PPS proposed rule, (81 FR 25057 through 25059), we invited public comments on whether the GORE IBE device is substantially similar to existing technologies and whether the technology meets the newness criterion.

Comment: The manufacturer of the GORE IBE device commented that several characteristics of the GORE IBE demonstrate that the technology is new, including differentiated delivery mechanisms to allow for effective use in the specific anatomy, use of a technique specific to the iliac bifurcation, facilitation of a unique approach not necessary in other areas of the aortic anatomy, and allowance for the only dedicated and on-label treatment of iliac aneurysms. The manufacturer indicated that the GORE IBE device received premarket approval on February 29, 2016.

With respect to the mechanism of action, the manufacturer indicated that all FDA-approved endovascular aneurysm repair (EVAR) devices designed to treat AAAs share the same fundamental mechanism of action, but that devices must be specifically designed to address anatomical constraints and specific pathophysiology. Another commenter also indicated that the GORE IBE differs from standard EVAR in that it is a bifurcated graft that requires increased work to deploy.

Response: We appreciate the additional information provided to us by the manufacturer and the other commenter. After reviewing the comments, we believe that the GORE IBE is a treatment option for a new patient population because it is the first stent-graft in its class for patients with iliac branch involvement. As a result, there is no other device to which to compare its mechanism of action because the GORE IBE is unique to the patient population that it is approved for use by the FDA. Therefore, the GORE IBE is not substantially similar to any existing technologies because it does not meet all three of the substantial similarity criteria.

After consideration of the public comments we received, we believe that the GORE IBE device meets the newness criterion, and we consider the technology to be ''new'' as of February 29, 2016, the date that the GORE IBE device received premarket approval.

With regard to the cost criterion, the applicant researched the FY 2014 MedPAR claims data to identify patients who may be eligible for treatment using the GORE IBE device. The applicant noted that cases eligible for the GORE IBE device would map to MS–DRGs 268 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC) and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC). The applicant provided two analyses. The first analysis searched for cases that may be potentially eligible for the GORE IBE device by identifying cases with endovascular aneurysm repair (EVAR) with iliac diagnoses. To identify these cases, the applicant searched for cases that had an ICD–9–CM primary procedure code of 39.71 (Endovascular implantation of other graft in abdominal aorta) in combination with a primary diagnosis code of 441.4 (Abdominal aneurysm without mention

of rupture) or 441.02 (Dissection of aorta, abdominal). The applicant excluded cases with a diagnosis code of 441.3 (Abdominal aneurysm, ruptured), and cases with atherosclerosis of the lower extremities (ICD–9–CM diagnosis code 440.20 through 440.28). The applicant then identified a subset of cases (1,615 cases) with significant iliac involvement (which indicated use of the prior technology as well as disease extent where the new technology could be used) by searching for cases with a secondary ICD–9–CM diagnosis code of 442.2 (Aneurysm of iliac artery) or 443.22 (Dissection of iliac artery). This subset of cases was used in the analysis with 205 cases that mapped to MS–DRG 268 and 1,410 cases that mapped to MS–DRG 269. As discussed below, the remaining cases (11,926 cases) were used to help evaluate and compare subsequent offset charge calculations (base EVAR cases).

Using the 1,615 cases, the applicant calculated an average unstandardized case-weighted charge per case of $121,527. Charges for the prior technology (implants), which would be offset by the new technology were established by subtracting the average implant charge in the 1,615 cases from the average implant charge in the base EVAR sample. The excess implant charge represents current implant charges being used in EVAR cases with iliac involvement, and was subtracted from the average unstandardized case-weighted charge per case.

The applicant compared the average unstandardized O.R. and radiology charges associated with the new technology from the clinical trial data with the unstandardized OR and radiology charges associated with the prior technology from the MedPAR data and noted that O.R. and radiology charges for resources related to the new technology and the prior technology were similar. However, with regard to charges in the intensive care unit (ICU), there was a reduction of 56 percent in ICU associated charges for the new technology. Therefore, the applicant offset the ICU associated charge by 56 percent and deducted this amount from the average unstandardized case-weighted charge per case. The applicant then standardized the charges, but noted that it did not inflate the charges. The applicant added charges for the GORE IBE device by converting the costs of the device to charges using the average CCR for implantable devices (0.337) as reported in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49429). The applicant noted that the cost of the technology was proprietary information. Based on the FY 2016 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $109,241. The applicant computed an average standardized case-weighted charge per case of $124,129. Because the average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

The second analysis was similar to the first analysis, but searched the MedPAR claims data file for cases with an EVAR with an iliac diagnosis and procedure instead of cases with EVAR and only an iliac diagnosis. The applicant used the same ICD–9–CM procedure and diagnoses codes as used in the first analysis, but used the following ICD–9–CM procedure codes to identify cases that had an iliac procedure: 39.79 (Other endovascular procedures on other vessels) in combination with 39.29 (Other (peripheral) vascular shunt or bypass), 39.79 in combination with 39.90 (Insertion of non-drug-eluting peripheral (non-coronary) vessel stent(s)) without 39.29, 39.90 in combination with 00.41 (Procedure on two vessels), 00.46 (Insertion of two vascular stents), and 00.47 (Insertion of three vascular stents) without 39.79 and 39.29. The applicant noted that the expected distribution of cases for the GORE IBE device is that 20 percent of the cases would map to MS–DRG 268 and 80 percent of the cases would map to MS–DRG 269. Because this analysis represents cases that had an actual iliac procedure, the applicant applied this distribution to the cases. The applicant then followed the same methodology above and removed charges for the prior technology and resources related to the prior technology, standardized the charges, and then added charges related to the GORE IBE device. Based on the FY 2016 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $113,015. The applicant computed an inflated average standardized case-weighted charge per case of $138,179. Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

With regard to the second analysis, the applicant imputed the distribution of cases. We indicated that we were not sure how the applicant determined which cases would map to MS–DRG 268 or MS–DRG 269, if the distribution was imputed. Also, the applicant did not disclose how many cases were found in the claims data after filtering the case volume using ICD–9–CM procedure codes identifying cases that had an iliac procedure. We invited public comments on whether the GORE IBE device meets the cost criterion, including with regard to the concerns we raised in the proposed rule.

Comment: The manufacturer of the GORE IBE device clarified the basis for the assumption regarding the DRG distribution of cases involving the IBE. According to the manufacturer, its analysis utilized a sample of 100 cases where a combination of the ICD–9 procedure and diagnosis codes strongly suggested the use of current alternative methods, that is, physician-developed methods, for preservation of internal iliac flow in conjunction with EVAR. The manufacturer reported that 80 percent were in the No MCC severity level, while 20 percent were in the MCC severity level. The manufacturer also examined a more conservative distribution of all EVAR cases, in which it found 87 percent with no MCC, and 13 percent with MCC. The manufacturer indicated that, using the conservative assumption, the threshold was still met.

Response: We appreciate the manufacturer's clarification of the basis for the assumption regarding the MS–DRG distribution of cases. After consideration of the public comments we received, we believe that the GORE IBE meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant indicated that current treatment approaches have substantial risks of complications that can negatively impact quality of life. Available treatment methods that do not preserve internal iliac artery perfusion increase risks for negative clinical outcomes; compared to methods that preserve the internal iliac artery, those that use contralateral hypogastric embolization result in a higher incidence of buttock claudication (15—55 percent), sexual dysfunction (5—45 percent), ischemia of the colon (2.6 percent), and rarely, ischemia of the spine. The applicant cited the ''12–04'' study,[17] which the applicant suggested showed the GORE IBE device to have 0 percent rates of buttock claudication, new onset erectile dysfunction, colonic ischemia, and spinal cord ischemia. The applicant also suggested that the 12–04 study showed the GORE IBE device to have reduced procedure time, reduced fluoroscopy time, reduced reintervention rates, and increased patency rates. The applicant

[17] DeRubertis BG, Quinones-Baldrich WJ, Greenberg JI, Jimenez JC, Lee JT. Results of a double-barrel technique with commercially available devices for hypogastric preservation during aortoilac endovascular abdominal aortic aneurysm repair. J Vasc Surg 2012;56:1252–1259.

asserted that because the GORE IBE device preserves flow to the internal iliac artery, the risk of complications is reduced, which represents a substantial clinical improvement relative to current treatment approaches. The applicant also stated that, compared with historical data for procedures done using contralateral hypogastric embolization, the GORE IBE device is associated with reduced procedure time, reduced fluoroscopy time, reduced reintervention rates, reduced incidence of aneurysm enlargement, and improved patency rates.

The applicant submitted several research articles with its application, which consisted of a few very small case series of 23 total patients published [18] [19] [20], as well as some abstracts of other case series. These publications describe the procedural results of using the device, with angiographic endpoints, and demonstrate the feasibility of insertion. The applicant also indicated that other treatment approaches, including open surgery, are done infrequently, while other approaches are not approved for this purpose. Therefore, the applicant indicated that it would be impractical to conduct comparative studies.

After reviewing the information provided by the applicant, we stated in the proposed rule that we have the following concerns: We stated that we were concerned about the lack of clinical studies comparing the GORE IBE device with alternative methods of treatment, and noted that the application did not provide data that supported its assertions that the GORE IBE device is associated with reduced procedure time, reduced fluoroscopy time, reduced reintervention rates, reduced incidence of aneurysm enlargement, and improved patency rates. We also noted that the applicant's assertions about decreased rates of complications appear to compare a small number of published cases of the use of the GORE IBE device with complication rates cited in the literature, which does not indicate whether there is a valid basis for comparison. We invited public comments on whether the GORE IBE device meets the substantial clinical improvement criterion in the proposed rule.

Comment: The manufacturer of the GORE IBE device indicated that the FDA-approved study design was appropriate and reflected real-world limitations associated with clinical studies in small, targeted populations. The manufacturer also noted that it was impractical to incorporate off-label alternatives, and that the surgical alternative is not preferred; therefore, neither of these approaches could be used as a comparison arm. However, the manufacturer provided an abstract of the IBE pivotal trial, described in the June 2016 supplement to the *Journal of Vascular Surgery,* which included a built-in control subgroup consisting of those patients that had bilateral aneurysms.[21] According to the manufacturer, these patients received the IBE device on one side, while flow on the other side was either sacrificed via coil or plug, or preserved with surgical bypass. Of the 21 patients in which the flow was sacrificed on one side, 29 percent experienced new-onset claudication on the side where the flow was sacrificed. There were no reports of claudication on the IBE treatment side. The manufacturer stated that this finding supports the benefit of flow preservation.

Another commenter also referred to a Society for Vascular Surgery practice guideline which described the importance of preserving internal iliac flow on at least one side, which supports the benefit of the GORE IBE device in improving quality of life. Another commenter supported the approval of a new technology add-on payment for the GORE IBE in that it allows for higher quality of care and improved quality of life.

Response: We appreciate the manufacturer's explanation of the built-in control subgroup, and we agree that this group represents a good comparison group for the GORE IBE device. We believe that the information presented by the manufacturer and other commenters demonstrates that the GORE IBE device represents a substantial clinical improvement over current treatment approaches.

After consideration of the public comments we received, we have determined that the GORE IBE device system meets all of the criteria for approval of new technology add-on payments for FY 2017. As discussed above, cases involving the GORE IBE device that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes: 04VC0EZ; 04VC0FZ; 04VC3EZ; 04VC3FZ; 04VC4EZ; 04VC4FZ; 04VD0EZ; 04VD0FZ; 04VD3EZ; 04VD3FZ; 04VD4EZ; and 04VD4FZ. In its new technology add-on payment application, the applicant stated that the projected cost of the GORE IBE device is $10,500. Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of the GORE IBE device is $5,250 for FY 2017.

g. Vistogard™ (Uridine Triacetate)

BTG International Inc., submitted an application for new technology add-on payments for the Vistogard™ for FY 2017. Vistogard™ (Uridine Triacetate) was developed as an antidote to Fluorouracil toxicity. Chemotherapeutic agent 5-fluorouracil (5–FU) is used to treat specific solid tumors. It acts upon deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) in the body, as uracil is a naturally occurring building block for genetic material. Fluorouracil is a fluorinated pyrimidine. As a chemotherapy agent, Fluorouracil is absorbed up by cells and causes the cell to metabolize into byproducts that are toxic and used to destroy cancerous cells. The byproducts fluorodoxyuridine monophosphate (F–dUMP) and floxuridine triphosphate (FUTP) are believed to do the following: Reduce DNA synthesis, lead to DNA fragmentation, and disrupt RNA synthesis. Fluorouracil is used to treat a variety of solid tumors such as colorectal, head and neck, breast, and ovarian cancer. With different tumor treatments, different dosages, and different dosing schedules, there is a risk for toxicity in these patients.

Patients may suffer from fluorouracil toxicity/death if 5–FU is delivered in slight excess or at faster infusion rates than prescribed. The cause of overdose can happen for a variety of reasons including: Pump malfunction, incorrect pump programming or miscalculated doses, and accidental or intentional ingestion.

According to the applicant, current treatment for fluorouracil toxicity is supportive care, including discontinuation of the drug, hydration, filgrastim for neutropenia, as well as antibiotics, antiemetics, and treatments that are required for potential

[18] DeRubertis BG, Quinones-Baldrich WJ, Greenberg JI, Jimenez JC, Lee JT. Results of a double-barrel technique with commercially available devices for hypogastric preservation during aortoilac endovascular abdominal aortic aneurysm repair. J Vasc Surg 2012;56:1252–1259.

[19] Ferrer C, De Crescenzo F, Coscarella C, Cao P. Early experience with the Excluder(R) iliac branch endoprosthesis. J Cardiovasc Surg 2014;55:679–683.

[20] Schönhofer S, Mansour R, Ghotbi R. Initial results of the management of aortoiliac aneurysms with GORE(R) Excluder(R) iliac branched endoprosthesis. J Cardiovasc Surg 2015;56:883–888.

[21] Schneider, D. B., Matsumura, J., Oderich, G. S., Lee, J. T., Peterson, B. G. (2016). Pivotal Results for the Gore Excluder Iliac Branch Endoprosthesis for Treatment of Aortoiliac Aneurysms in the IBE 12–04 Prospective, Multicenter Study. *Journal of Vascular Surgery, 63, 6S.*

gastrointestinal and cardiovascular compromise. Vistogard ™ is an antidote to Fluorouracil toxicity and is a pro-drug of uridine. Once the drug is metabolized into uridine, it competes with the toxic byproduct FUTP in binding to RNA, thus reducing the impact FUTP has on cell death.

With regard to the newness criterion, in the proposed rule, we stated that Vistogard ™ received FDA approval on December 11, 2015. The applicant noted that Vistogard ™ is the first FDA approved antidote used to reverse fluorouracil toxicity. The applicant submitted a request for a unique ICD–10–PCS procedure code and was granted approval for the following procedure code: XW0DX82 (Introduction of Uridine Triacetate into Mouth and Pharynx, External Approach, New Technology Group 2). The new code is effective on October 1, 2016.

Comment: The manufacturer commented that the start of the newness period for Vistogard ™ should be established as March 2, 2016. The manufacturer explained that the FDA approved Vistogard ™ on December 11, 2015 under Priority Review. The manufacturer stated that this approval was granted approximately 3 months earlier than the PDUFA (Prescription Drug User Fee Act) User Fee goal date of March 10, 2016. Commercial availability of Vistogard ™ occurred March 2, 2016 due to the need for receipt of final labeling, contracting manufacturing schedules, and final packaging.

Response: We agree with the commenter that, due to the delay in availability described above, the date the newness period begins for Vistogard ™ is March 2, 2016, instead of December 11, 2015.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether the product uses the same or a similar mechanism of action to achieve a therapeutic outcome, in the proposed rule, we stated that the applicant explained that Vistogard ™ is the first FDA-approved antidote used to reverse fluorouracil toxicity. The applicant maintained that Vistogard ™ has a unique mechanism of action that is not comparable to any other drug's mechanism of action that is currently available on the U.S. market. The applicant described in technical detail how the novel and unique mechanism of action provides bioavailable uridine, a direct biochemical antagonist of 5–FU toxicity; quickly absorbs into the gastrointestinal tract due to its lipophilic nature; in normal cells, stops the process of cell damage and cell destruction caused by 5–FU and counteracts the effects of 5–FU toxicity; protects normal cells and allows recovery from damage caused by 5–FU, without interfering with the primary antitumor mechanism of 5–FU; and uses uridine derived from Vistogard ™ to convert it into uridine triphosphate (UTP), which competes with FUTP for incorporation into RNA, preventing further cell destruction and dose-limiting toxicities.

With regard to the second criterion, whether the product is assigned to the same or a different MS–DRG, in the proposed rule we stated that the applicant noted that Xuriden (uridine triacetate) was also approved by the FDA on September 4, 2015, as a pyrimidine analog for uridine replacement indicated for the treatment of hereditary orotic aciduria (HOA). According to the applicant, HOA is a rare, potentially life-threatening, genetic disorder in which patients (primarily pediatric patients) lack the ability to synthesize adequate amounts of uridine and consequently can suffer from hematologic abnormalities, failure to thrive, a range of developmental delays, and episodes of crystalluria leading to obstructive uropathy. The applicant stated that, although Xuriden is approved as a chronic, once daily medication (not to exceed 8 grams) that is administered orally in the patient's home and also used to replace uridine, Xuriden is not administered in a hospital setting and cases involving the use of Xuriden would not be assigned to the same MS–DRGs associated with the use of Vistogard ™ in the treatment of patients experiencing 5–FU overdose or severe toxicity. Therefore, the applicant maintained that no other technology similar to Vistogard ™ would map to the same MS–DRGs as cases involving the use of Vistogard ™.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, similar to above, in the proposed rule we stated that the applicant maintained that Vistogard ™ is the first FDA approved antidote to reverse fluorouracil toxicity and, therefore, no other technology treats this disease or patient population to reverse fluorouracil toxicity. Therefore, the applicant believed that Vistogard ™ is not substantially similar to any other currently approved technology. We invited public comments on whether Vistogard ™ is substantially similar to existing technologies and whether it meets the newness criterion in the proposed rule.

Comment: The manufacturer reiterated that Vistogard ™ is not substantially similar to any existing technology and that it meets the newness criterion.

Response: After consideration of the information provided by the applicant, we agree that Vistogard ™ is not substantially similar to any existing technology and meets the newness criterion.

With regard to the cost criterion, in the proposed rule, we stated that the applicant searched the claims data from the 2013 and 2014 Inpatient SAFs for cases that may be eligible for treatment involving Vistogard ™. Specifically, the applicant searched for cases reporting a primary ICD–9–CM diagnosis code for colorectal cancer, head and neck cancer, gastric cancers and pancreatic cancer. The applicant further narrowed the potential target patient population by identifying cases reporting toxicity due to an antineoplastic. In order to include only patients diagnosed with severe toxicity that would be eligible for treatment using Vistogard ™, using revenue center codes and ICD–9–CM V codes, the applicant included an additional cohort of cases representing patients admitted from the emergency department, an observation unit, another short-term, acute care hospital, or who have received chemotherapy treatment during the inpatient stay included on the claim. Because 5–FU toxicity is associated with a high mortality rate, the applicant identified a subgroup of patients diagnosed with chemotherapy toxicity who expired during their inpatient visit or within 7 days of discharge. The applicant provided two analyses to determine that the technology meets the cost criterion: One analysis of patients that experienced toxicity with mortality and a second analysis using the broader chemotherapy toxicity cohort, which includes patients who did not expire. The table below provides the diagnosis codes and information the applicant used to identify cases for both of these analyses.

Criterion	ICD–9 code	Description
Colorectal, head and neck, gastric, or pancreatic cancer (at least one code).	153.x	Malignant neoplasm of colon.
	154.x	Malignant neoplasm of rectum, rectosigmoid junction, and anus.
	171.0	Malignant neoplasm of head, face, and neck.
	151.x	Malignant neoplasm of stomach.
	157.x	Malignant neoplasm of pancreas.
Toxicity due to an antineoplastic (at least one code).	963.1	Poisoning by antineoplastic and immunosuppressive drugs.
	E933.1	Antineoplastic and immunosuppressive drugs causing adverse effects in therapeutic use.
Admission to Inpatient Setting. Admitted from ED	Revenue Center	Revenue Center Codes 450, 451, 452, 456, 459.
or observation unit	Revenue Center	Revenue Center Codes 760, 761, 762, 769.
or short-term, acute care hospital	N/A	Source of admission code = ''4''. ''Transfer from hospital (Different facility)''.
or received chemotherapy during inpatient stay	V58.0	Encounter or admission for radiation.
	V58.11	Encounter for antineoplastic chemotherapy.
	V58.12	Encounter for antineoplastic immunotherapy (Must be primary diagnosis on the claim).
Expired during inpatient stay or within seven days of discharge (at least one code) [a].	N/A	Determined by patient discharge status code.
	N/A	If date of death in 100 percent. Denominator File pertaining to the year of the claim was within 7 days of claim discharge date.

[a] Required only for toxicity with mortality cohort. Source: KNG Health analysis of 2013–2014 100% Inpatient Standard Analytic Files and 2013–2014 100% Denominator Files.

Under the first analysis, the applicant found 76 cases with 18.42 percent of those cases mapping to MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation >96 hours with MCC), and the remaining number of cases mapping to MS–DRGs with less than 11 cases. According to the applicant, the results of the analysis of the MS–DRGs with less than 11 cases could not be discussed separately because of the small sample sizes. The applicant believed that it was unnecessary to remove any charges for other previously used technologies because although Vistogard™ is singular in its ability to treat 5–FU toxicity, the associated charges for palliative care would continue to be necessary to treat the symptoms of the toxicity, even though it is possible that the use of Vistogard™ may reduce a patient's hospital length of stay. To update the charge data to the current fiscal year, the applicant inflated the charges based on the charge inflation factor of 1.048116 in the FY 2016 IPPS/LTCH proposed rule (80 FR 24632). A 1-year inflation factor was applied three times for FY 2013 claims and two times for FY 2014 claims, inflating all claims to FY 2016. This resulted in an inflated average standardized case-weighted charge per case of $51,451. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $46,233 (all calculations above were performed using unrounded numbers). The applicant noted that the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold amount without including charges for Vistogard™. Therefore, because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

Under the second analysis, the applicant used the same methodology it used in its first analysis, except that the analysis included cases representing patients who did not expire. The applicant found 879 cases with 8.53 percent of those cases mapping to MS–DRG 392 (Esophagitis, Gastroenteritis and Miscellaneous Digestive System Disorders without MCC), and the remaining number of cases spread across several MS–DRGs. The inflated average standardized case-weighted charge per case was $42,708. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $42,377 (all calculations above were performed using unrounded numbers). Similar to the results of the first analysis, the applicant noted that the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold amount without including charges for Vistogard™. Therefore, because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology also meets the cost criterion under the second analysis.

We noted in the proposed rule that the applicant used the inflation factor of 1.048116 from the FY 2016 IPPS/LTCH proposed rule instead of the inflation factor of 1.037616 from the FY 2016 IPPS/LTCH final rule (80 FR 49784). We stated that we believe that the applicant should use the most recent data available, which is the inflation factor from the final rule. The inflation factor from the FY 2016 IPPS/LTCH final rule is lower than the inflation factor from the proposed rule. However, the difference between these two factors is marginal. Also, as the applicant noted, it did not include charges for Vistogard™ in its analysis. Therefore, we stated that we believe that it is likely that the applicant would still meet the cost criterion under both analyses even if it used the lower inflation factor from the FY 2016 final rule. We invited public comments on whether Vistogard™ meets the cost criterion under both analyses.

Comment: The manufacturer commented that it agreed with our analysis that, regardless of the inflation factor used, Vistogard™ would still meet the cost criterion. The manufacturer supplied revised data with the correct inflation factor that demonstrated that the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold.

Response: We thank the commenter for providing a revised analysis, and we agree that Vistogard™ meets the cost criterion.

With regard to substantial clinical improvement, the applicant maintained that Vistogard™ represents a substantial clinical improvement. The applicant noted that Vistogard™ is the first and only antidote indicated to treat adult and pediatric patients following a fluorouracil overdose, regardless of the presence of symptoms or whether a patient exhibits early-onset, severe or life-threatening toxicity within 96 hours following the conclusion of fluorouracil

or capecitabine administration. The applicant provided data from two studies (Study 1, an open-label, single arm, multi-center expanded access study and Study 2, an open-label, single arm, multi-center emergency use study), which combined enrolled 135 patients. The applicant noted that 130 patients treated with Vistogard™ survived through the 30-day treatment and observation period (95 percent Confidence Interval: 0.92, 0.99). Of the 135 patients, 30 percent were 65 years old and older, including 11 percent of patients who were 75 years old and older.

According to the applicant, the studies' results demonstrate that Vistogard™ reduced the incidence, severity and virulence of toxicities associated with 5–FU toxicity due to overdose or rapid onset. Specifically, the applicant noted the following results:

- Vistogard™ ameliorated the progression of mucositis, leukopenia and thrombocytopenia; leukopenia and thrombocytopenia were resolved in almost all patients by the 4th week, indicating recovery of the hematopoietic system; mucositis also was resolved in almost all patients within the 30-day observation period with the incidence of serious (Grade 3 or 4) mucositis being very low; and no grade 4 mucositis was observed in any patients who received treatment using Vistogard™ within 96 hours after 5–FU.
- Thirty-eight percent of patients who experienced 5–FU overdose were able to resume chemotherapy treatment in less than 30 days after 5–FU toxicity, with the majority of these patients resuming treatment within 21 days. According to the applicant, 21 percent of the patients who presented with rapid onset of serious toxicities resumed chemotherapy treatment (typically with a different agent than 5–FU) in less than 30 days, with an overall median time to resumption of chemotherapy of 19 days.
- The safety and tolerability profile of Vistogard™ is consistent with what would be expected for patients diagnosed with cancer following 5–FU chemotherapy treatment, but is generally less in severity and incidence when compared to what would be expected with patients who experience a 5–FU overdose. Specifically, during Study 1, there were no patients that discontinued uridine triacetate treatment as a result of adverse events, and during Study 2, three patients discontinued uridine triacetate treatment as a result of adverse events, one of which was considered possibly related to uridine triacetate (nausea and vomiting).

We invited public comments on whether Vistogard™ meets the substantial clinical improvement criterion in the proposed rule.

Comment: The manufacturer reiterated the points described above and asserted that Vistogard™ meets the substantial clinical improvement criterion.

Response: After consideration of the information provided by the applicant, we agree that Vistogard™ meets the substantial clinical improvement criterion. For the reasons described above and after consideration of the public comments we received, we have determined that Vistogard™ meets all of the criteria for approval of new technology add-on payments for FY 2017.

Comment: The manufacturer commented that with the implementation of ICD–10, the following series of codes are expected to be used to distinguish cases with 5–FU overdose or severe toxicities:

- T45.1X1A, T45.1X1D and T45.1X1S (Poisoning by antineoplastic and immunosuppressive drugs, accidental (unintentional) initial encounter, subsequent encounter or sequela). The former ICD–9 code (963.1) has been divided into subcodes.
- T45.1X5A, T45.1X5D, T45.1X5S (Adverse effect of anti neoplastic and immunosuppressive drugs initial encounter, subsequent encounter or sequela).

The commenter explained that because 5–FU toxicity is a rare, unintentional byproduct of chemotherapy with 5–FU, it is expected that the primary code associated with 5–FU overdose or severe toxicity cases will be T45.1X1 with the ''accidental'' designation.

Response: We thank the commenter for explaining the coding with regard to 5–FU overdose or severe toxicities. In order to pay for cases of Vistogard™ consistent with the FDA labeling, cases involving Vistogard™ that are eligible for new technology add-on payments will be identified by any one of ICD–10–PCS diagnosis codes T45.1X1A, T45.1X1D, T45.1X1S, T45.1X5A, T45.1X5D, and T45.1X5S in combination with ICD–10–PCS procedure code XW0DX82. According to the applicant, the wholesale acquisition cost (WAC) of Vistogard™ is $3,750.00 per each 10g packet of oral granules. Recommended adult dosing per the Vistogard™ label is 10g (one packet every 6 hours for a minimum of 20 doses over 5 days). The total cost is 20 packets × WAC of $3,750.00 per packet which equals $75,000 per patient. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of Vistogard™ is $37,500 for FY 2017.

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the FY 2017 hospital wage index based on the statistical areas appears under sections III.A.2. and G. of the preamble of this final rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. (CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, and IV. The OMB control number for approved collection of this information is 0938–0050.) This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The adjustment for FY 2017 is discussed in section II.B. of the Addendum to this final rule.

As discussed in section III.J. of the preamble of this final rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The budget neutrality adjustment for FY 2017 is discussed in

section II.A.4.b. of the Addendum to this final rule. We also note that, under section III.J.2. of the preamble of this final rule, we are finalizing an April 21, 2016 interim final rule with comment period that addressed modifications to limitations on redesignation by the Medicare Geographic Classification Review Board (MGCRB), and included regulatory changes to codify the application and interpretation of two judicial decisions.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are applying to the FY 2017 wage index appears under sections III.E.3. and F. of the preamble of this final rule.

2. Core-Based Statistical Areas (CBSAs) Revisions for the FY 2017 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion of our implementation of the new OMB labor market area delineations beginning with the FY 2015 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. As we discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25062), on July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. The complete list of statistical areas incorporating these changes is provided in the attachment to OMB Bulletin No. 15–01. According to OMB, ''[t]his bulletin establishes revised delineations for the Nation's Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provides delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas.'' A copy of this bulletin may be obtained on the Web site at: *https://www.whitehouse.gov/omb/bulletins_default.*

OMB Bulletin No. 15–01 made the following changes that are relevant to the IPPS wage index:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban new CBSA 21420 called Enid, OK.
- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA 31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City (SSA State county code 49088, FIPS State County Code 51515) is now part of the county of Bedford, VA (SSA State county code 49090, FIPS State County Code 51019). However, the CBSA remains Lynchburg, VA 31340.
- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

We believe that it is important for the IPPS to use the latest labor market area delineations available as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions (79 FR 28055). Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25062), we proposed to implement these revisions, effective October 1, 2016, beginning with the FY 2017 wage indexes. We proposed to use these new definitions to calculate area wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 and the FY 2015 IPPS final rules. For FY 2017, Tables 2 and 3 for the proposed rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS Web site reflected these CBSA changes. We invited public comments on these proposals.

We did not receive any public comments on our proposal to implement the revisions to the CBSAs effective October 1, 2016, beginning with the FY 2017 hospital wage index, as proposed in the FY 2017 IPPS/LTCH PPS proposed rule. Therefore, we are finalizing our proposal without modification. Tables 2 and 3 for this final rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS Web site reflect these CBSA changes.

B. Worksheet S–3 Wage Data for the FY 2017 Wage Index

The FY 2017 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2013 (the FY 2016 wage indexes were based on data from cost reporting periods beginning during FY 2012).

1. Included Categories of Costs

The FY 2017 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty);
- Home office costs and hours;
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)); and
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2016, the wage index for FY 2017 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and

residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The FY 2017 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398).

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

C. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2017 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report (Form CMS–2552–10, OMB control number 0938–0050) for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013. For wage index purposes, we refer to cost reports during this period as the ''FY 2013 cost report,'' the ''FY 2013 wage data,'' or the ''FY 2013 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. No. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the FY 2017 wage index includes FY 2013 data submitted to us as of June 28, 2016. As in past years, we performed an extensive review of the wage data, mostly through the use of edits for reasonableness designed to identify aberrant data.

We asked our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2017 wage index, we identified and excluded 62 providers with aberrant data that should not be included in the wage index. We stated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25063) that, of these 62 providers that we excluded from the proposed wage index, 47 have data that we did not expect to change such that the data would be included in the final wage index (for example, among the reasons these providers were excluded are the following: they are low Medicare utilization providers, they closed and failed edits for reasonableness, or they have extremely high or low average hourly wages that are atypical for their CBSAs). We stated in the proposed rule that if data elements for some of these providers were corrected, we intend to include those providers in the calculation of the final FY 2017 wage index (81 FR 25063). We also adjusted certain aberrant data and included these data in the proposed wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967).

In constructing the proposed FY 2017 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2013, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believed that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For the proposed rule, we removed 3 hospitals that converted to CAH status on or after February 5, 2015, the cut-off date for CAH exclusion from the FY 2016 wage index, and through and including January 22, 2016, the cut-off date for CAH exclusion from the FY 2017 wage index. After removing hospitals that converted to CAH status, we calculated the proposed FY 2017 wage index based on 3,345 hospitals.

Comment: One commenter expressed appreciation for CMS' efforts over the past 2 years to ''refine and augment its area wage index audit protocols to ensure more consistency across the MACs,'' and observed that this has resulted in fewer hospitals being excluded from the final wage index. The commenter stated that several member hospitals had a ''very positive experience in working with their MACs, despite a very challenging timeline.'' For those hospitals that are excluded due to a higher than average average hourly wage, the commenter requested that CMS make transparent the audit thresholds it uses to exclude these hospitals, as hospitals remain concerned that, in some instances, having a higher than average average hourly wage will remain unacceptable to CMS.

Response: We appreciate the commenter's acknowledgement of the efforts we and the MACs invest in the wage index review process, and recognize the improved collaboration between hospitals and the MACs. As part of our efforts to assure that hospitals are aware of whether or not their wage data are excluded from the development of the wage index, we note that, for the FY 2017 wage index development cycle, we have added additional tabs to the Public Use Files (PUFs) that we post on our Web site. These tabs specifically list the hospitals and their respective wage data and occupational mix data that have been removed from the wage index (the various FY 2017 PUFs are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html*). As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under this section of the Act, we have discretion to remove aberrant hospital data from the wage index PUFs to help ensure that the costs attributable to wages and wage-related costs in fact reflect the relative hospital wage level in the hospitals' geographic area. We appreciate that hospitals remain concerned that, in some instances, having a higher than average average hourly wage might be unacceptable to CMS, depending on the circumstances, but reasonableness and relativity to each area's average hourly wages have been longstanding tenets of the wage index development process that CMS has articulated in rulemaking. Therefore, for the FY 2017 wage index, as we have done in previous years, we have exercised our discretion to remove certain hospitals from the wage index that have unusually high or unusually low average hourly wages relative to the

average hourly wages of the hospitals in the same geographic area. We note that it has never been CMS' policy to disclose audit protocol; the protocol is for CMS and MAC internal use only. In addition, we note that foreknowledge of an audit threshold should not in any way influence the wages and hours that hospitals report on Worksheet S–3; as with all cost report data, hospitals must attest to the accuracy of what they report on the Medicare cost reports, without regard to whether or not their data will be subjected to an audit.

Since the development of the FY 2017 proposed wage index, as a result of further review by the MACs and the April and May appeals processes, we received improved data for 11 hospitals. Therefore, we are including the wage data of these 11 hospitals in the final wage index. However, we also have deleted the wage data of 2 additional hospitals whose data were determined to be aberrant, and the hospitals were not responsive to requests by the MAC to provide supporting documentation. For this final rule, we learned of an additional 4 hospitals that converted to CAH status on or after February 5, 2015, and through and including January 22, 2016, the cut-off date for CAH exclusion from the FY 2017 wage index. Thus, for this final rule, we removed 7 hospitals that converted to CAH status on or after February 5, 2015, and through and including January 22, 2016 (3 CAHs removed for the proposed rule, and 4 additional CAHs removed for this final rule). Hospitals that are excluded from the wage index remain excluded for a variety of reasons, such as, but not limited to, unresponsiveness to requests for documentation or insufficiently documented data, terminated hospitals' failed edits for reasonableness, or low Medicare utilization. Accordingly, the final FY 2017 wage index is based on the wage data of 3,350 hospitals (3,345 + 11 − 2 − 4 = 3,350).

For the final FY 2017 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located in the same manner that we allotted such hospitals' data in the FY 2016 wage index (80 FR 49489 through 49491). Table 2, which contains the final FY 2017 wage index associated with this final rule (available via the Internet on the CMS Web site), includes separate wage data for the campuses of 9 multicampus hospitals.

D. Method for Computing the FY 2017 Unadjusted Wage Index

The method used to compute the FY 2017 wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012, FY 2013, FY 2014, FY 2015, and FY 2016 final wage indexes without an occupational mix adjustment (76 FR 51591 through 51593, 77 FR 53366 through 53367, 78 FR 50587 through 50588, 79 FR 49967 and 80 FR 49491 through 49492, respectively).

Comment: One commenter requested CMS to consider developing a process for determining a wage index that would reward hospitals that invest in the workforce and raise the wages of the lowest paid workers, rather than relying primarily on the average hourly wages of the labor market area as a whole.

Response: Section 1886(d)(3)(E) of the Act requires the Secretary to adjust for area differences in hospital wage levels by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. The statute does not direct the Secretary to develop a wage index that rewards hospitals for workforce investment or other labor initiatives.

Comment: One commenter requested that CMS establish a floor wage index for providers in Puerto Rico that is not lower than the ratio of Puerto Rico nonhealth care wages to U.S. nonhealth care wages, using data from the Occupational Employment Statistics (OES) of the U.S. Bureau of Labor Statistics (BLS).

Response: We appreciate this comment. However, we consider it to be outside the scope of the FY 2017 IPPS/LTCH PPS proposed rule. Therefore, we are not responding to the comment at this time.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2012, through April 15, 2014, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and as discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25063 through 25064), we did not propose any changes to the usage for FY 2017, nor have received any public comments on this issue. Therefore, for FY 2017, we used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/2012	11/15/2012	1.02321
11/14/2012	12/15/2012	1.02183
12/14/2012	01/15/2013	1.02040
01/14/2013	02/15/2013	1.01894
02/14/2013	03/15/2013	1.01743
03/14/2013	04/15/2013	1.01592
04/14/2013	05/15/2013	1.01443
05/14/2013	06/15/2013	1.01297
06/14/2013	07/15/2013	1.01152
07/14/2013	08/15/2013	1.01006
08/14/2013	09/15/2013	1.00859
09/14/2013	10/15/2013	1.00711
10/14/2013	11/15/2013	1.00561
11/14/2013	12/15/2013	1.00408
12/14/2013	01/15/2014	1.00260
01/14/2014	02/15/2014	1.00124
02/14/2014	03/15/2014	1.00000
03/14/2014	04/15/2014	0.99878

For example, the midpoint of a cost reporting period beginning January 1, 2013, and ending December 31, 2013, is June 30, 2013. An adjustment factor of 1.01152 would be applied to the wages of a hospital with such a cost reporting period.

Using the data as previously described, the FY 2017 national average hourly wage (unadjusted for occupational mix) is $41.1982.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25076) and in section IV.A. of the preamble of this final rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico-specific wage index that was applied to the labor share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25064), because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as

amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico-specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) (which is $41.1982 for this FY 2017 final rule) and the national wage index, which is applied to the national labor share of the national standardized amount. We did not receive any public comments on this issue. Accordingly, for FY 2017, as we proposed (81 FR 25064), we are not establishing a Puerto Rico-specific overall average hourly wage or wage index.

E. Occupational Mix Adjustment to the FY 2017 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2013 Occupational Mix Survey for the FY 2017 Wage Index

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We collected data in 2013 to compute the occupational mix adjustment for the FY 2016, FY 2017, and FY 2018 wage indexes. A new measurement of occupational mix is required for FY 2019.

The 2013 survey included the same data elements and definitions as the previous 2010 survey and provided for the collection of hospital-specific wages and hours data for nursing employees for calendar year 2013 (that is, payroll periods ending between January 1, 2013 and December 31, 2013). We published the 2013 survey in the **Federal Register** on February 28, 2013 (78 FR 13679 through 13680). This survey was approved by OMB on May 14, 2013, and is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/Medicare-Wage-Index-Occupational-Mix-Survey2013.html*. The 2013 Occupational Mix Survey Hospital Reporting Form CMS–10079 for the Wage Index Beginning FY 2016 (in Excel format) is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/Medicare-Wage-Index-Occupational-Mix-Survey2013.html*. Hospitals were required to submit their completed 2013 surveys to their MACs by July 1, 2014. The preliminary, unaudited 2013 survey data were posted on the CMS Web site on July 11, 2014. As with the Worksheet S–3, Parts II and III cost report wage data, we asked our MACs to revise or verify data elements in hospitals' occupational mix surveys that result in certain edit failures.

2. Development of the 2016 Medicare Wage Index Occupational Mix Survey for the FY 2019 Wage Index

As stated earlier, section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We collected data in 2013 to compute the occupational mix adjustment for the FY 2016, FY 2017, and FY 2018 wage indexes. A new measurement of occupational mix is required for FY 2019. The FY 2019 occupational mix adjustment will be based on a new calendar year (CY) 2016 survey. The CY 2016 survey (CMS Form CMS–10079) is currently awaiting approval by OMB, and can be accessed at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201512-0938-011*.

3. Calculation of the Occupational Mix Adjustment for FY 2017

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25065), for FY 2017, we proposed to calculate the occupational mix adjustment factor using the same methodology that we used for the FY 2012, FY 2013, FY 2014, FY 2015, and FY 2016 wage indexes (76 FR 51582 through 51586, 77 FR 53367 through 53368, 78 FR 50588 through 50589, 79 FR 49968, and 80 FR 49492 through 49493, respectively) and to apply the occupational mix adjustment to 100 percent of the FY 2017 wage index. Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2017 wage index. For the proposed FY 2017 wage index, we used the Worksheet S–3, Parts II and III wage data of 3,345 hospitals, and we used the occupational mix surveys of 3,143 hospitals for which we also have Worksheet S–3 wage data, which represented a ''response'' rate of 94 percent (3,143/3,345). For the proposed FY 2017 wage index, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586).

Comment: One commenter stated that all hospitals should be obligated to submit the occupational mix survey because failure to complete the survey jeopardizes the accuracy of the wage index. The commenter suggested that a penalty be instituted for nonsubmitters. This commenter also requested that, pending CMS' analysis of the Commuting Based Wage Index and given the Institute of Medicine's study on geographic variation in hospital wage costs, CMS eliminate the occupational mix survey and the significant reporting burden it creates.

Response: We appreciate the commenter's concern about the accuracy of the wage index. We have continually requested that all hospitals complete and submit the occupational mix surveys. We did not establish a penalty for hospitals that did not submit the 2013 occupational mix survey. However, we are continuing to consider for future rulemaking various options for ensuring full compliance with future occupational mix surveys. Regarding the commenter's request that CMS eliminate the occupational mix survey, this survey is necessary to meet the provisions of section 1886(d)(3)(E) of the Act, which requires us to measure the earnings and paid hours of employment by occupational category.

After consideration of the public comments we received, for FY 2017, we are adopting as final our proposal to calculate the occupational mix adjustment factor using the same methodology that we have used since

the FY 2012 wage index. For the final FY 2017 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,350 hospitals, and we are using the occupational mix surveys of 3,149 hospitals for which we also have Worksheet S–3 wage data, which represents a ''response'' rate of 94 percent (3,149/3,350). For the final FY 2017 wage index, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the FY 2017 occupational mix adjusted national average hourly wage is $41.1615.

F. Analysis and Implementation of the Occupational Mix Adjustment and the FY 2017 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this final rule, for FY 2017, we are applying the occupational mix adjustment to 100 percent of the FY 2017 wage index. We calculated the occupational mix adjustment using data from the 2013 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the FY 2017 wage index results in a national average hourly wage of $41.1615. Previously, we would also provide a Puerto Rico overall average hourly wage. As discussed in the proposed rule (81 FR 25076) and in section IV.A. of the preamble of this final rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico-specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016 under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico-specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (adjusted for occupational mix) (which is $41.1615 for this FY 2017 final rule) and the national wage index, which is applied to the national labor share of the national standardized amount. Accordingly, for FY 2017, we did not propose a Puerto Rico-specific overall average hourly wage or wage index in the proposed rule (81 FR 25065), nor are we establishing such for this final rule.

The FY 2017 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational mix nursing subcategory	Average hourly wage
National RN	$38.83416971
National LPN and Surgical Technician	22.73766832
National Nurse Aide, Orderly, and Attendant	15.95353295
National Medical Assistant	18.04809696
National Nurse Category	32.8589243

The national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $32.8589243. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2013 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the national percentage of hospital employees in the nurse category is 42.6 percent, and the national percentage of hospital employees in the all other occupations category is 57.4 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 25.7 percent in one CBSA to a high of 80.5 percent in another CBSA.

We compared the FY 2017 occupational mix adjusted wage indexes for each CBSA to the unadjusted wage indexes for each CBSA. As a result of applying the occupational mix adjustment to the wage data, the final wage index values for 221 (54.2 percent) urban areas and 24 (51.1 percent) rural areas will increase. The final wage index values for 104 (25.5 percent) urban areas will increase by greater than or equal to 1 percent but less than 5 percent, and the final wage index values for 6 (1.5 percent) urban areas will increase by 5 percent or more. The final wage index values for 10 (21.3 percent) rural areas will increase by greater than or equal to 1 percent but less than 5 percent, and no rural areas' final wage index values will increase by 5 percent or more. However, the wage index values for 186 (45.6 percent) urban areas and 23 (48.9 percent) rural areas will decrease. The final wage index values for 89 (21.8 percent) urban areas will decrease by greater than or equal to 1 percent but less than 5 percent, and no urban areas' final wage index value will decrease by 5 percent or more. The final wage index values of 7 (14.9 percent) rural areas will decrease by greater than or equal to 1 percent and less than 5 percent, and no rural areas' final wage index values will decrease by 5 percent or more. The largest positive impacts will be 17.4 percent for an urban area and 2.9 percent for a rural area. The largest negative impacts will be 4.9 percent for an urban area and 2.1 percent for a rural area. One urban area's wage index, but no rural area wage indexes, will remain unchanged by application of the occupational mix adjustment. These results indicate that a larger percentage of urban areas (54.2 percent) will benefit from the occupational mix adjustment than will rural areas (51.1 percent).

G. Transitional Wage Indexes

1. Background

In the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28060 and 49957, respectively), we stated that, overall, we believed implementing the new OMB labor market area delineations would result in wage index values being more representative of the actual costs of labor in a given area. However, we recognized that some hospitals would experience decreases in wage index values as a result of the implementation of these new OMB labor market area delineations. We also realized that some hospitals would have higher wage index values due to the implementation of the new OMB labor market area delineations.

The FY 2015 IPPS/LTCH PPS final rule (79 FR 49957) explained the methodology utilized in implementing prior transition periods when adopting

changes that have significant payment implications, particularly large negative impacts. Specifically, for FY 2005, in the FY 2005 IPPS final rule (69 FR 49032 through 49034), we provided transitional wage indexes when the OMB definitions were implemented after the 2000 Census. The FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49962) established similar transition methodologies to mitigate any negative payment impacts experienced by hospitals due to our adoption of the new OMB labor market area delineations for FY 2015.

As finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49960) and as discussed below, for FY 2017, we will be in the third and final year of two 3-year transition periods for wage index: (1) For hospitals that, for FY 2014, were located in an urban county that became rural under the new OMB delineations, and had no form of wage index reclassification or redesignation in place for FY 2015 (that is, MGCRB reclassifications under section 1886(d)(10) of the Act, redesignations under section 1886(d)(8)(B) of the Act, or rural reclassifications under section 1886(d)(8)(E) of the Act); and (2) for hospitals deemed urban under section 1886(d)(8)(B) of the Act where the urban area became rural under the new OMB delineations.

2. Transition for Hospitals in Urban Areas That Became Rural

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49959), for hospitals that, for FY 2014, were located in an urban county that became rural under the new OMB delineations, and had no form of wage index reclassification or redesignation in place for FY 2015 (that is, MGCRB reclassifications under section 1886(d)(10) of the Act, redesignations under section 1886(d)(8)(B) of the Act, or rural reclassifications under section 1886(d)(8)(E) of the Act), we adopted a policy to assign them the urban wage index value of the CBSA in which they were physically located for FY 2014 for a period of 3 fiscal years (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied to the area wage index). FY 2017 will be the third year of this transition policy. We did not propose to make any changes to this policy in the FY 2017 IPPS/LTCH PPS proposed rule, and therefore we are not making any changes to this policy in this final rule. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49495), we stated our belief that it is appropriate to apply a 3-year transition period for hospitals located in urban counties that would become rural under the new OMB delineations, given the potentially significant payment impacts for these hospitals. We continue to believe that assigning the wage index of the hospitals' FY 2014 area for a 3-year transition is the simplest and most effective method for mitigating negative payment impacts due to the adoption of the new OMB delineations.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959), we noted that there were situations where a hospital could not be assigned the wage index value of the CBSA in which it was geographically located in FY 2014 because that CBSA split and no longer exists and some or all of the constituent counties were added to another urban labor market area under the new OMB delineations. If the hospital could not be assigned the wage index value of the CBSA in which it was geographically located in FY 2014 because that CBSA split apart and no longer exists, and some or all of its constituent counties were added to another urban labor market area under the new OMB delineations, we established that hospitals located in such counties that became rural under the new OMB delineations were assigned the wage index of the urban labor market area that contained the urban county in their FY 2014 CBSA to which they were closest (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied). Any such assignment made in FY 2015 and continued in FY 2016 will continue for FY 2017, except as discussed later in this section. We continue to believe this approach minimizes the negative effects of the change in the OMB delineations.

Under the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, if a hospital for FY 2014 was located in an urban county that became rural beginning in FY 2015 under the new OMB delineations and such hospital sought and was granted reclassification or redesignation for FY 2015 or FY 2016, or such hospital seeks and is granted any reclassification or redesignation for FY 2017, the hospital will permanently lose its 3-year transitional assigned wage index status, and will not be eligible to reinstate it. We established the transition policy to assist hospitals if they experience a negative payment impact specifically due to the adoption of the new OMB delineations in FY 2015. If a hospital chooses to forego this transition adjustment by obtaining some form of reclassification or redesignation, we do not believe reinstatement of this transition adjustment would be appropriate. The purpose of the transition adjustment policy is to assist hospitals that may be negatively impacted by the new OMB delineations in transitioning to a wage index based on these delineations. By obtaining a reclassification or redesignation, we believe that the hospital has made the determination that the transition adjustment is not necessary because it has other viable options for mitigating the impact of the transition to the new OMB delineations.

As we did for FY 2015 (79 FR 49959) and FY 2016 (80 FR 49495), with respect to the wage index computation for FY 2017, we followed our existing policy regarding the inclusion of a hospital's wage index data in the CBSA in which it is geographically located (we refer readers to Step 6 of the method for computing the unadjusted wage index in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592)). Accordingly, for FY 2017, the wage data of all hospitals receiving this type of 3-year transition adjustment were included in the statewide rural area in which they are geographically located under the new OMB labor market area delineations. After the 3-year transition period, beginning in FY 2018, these formerly urban hospitals will receive their statewide rural wage index, absent any reclassification or redesignation.

In addition, we established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959) that the hospitals receiving this 3-year transition because they are in counties that were urban under the FY 2014 CBSA definitions, but are rural under the new OMB delineations, will not be considered urban hospitals. Rather, they will maintain their status as rural hospitals for other payment considerations. This is because our application of a 3-year transitional wage index for these newly rural hospitals only applies for the purpose of calculating the wage index under our adoption of the new OMB delineations.

We did not receive any public comments regarding the 3-year transition policy for hospitals that were located in an urban county that became rural under the new OMB delineations. Fiscal year 2017 is the third and final year of this 3-year transition period. We also remind hospitals that if any affected hospital is approved for any wage index reclassification or redesignation in FY 2017, it will no longer be eligible for the remaining year of this transitional wage index.

3. Transition for Hospitals Deemed Urban Under Section 1886(d)(8)(B) of the Act Where the Urban Area Became Rural Under the New OMB Delineations

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959 through 49960) and FY 2016 IPPS/LTCH PPS final rule (80 FR 49495 through 49496), there were some hospitals that, for FY 2014, were geographically located in rural areas but were deemed to be urban under section 1886(d)(8)(B) of the Act. For FY 2015, some of these hospitals redesignated under section 1886(d)(8)(B) of the Act were no longer eligible for deemed urban status under the new OMB delineations, as discussed in detail in section III.H.3. of the preamble of the FY 2015 IPPS/LTCH PPS final rule. Similar to the policy implemented in the FY 2005 IPPS final rule (69 FR 49059), and consistent with the FY 2015 policy we established for other hospitals in counties that were urban and became rural under the new OMB delineations, we finalized a policy to apply a 3-year transition to these hospitals redesignated to urban areas under section 1886(d)(8)(B) of the Act for FY 2014 that are no longer deemed urban under the new OMB delineations and revert to being rural.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25067), for FY 2017, we did not propose to make any changes to this policy. We will continue the third and final year of the implementation of our policy to provide a 3-year transition adjustment to hospitals that are deemed urban under section 1886(d)(8)(B) of the Act under the FY 2014 labor market area delineations, but are considered rural under the new OMB delineations, assuming no other form of wage index reclassification or redesignation is granted. We assign these hospitals the area wage index value of hospitals reclassified to the urban CBSA (that is, the attaching wage index) to which they were redesignated in FY 2014 (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied). If the hospital cannot be assigned the reclassified wage index value of the CBSA to which it was redesignated in FY 2014 because that CBSA was split apart and no longer exists, and some or all of its constituent counties were added to another urban labor market area under the new OMB delineations, such hospitals are assigned the wage index of the hospitals reclassified to the urban labor market area that contained the urban county in their FY 2014 redesignated CBSA to which they were closest. We assign these hospitals the area wage index of hospitals reclassified to a CBSA because hospitals deemed urban under section 1886(d)(8)(B) of the Act are treated as reclassified under current policy, under which such hospitals receive an area wage index that includes wage data of all hospitals reclassified to the area. This wage index assignment will be forfeited if the hospital obtains any form of wage index reclassification or redesignation.

We did not receive any public comments regarding the 3-year transition policy for hospitals deemed urban under section 1886(d)(8)(B) of the Act where the urban area became rural under the new OMB delineations. Fiscal year 2017 is the third and final year of this 3-year transition period. We also remind hospitals that if any affected hospital is approved for any wage index reclassification or redesignation in FY 2017, it will no longer be eligible for the remaining year of this transitional wage index.

4. Budget Neutrality

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50372 through 50373), for FY 2015, and in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49496), for FY 2016, we applied the 3-year transition wage index adjustments in a budget neutral manner. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25067), for FY 2017, we proposed to apply the 3-year transition adjustments in a budget neutral manner. We proposed to make an adjustment to the standardized amount to ensure that the total payments, including the effect of the transition provisions, would equal what payments would have been if we were not providing for any transitional wage indexes under the new OMB delineations. For a complete discussion on the budget neutrality adjustment for FY 2017, we refer readers to section II.A.4.b. of the Addendum to this final rule, where we also address any public comments we received.

We did not receive any public comments on these proposals. In this final rule, for FY 2017, we are applying the 3-year transition adjustments in a budget neutral manner. We are making an adjustment to the standardized amount to ensure that the total payments, including the effect of the transition provisions, will equal what payments would have been if we were not providing for any transitional wage indexes under the new OMB delineations.

H. Application of the Rural, Imputed, and Frontier Floors

1. Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the ''rural floor.'' Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25067), based on the proposed FY 2017 wage index associated with the proposed rule (which is available via the Internet on the CMS Web site), we estimated that 371 hospitals would receive an increase in their FY 2017 wage index due to the application of the rural floor.

Comment: Several commenters appreciated CMS' providing a State-specific analysis of impacts in the proposed rule and requested additional long-term analysis of State-specific and aggregate payment distortions produced by nationwide rural floor budget neutrality.

Response: We appreciate the commenters' continued concern regarding rural floor budget neutrality. We are publishing a State-specific rural floor analysis of impacts in Appendix A of this final rule, as we have done in previous rules. However, we question the usefulness of additional long-term analysis of State-specific effects of national rural floor budget neutrality, given that we are currently required by section 3141 of Public Law 111–148 to apply budget neutrality on a national level in implementing the rural floor and the imputed rural floor.

Comment: One commenter expressed concern that the current application of the rural floor does not reflect the needs of rural hospitals, and suggested that CMS include a provision in the final rule that requires States to have at least 5 percent of its IPPS hospitals in federally recognized rural areas before a rural floor can be established in the State.

Response: We appreciate the commenter's input. However, we did not propose such a provision in the proposed rule, and thus we are not adopting such a policy in this final rule. Furthermore, we note that section 4410(a) of Public Law 105–33 requires that, for purposes of section 1886(d)(3)(E) of the Act, for discharges occurring on or after October 1, 1997, the area wage index applicable under

such section to any hospital which is not located in a rural area (as defined in section 1886(d)(2)(D) of such Act) may not be less than the area wage index applicable under such section to hospitals located in rural areas in the State in which the hospital is located.

Comment: Many commenters expressed concern about the decline in the proposed Massachusetts rural wage index, due partially to preliminary audit adjustments made by the MAC to Nantucket Cottage Hospital's FY 2017 wage data, and certain errors identified by Nantucket Cottage Hospital in the FY 2017 wage data it submitted. The commenters stated that an abrupt decline in payment would have a negative impact for Massachusetts hospitals, particularly for hospitals in parts of the State lagging economically. In addition, several commenters noted that because of the calculation of the alternative methodology for the imputed floor, a decline in the Massachusetts rural floor would have a negative payment impact on hospitals in Rhode Island.

The commenters urged CMS to exercise its discretion in this situation to grant wage data correction requests outside of the prescribed FY 2017 Wage Index Timeline and accept Nantucket Cottage Hospital's request to correct its data errors, which were submitted to the MAC after the specified deadline. Many commenters also believed it would be ''sound public policy'' for CMS to use the most accurate data available in order to prevent one hospital's data errors from having a negative effect on Medicare payments of other hospitals. One commenter did not believe CMS should knowingly use the incorrect wage data and cautioned that Massachusetts hospitals' efforts at cost reform may be jeopardized due to the negative financial impact of finalizing the proposed rural wage index.

Several commenters believed that, because the rural floor is subject to a budget neutrality adjustment, the impact of accepting Nantucket Cottage Hospital's wage data correction would be spread across hospitals nationwide and would minimally impact any particular hospital, but the effects of not correcting the data error would be significant for hospitals in Massachusetts.

Conversely, other commenters requested that CMS deny Nantucket Cottage Hospital's request to correct its wage index data, as the request was submitted nearly 2 months after the agency's deadline. The commenters emphasized that Nantucket Cottage Hospital should be held to the same standards as hospitals nationwide. Several commenters stated that CMS would establish a ''troubling'' precedent by disregarding CMS rules and regulations, which provide ample opportunity to correct wage data through the agency's normal review process and deadlines.

Commenters also noted that the redistributive effect of nationwide rural floor budget neutrality would further lower wage index values for hospitals nationwide to pay for additional increases in Massachusetts's rural floor. One commenter requested that CMS deny Nantucket Cottage Hospital's request in order to ensure access to care in rural hospitals in States other than Massachusetts that the commenter stated are struggling in part due to receipt of a wage index that is lower than it would be in the absence of a high Massachusetts rural floor.

Response: We appreciate all of the commenters' concerns about the Massachusetts rural wage index. It is our intent to ensure that the wage index is calculated from the best available data, consistent with our wage index policies and development timeline. We have determined that the corrections requested by Nantucket Cottage Hospital fall outside the applicable deadline set forth in the FY 2017 Wage Index Development Timetable finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49987 through 49990) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49506 through 49507), and available on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2017-WI-Time-Table.pdf*. The annual Wage Index Development Timetable has been established through rulemaking, and plays an important role in maintaining the integrity and fairness of the wage index calculation. We have consistently stated in annual IPPS rulemaking that hospitals that do not meet the procedural deadlines set forth in the IPPS rule will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes (for example, 79 FR 28081, 79 FR 49986, 80 FR 24473, 80 FR 49503, and 81 FR 25073). Therefore, we are not incorporating the adjustments requested by Nantucket Cottage Hospital for the FY 2017 final rule wage index. Separately, we also have determined that the adjustments made by the MAC in this situation could ideally have been made earlier in the process, and we are not incorporating those adjustments for the FY 2017 final rule wage index. We note that the average hourly wage of Nantucket Cottage Hospital that was used in calculating the proposed FY 2017 wage index did not include the MAC's nor the hospital's requested adjustments. Accordingly, we are finalizing Nantucket Cottage Hospital's unadjusted average hourly wage as proposed for the Massachusetts's rural wage index, which is the same unadjusted average hourly wage that was used in the FY 2017 IPPS/LTCH PPS proposed rule wage index (which neither incorporated the MAC audit adjustment nor additional adjustment requests by the hospital).

Comment: Commenters opposed the continued application of a nationwide rural floor budget neutrality adjustment, noting that the policy allows for manipulation of the wage index system so that hospitals in some States benefit at the expense of many hospitals in other States. Commenters pointed to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74192) where CMS expressed concern that a change in hospital status can significantly inflate wage indexes in a State, causing a reduction to all hospital wage indexes as a result of nationwide budget neutrality for the rural floor. One commenter specifically disagreed with what it called the ''political maneuvers'' used to unfairly manipulate the rural floor in Massachusetts and other States. Commenters reiterated that the wage index system is in need of reform to ensure that payments accurately reflect actual wage costs.

Response: We appreciate the commenters' concerns about application of the nationwide rural floor budget neutrality policy. However, for discharges occurring on or after October 1, 2010, for purposes of applying the rural floor and the imputed rural floor, section 3141 of the Affordable Care Act replaced the statewide budget neutrality adjustment policy with the national budget neutrality adjustment policy that was in place during FY 2008. That is, section 3141 required that budget neutrality for the rural and imputed floor be applied ''through a uniform, national adjustment to the area wage index'' instead of within each State beginning in FY 2011 (75 FR 50160). Accordingly, we do not have the authority to calculate rural floor budget neutrality in a State-specific manner.

After consideration of the public comments we received, and based on the final FY 2017 wage index associated with this final rule (which is available via the Internet on the CMS Web site), we estimate that 397 hospitals will receive an increase in their FY 2017 wage index due to the application of the rural or imputed floor.

2. Imputed Floor for FY 2017

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the ''imputed floor'' policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have argued that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. Since its initial implementation, we have extended the imputed floor policy six times, the last of which was adopted in the FY 2016 IPPS/LTCH PPS final rule and is set to expire on September 30, 2016. (We refer readers to further discussions of the imputed floor in the FY 2014, FY 2015, and FY 2016 IPPS/LTCH PPS final rules (78 FR 50589 through 50590, 79 FR 49969 through 49970, and 80 FR 49497 through 49498, respectively) and to the regulations at 42 CFR 412.64(h)(4).) Currently, there are three all-urban States—Delaware, New Jersey, and Rhode Island—with a range of wage indexes assigned to hospitals in these States, including through reclassification or redesignation. (We refer readers to discussions of geographic reclassifications and redesignations in section III.J. of the preamble of this final rule.)

In computing the imputed floor for an all-urban State under the original methodology, which was established beginning in FY 2005, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State's own ratio to the average ratio for all-urban States and whichever is higher is multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State. As of FY 2012, there were only two all-urban States—New Jersey and Rhode Island—and only New Jersey benefitted under this methodology. Under the previous OMB labor market area delineations, Rhode Island had only one CBSA (Providence-New Bedford-Fall River, RI-MA) and New Jersey had 10 CBSAs. Therefore, under the original methodology, Rhode Island's own ratio equaled 1.0, and its imputed floor was equal to its original CBSA wage index value. However, because the average ratio of New Jersey and Rhode Island was higher than New Jersey's own ratio, this methodology provided a benefit for New Jersey, but not for Rhode Island.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), we retained the imputed floor calculated under the original methodology as discussed above, and established an alternative methodology for computing the imputed floor wage index to address the concern that the original imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indexes (New Jersey) but could not benefit the other all-urban State (Rhode Island). The alternative methodology for calculating the imputed floor was established using data from the application of the rural floor policy for FY 2013. Under the alternative methodology, we first determined the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. (Table 4D associated with the FY 2013 IPPS/LTCH PPS final rule (which is available via the Internet on the CMS Web site) included the CBSAs receiving a State's rural floor wage index.) The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values then is increased by this factor, the result of which establishes the State's alternative imputed floor. We amended § 412.64(h)(4) of the regulations to add new paragraphs to incorporate the finalized alternative methodology, and to make reference and date changes. In summary, for the FY 2013 wage index, we did not make any changes to the original imputed floor methodology at § 412.64(h)(4) and, therefore, made no changes to the New Jersey imputed floor computation for FY 2013. Instead, for FY 2013, we adopted a second, alternative methodology for use in cases where an all-urban State has a range of wage indexes assigned to its hospitals, but the State cannot benefit under the original methodology.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50589 through 50590), we extended the imputed floor policy (both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2014, while we continued to explore potential wage index reforms.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49969 through 49970), for FY 2015, we adopted a policy to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2015, as we continued to explore potential wage index reforms. In that final rule, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect the 1-year extension of the imputed floor.

As discussed in section III.B. of the preamble of that FY 2015 IPPS/LTCH PPS final rule, we adopted the new OMB labor market area delineations beginning in FY 2015. Under the new OMB delineations, Delaware became an all-urban State, along with New Jersey and Rhode Island. Under the new OMB delineations, Delaware has three CBSAs, New Jersey has seven CBSAs, and Rhode Island continues to have only one CBSA (Providence-Warwick, RI-MA). We refer readers to a detailed discussion of our adoption of the new OMB labor market area delineations in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule. Therefore, under the adopted new OMB delineations discussed in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule, Delaware became an all-urban State and was subject to an imputed floor as well for FY 2015.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49497 through 49498), for FY 2016, we extended the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2016. In that final rule, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect this additional 1-year extension.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25068), for FY 2017, we proposed to extend the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2017. We proposed to revise the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect this proposed additional 1-year extension. We invited public comments on the proposed additional 1-year extension of the imputed floor through September 30, 2017.

Comment: Several commenters supported CMS' proposal to extend the imputed floor for 1 year, stating that it establishes an approach to remedy the competitive disadvantage suffered by all-urban States due to several unique factors common to these areas. However, these commenters urged CMS to make the imputed rural floor policy permanent rather than continue the policy through 1-year extensions, and to reevaluate the imputed floor policy only in the context of broader wage index reform. Other commenters opposed the proposed 1-year extension, stating that this type of floor should apply only when required by statute. One commenter questioned CMS' statutory authority for extending the imputed rural floor.

Response: We appreciate the positions of commenters that both support and oppose the proposal to extend the

imputed floor. We adopted the imputed floor policy to address concerns from hospitals in all-urban States and subsequently extended it through notice-and-comment rulemaking. As we stated in the FY 2005 IPPS final rule (69 FR 49110), we note that the Secretary has broad authority under section 1886(d)(3)(E) of the Act to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wage and wage-related cost of the DRG prospective payment rates for area differences in hospital wage levels by a factor (established by the Secretary). Therefore, we believe that we do have the discretion to adopt a policy that would adjust wage indexes in the stated manner.

However, we also understand the commenters' opposition to extending the imputed floor. In the FY 2008 IPPS final rule (72 FR 47322) and FY 2009 IPPS final rule (73 FR 48570 through 48574), we expressed our concern that the imputed rural floor creates a disadvantage in the application of the wage index to hospitals in States with rural hospitals but no urban hospitals receiving the rural floor. Therefore, we have not made the imputed rural floor policy permanent. We will give further consideration to all public comments if and when wage index reform is considered.

After consideration of the public comments we received, we are finalizing our proposal without modification to extend the imputed floor policy under both the original methodology and the alternative methodology for an additional year, through September 30, 2017. We also are adopting as final the proposed revisions to §§ 412.64(h)(4) and (h)(4)(vi) to reflect the 1-year extension of the imputed floor. The wage index and impact tables associated with this FY 2017 IPPS/LTCH PPS final rule (which are available on the Internet via the CMS Web site) reflect the continued application of the imputed floor policy at § 412.64(h)(4) and a national budget neutrality adjustment for the imputed floor for FY 2017. There are 18 hospitals in New Jersey that will receive an increase in their FY 2017 wage index due to the continued application of the imputed floor policy under the original methodology, and 10 hospitals in Rhode Island that will benefit under the alternative methodology. In the proposed rule (81 FR 25068), we stated that no providers in Delaware would benefit under the original methodology or the alternative methodology. However, for the final FY 2017 wage index, we have determined that, in fact, 2 hospitals in Delaware will benefit under the alternative methodology. Therefore, for this final rule, we are applying the imputed floor to these hospitals in Delaware using the alternative methodology. Tables 2 and 3 associated with this final rule (which are available via the Internet on the CMS Web site) reflect the application of the imputed floor to 2 hospitals in Delaware.

3. State Frontier Floor for FY 2017

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000 (we refer readers to regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161)). In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25068), we did not propose any changes to the frontier floor policy for FY 2017. We stated in the proposed rule that 50 hospitals would receive the frontier floor value of 1.0000 for their FY 2017 wage index in the proposed rule. These hospitals are located in Montana, Nevada, North Dakota, South Dakota, and Wyoming.

We did not receive any public comments on the application of the State frontier floor for FY 2017. In this final rule, 50 hospitals will receive the frontier floor value of 1.0000 for their FY 2017 wage index. These hospitals are located in Montana, Nevada, North Dakota, South Dakota, and Wyoming.

The areas affected by the rural, imputed, and frontier floor policies for the FY 2017 wage index are identified in Table 2 associated with this final rule, which is available via the Internet on the CMS Web site.

I. FY 2017 Wage Index Tables

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49498 and 49807 through 49808), we finalized a proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Prior to FY 2016, the wage index tables had consisted of 12 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 9A, and 9C) that were made available via the Internet on the CMS Web site. Effective beginning FY 2016, with the exception of Table 4E, we streamlined and consolidated 11 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4F, 4J, 9A, and 9C) into 2 tables (Tables 2 and 3). We refer readers to section VI. of the Addendum to this final rule for a discussion of the final wage index tables for FY 2017.

J. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) Except as discussed in section III.J.2. of the preamble of this final rule, the general policies for reclassifications and redesignations for FY 2017, and the policies for the effects of hospitals' reclassifications and redesignations on the wage index, are the same as those discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

2. Finalization of Interim Final Rule With Comment Period on Provisions Related To Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board (MGCRB)

On April 21, 2016, CMS published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) which included provisions amending our regulations to allow hospitals nationwide to reclassify based on acquired rural status, effective with reclassification applications due to the MGCRB on September 1, 2016 for reclassifications first effective for FY

2018. In addition, effective with the display date of the IFC, eligible hospitals with an existing MGCRB reclassification also may seek rural reclassification under § 412.103 for IPPS payment (such as DSH) and other purposes (such as eligibility for the section 340B program), but keep their existing MGCRB reclassification (which would control for wage index purposes). We also finalized and began to apply the policies in the IFC when deciding timely appeals before the Administrator for FY 2017 that were denied by the MGCRB due to the application of the superseded regulations, which did not permit simultaneous rural reclassification and MGCRB reclassifications. These additional regulatory changes were implemented to codify the application and interpretation of the judicial decisions resulting from the adjudication of *Geisinger Community Medical Center* v. *Secretary, United States Department of Health and Human Services,* 794 F.3d 383 (3d Cir. 2015) and *Lawrence + Memorial Hospital* v. *Burwell,* No. 15–164, 2016 WL 423702 (2d Cir. February 4, 2015) in a nationally consistent manner.

We note that, in the April 21, 2016 IFC, we found good cause for waiving notice-and-comment rulemaking and the 60-day delay in effective date, given the decisions of the courts of appeals and the public interest in consistent application of a Federal policy nationwide. We stated that revising the regulation text at § 412.230(a)(5)(ii) and removing the regulation text at § 412.230(a)(5)(iii) through an IFC and subsequent final rule rather than through the normal notice-and-comment rulemaking cycle and waiving the 60-day delay of effective date would ensure a uniform national reclassification policy. By reason of the court decisions, this policy has already been effective since July 23, 2015, in the Third Circuit and February 4, 2016 in the Second Circuit. Absent such a policy, the wage index for acute care hospitals paid under the IPPS would have remained confusingly inconsistent across jurisdictions. Even though we waived notice of proposed rulemaking requirements and issued the provisions on an interim basis with subsequent issuance of a final rule, we provided a 60-day public comment period. In this section of this final rule, we are responding to the public comments that we received on these provisions in the April 21, 2016 IFC and finalizing the interim policies.

a. Background

Hospitals may seek to have their geographic designation reclassified. Under section 1886(d)(8)(E) of the Act, a qualifying inpatient prospective payment hospital located in an urban area may apply for rural status. Specifically, section 1886(d)(8)(E) of the Act states that not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital, the Secretary shall treat the hospital as being located in the rural area (as defined in the statute) of the State in which the hospital is located if certain criteria are met. The regulations governing these geographic redesignations are codified under § 412.103. We also refer readers to the final rule published in the August 1, 2000 **Federal Register** entitled, ''Medicare Program; Provisions of the Balanced Budget Refinement Act of 1999; Hospital Inpatient Payments and Rates and Costs of Graduate Medical Education'' (65 FR 47029 through 47031) for a discussion of the general criteria for reclassifying from urban to rural under this statute. In addition, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51596), we discussed the effects on the wage index of an urban hospital reclassifying to a rural area of its State, if the urban hospital meets the requirements under § 412.103. Hospitals that are located in States without any geographically rural areas are ineligible to apply for rural reclassification in accordance with the provisions of § 412.103.

In addition, as discussed under section III.J.1. of the preamble of this final rule, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (generally by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in §§ 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies applicable to reclassifications under the MGCRB process are also discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596).

b. Criteria for an Individual Hospital Seeking Redesignation to Another Area (§ 412.103)—Application of Policy Provisions

Our policy in effect prior to the issuance of the April 21, 2016 IFC limited certain redesignations in order to preclude hospitals from obtaining urban to rural redesignation under § 412.103, and then using that obtained rural status to receive an additional reclassification through the MGCRB. In the April 21, 2016 IFC, we referred readers to § 412.230(a)(5)(iii) as it existed at that time, which stated that an urban hospital that has been granted redesignation as rural under § 412.103 cannot receive an additional reclassification by the MGCRB based on this acquired rural status for a year in which such redesignation is in effect. In other words, § 412.230(a)(5)(iii) prohibited a hospital from simultaneously receiving an urban to rural redesignation under § 412.103 and a reclassification under the MGCRB.

As discussed in the April 21, 2016 IFC, on July 23, 2015 the Court of Appeals for the Third Circuit issued a decision in *Geisinger Community Medical Center* v. *Secretary, United States Department of Health and Human Services,* 794 F.3d 383 (3d Cir. 2015). Geisinger Community Medical Center (''Geisinger''), a hospital located in a geographically urban CBSA, obtained rural status under § 412.103, but was unable to receive additional reclassification through the MGCRB while still maintaining its rural status under § 412.230(a)(5)(iii). Under the regulations prior to the April 21, 2016 IFC, to receive reclassification through the MGCRB under existing regulations, *Geisinger* would have had to first cancel its § 412.103 urban-to-rural redesignation and use the proximity requirements for an urban hospital rather than take advantage of the broader proximity requirements for reclassification granted to rural hospitals. (In the April 21, 2016 IFC, we referred readers to § 412.230(b)(1), which states that a hospital demonstrates a close proximity with the area to which it seeks redesignation if the distance from the hospital to the area is no more than 15 miles for an urban hospital and no more than 35 miles for a rural hospital.) *Geisinger* challenged as unlawful the regulation at § 412.230(a)(5)(iii) requiring cancelation of its rural reclassification prior to

applying for reclassification through the MGCRB. In *Geisinger Community Medical Center* v. *Burwell,* 73 F. Supp.3d 507 (M.D. Pa. 2014), the District Court for the Middle District of Pennsylvania upheld the regulation at § 412.230(a)(5)(iii) and granted summary judgment in favor of CMS. The Court of Appeals for the Third Circuit reversed the decision of the District Court, holding that the language of section 1886(d)(8)(E)(i) of the Act is unambiguous in its plain intent that ''the Secretary shall treat the hospital as being located in the rural area,'' inclusive of MGCRB reclassification purposes, thus invalidating the regulation at § 412.230(a)(5)(iii). On February 4, 2016, the Court of Appeals for the Second Circuit issued its decision in *Lawrence + Memorial Hospital* v. *Burwell,* No. 15–164, 2016 WL 423702 (2d Cir. February 4, 2016), essentially following the reasoning of the Third Circuit *Geisinger* decision.

We stated in the IFC that while these decisions currently apply only to hospitals located within the jurisdictions of the Second and Third Circuits, we believed that maintaining the regulations at § 412.230(a)(5)(iii) in other circuits would constitute inconsistent application of the reclassification policy based on jurisdictional regions. In the interest of creating a uniform national reclassification policy, in the IFC, we removed the regulation text at § 412.230(a)(5)(iii). We also revised the regulation text at § 412.230(a)(5)(ii) to allow more than one reclassification for those hospitals redesignated as rural under § 412.103, and simultaneously seeking reclassification through the MGCRB. Specifically, we revised § 412.230(a)(5)(ii) to state that a hospital may not be redesignated to more than one area, except for an urban hospital that has been granted redesignation as rural under § 412.103 and receives an additional reclassification by the MGCRB. Therefore, effective for reclassification applications due to the MGCRB by September 1, 2016, for reclassification first effective for FY 2018, a hospital may apply for a reclassification under the MGCRB while still being redesignated from urban to rural under § 412.103. Such hospitals are eligible to use distance and average hourly wage criteria designated for rural hospitals at § 412.230(b)(1) and (d)(1). In addition, we provided that, effective with the public display date of the IFC, a hospital that has an active MGCRB reclassification and is then approved for redesignation under § 412.103 will not lose its MGCRB reclassification; that is, a hospital with an active MGCRB reclassification can simultaneously maintain rural status under § 412.103, and receive a reclassified urban wage index during the years of its active MGCRB reclassification and will still be considered rural under section 1886(d) of the Act and for other purposes. We also stated that we will apply the policy adopted in the April 21, 2016 IFC when deciding timely appeals before the Administrator under § 412.278 for FY 2017 that were denied by the MGCRB due to existing provisions of § 412.230(a)(5)(ii) and (iii), which did not permit simultaneous § 412.103 and MGCRB reclassifications.

Apart from the direct impact on reclassifying hospitals previously discussed in this section, we also considered how to treat the wage data of hospitals that maintain simultaneous reclassifications under both the § 412.103 and the MGCRB processes. Under the wage index calculation procedures that applied prior to issuance of the IFC, the wage data for a hospital geographically located in an urban area with a § 412.103 redesignation was included in the wage index for its home geographic area. It is also included in its State rural wage index, if including wage data for hospitals with rural reclassification raises the state's rural floor. In addition, the wage data for a hospital located in an urban area, and that is approved by the MGCRB to reclassify to another urban area (or another State's rural area), are included in its home area wage index calculation, and in the calculation for the reclassified ''attaching'' area. In the IFC, we referred readers to the FY 2012 IPPS final rule (76 FR 59595 through 59596) for a full discussion of the effect of reclassification on wage index calculations. Furthermore, as discussed in the FY 2007 IPPS final rule (71 FR 48020 through 48022), hospitals could not simultaneously maintain more than one wage index status (for example, a hospital could not simultaneously maintain a § 412.103 rural redesignation and an MGCRB reclassification, nor could a hospital receive an outmigration adjustment while also maintaining MGCRB or Lugar status). However, as a consequence of the court decisions previously discussed, we revised our regulations and created a rule that applies to all hospitals nationally, regarding the treatment of the wage data of hospitals that have both a § 412.103 redesignation and an MGCRB reclassification. In the IFC, we established that if a hospital with a § 412.103 redesignation is approved for an additional reclassification through the MGCRB process, and the hospital accepts its MGCRB reclassification, the Core-Based Statistical Area (CBSA) to which the hospital is reclassified under the MGCRB prescribes the area wage index that the hospital will receive; the hospital will not receive the wage index associated with the rural area to which the hospital is redesignated under § 412.103. That is, when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification will control for wage index calculation and payment purposes. Therefore, although we amended our policy with the IFC to allow a hospital to simultaneously have a reclassification under the MGCRB and an urban to rural redesignation under § 412.103, we separately clarified that we will exclude hospitals with § 412.103 redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. In these circumstances, we stated that we believe it is appropriate to rely on the urban MGCRB reclassification to include the hospital's wage data in the calculation of the urban CBSA wage index. Further, we stated that we believe it is appropriate to rely on the urban MGCRB reclassification to ensure that the hospital is paid based on its urban MGCRB wage index. That is, while rural reclassification confers other rural benefits besides the wage index under section 1886(d) of the Act, a hospital that chooses to pursue reclassification under the MGCRB (while also maintaining a rural redesignation under § 412.103) would do so solely for wage index payment purposes.

As previously stated, when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification will control for wage index calculation and payment purposes. That is, if an application for urban reclassification through the MGCRB is approved, and is not withdrawn or terminated by the hospital within the established timelines, we will consider, as is current practice, the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We indicated that the hospital's geographic CBSA and reclassified CBSA would be reflected accordingly in Tables 2 and 3, associated with the annual IPPS/LTCH PPS proposed and final rules, which are available through the Internet on the CMS Web site.) However, in the absence of an active MGCRB reclassification, if

the hospital has an active § 412.103 redesignation, CMS will treat the hospital as rural under § 412.103 redesignation for IPPS payment and other purposes, including purposes of calculating the wage indices reflected in Tables 2 and 3 of the annual IPPS/LTCH PPS proposed and final rules

Comment: One commenter requested that, as part of the IPPS rulemaking process, CMS release data on the hospitals that have been granted redesignation under § 412.103 and receive an additional reclassification by the MGCRB. The commenter noted that while, in the payment impact file, there is a ''401 hospital'' field that indicates whether a hospital has been redesignated as rural under § 412.103, it appears that hospitals that have both a § 412.103 redesignation and an MGCRB reclassification do not have a ''Yes'' in the ''401 hospital'' field. The commenter requested that this field be labeled ''Yes'' when a hospital with a § 412.103 redesignation also receives an MGCRB reclassification.

Response: We agree with the commenter's request and will include a column in the public use impact file posted on the CMS Web site in conjunction with the IPPS rules to indicate that a hospital has a § 412.103 redesignation when it also has an MGCRB reclassification. This file can be located by visiting the following link *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* and selecting that IPPS regulation's home page on the left side of the screen. The impact files are located under ''Impact File and Data Files''.

Comment: Two commenters noted that the regulations at § 412.103 still require that an urban hospital requesting rural status use the statewide rural wage index for at least a 12-month period before the facility can be reclassified using the rural proximity requirement. The commenters requested that CMS clarify that those hospitals that have already used the rural wage index for one or more previous 12-month periods are allowed to choose to use their home geographic wage index, rather than the § 412.103 rural wage index, for the 12 months prior to receiving a MGCRB reclassification for FY 2018 or years beyond.

Response: We are unsure of the meaning of the commenter's statement ''the regulations at § 412.103 still require that an urban hospital requesting rural status use the statewide rural wage index for at least a 12 month period before the facility can be reclassified using the rural proximity requirement.'' The regulations at § 412.103 do not indicate a time period for using the statewide rural wage index before a hospital can be reclassified using the rural proximity requirement; rather, the 12-month time period referenced at § 412.103 pertains to cancellation of rural reclassification for a hospital classified as a rural referral center based on a § 412.103 reclassification. We also do not understand the commenter's request for clarification that hospitals that have received the rural wage index for 12 months be allowed to use their geographic home wage index prior to receiving an MGCRB reclassification for FY 2018 and after, because the regulations do not address payment at the rural wage index for a period of time in order to receive an MGCRB reclassification based on a § 412.103 redesignation. We reiterate that, as indicated in the IFC, when there is both an MGCRB reclassification and a § 412.103 redesignation, the MGCRB reclassification will control for wage index calculation and payment purposes; the hospital will not receive the wage index associated with the rural area to which the hospital is redesignated under § 412.103. We also reiterate that for any period of time that a hospital has a § 412.103 redesignation but not a MGCRB reclassification, the hospital will be paid using the rural wage index, and not its geographic home wage index.

Comment: One commenter requested clarification as to whether a hospital redesignated as rural under § 412.103 can use that rural status to reclassify to a nearby rural area. The commenter asked that CMS clarify whether a hospital redesignated as rural will be treated as rural for purposes of a rural to rural reclassification application.

Response: We are clarifying that a hospital redesignated as rural under § 412.103 can use that rural status to reclassify via the MGCRB to another rural or urban area, provided it meets the distance and average hourly wage criteria under § 412.230(b)(1), (d)(1)(iii)(C), and (d)(1)(iv)(E).

Comment: One commenter requested clarification on several aspects of the amended regulations. The commenter requested that CMS clarify that—

- The rural distance and average hourly wage criteria will be used for hospitals with a § 412.103 redesignation;
- The hospital's average hourly wage data are to be compared to the average hourly wage data for the State's rural area for purposes of determining whether the hospital meets the criterion in § 412.230(d)(l)(iii)(C);
- A rural redesignated hospital can undergo an MGCRB reclassification back to the CBSA in which it is physically located;
- Hospitals redesignated as rural can have dual MGCRB reclassifications, with the termination or withdrawal of one of the reclassifications after the issuance of the IPPS proposed rule, consistent with § 412.273;
- Hospitals redesignated as rural can still be part of an urban group seeking redesignation to another urban area for the geographic area where they are physically located, in accordance with § 412.234;
- In all future years, hospitals that already have an MGCRB reclassification can receive a § 412.103 redesignation without losing their MGCRB reclassification; and
- If a hospital has both an MGCRB reclassification and a § 412.103 redesignation, the wage data will be included in the urban area to which it is reclassified, rather than the rural area.

Response: The commenter is correct that the rural distance and average hourly wage criteria will be used for hospitals with a § 412.103 redesignation. However, the commenter's statement that the average hourly wage of a hospital with a § 412.103 redesignation is compared to the average hourly wage of hospitals in the State's rural area under § 412.230(d)(1)(iii)(C) is incorrect. Instead, the hospital's average hourly wage would be compared to the average hourly wage of all other hospitals in its urban geographic location using the rural distance and average hourly wage criteria. The commenter is correct that a § 412.103 rural redesignated hospital can undergo an MGCRB reclassification back to the CBSA in which it is physically located if it meets the criteria for use of an urban or other rural area's wage index at § 412.230(d) using the average hourly wage criteria specified for rural hospitals. We are unsure of the meaning of ''dual MGCRB reclassifications'' because a hospital can only have one MGCRB reclassification at a time.

We refer the commenter to the regulations at § 412.273 which describe the policies for withdrawing an MGCRB application, terminating an approved 3-year MGCRB reclassification, or canceling a previous withdrawal or termination. The policies at § 412.273 apply to all MGCRB reclassifications, including those that are held in addition to a § 412.103 redesignation.

The commenter is correct that a geographically urban hospital redesignated as rural under § 412.103 can still apply for group reclassification

with other urban hospitals located in the same geographically urban area to another urban area via the MGCRB, in accordance with § 412.234, and that effective with the IFC display date (April 18, 2016) and for future years, hospitals that already have an MGCRB reclassification can receive a § 412.103 redesignation without losing their MGCRB reclassification. Finally, we are reiterating that wage data for a hospital with both an MGCRB reclassification and a § 412.103 redesignation would be included in the post-reclassified wage index of the area to which it is reclassified under the MGCRB, and not the rural area to which it is reclassified under § 412.103.

Comment: One commenter requested that CMS repeal the provision § 412.103(g)(2) because the new policy has rendered this provision irrelevant. The commenter referenced CMS' discussion of this issue in the FY 2008 IPPS final rule (72 FR 47371 through 47373), and stated that the goal of creating this minimum time period was to disincentivize hospitals to receive a rural redesignation, obtain rural referral center status to achieve favorable MGCRB treatment, and then terminate their rural status. The commenter believed that because hospitals can now be both an urban and a rural referral center, this disincentive is no longer necessary.

Response: We appreciate the commenter's suggestion. The discussion in the FY 2008 IPPS final rule referenced by the commenter addressed a revision to § 412.103(g) to require that, for a hospital that obtains rural referral center status based on acquired rural status under § 412.103, the hospital's cancellation of its acquired rural status under § 412.103 is effective after it has been paid as rural for at least one 12-month cost reporting period, and not until the beginning of a Federal fiscal year following both the request for cancellation and the 12-month cost reporting period. The discussion in the FY 2008 IPPS final rule noted our concerns about hospitals that acquire rural status to become rural referral centers and then cancel acquired rural status after a brief period of time in order to take advantage of special MGCRB reclassification rules, which was the basis for the revisions to the regulation at § 412.103(g). Because we did not propose a change in the regulation regarding the interplay of rural redesignations and rural referral center status in particular, we are not amending these regulations at this time, but may address this issue in future rulemaking.

In summary, for reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. In addition, effective with the public display date of the IFC (April 18, 2016), a hospital with an active MGCRB reclassification may also acquire rural status under § 412.103. We stated that we also will apply the policy in the April 21, 2016 IFC when deciding timely appeals before the Administrator under § 412.278 for FY 2017 that were denied by the MGCRB due to then existing provisions of § 412.230(a)(5)(ii) and (iii), which did not permit simultaneous § 412.103 redesignation and MGCRB reclassifications. When there is both an MGCRB reclassification and a § 412.103 reclassification, the MGCRB reclassification will control for wage index calculation and payment purposes. For a discussion regarding budget neutrality adjustments for FY 2017 and subsequent years for hospitals that have a reclassification under § 412.103 and an MGCRB reclassification, we refer readers section II.A.4. of the Addendum to this FY 2017 IPPS/LTCH PPS final rule.

c. Final Rule Provisions

In this final rule, we are finalizing the provisions of the April 21, 2016 IFC without modification. We also are finalizing without modification our removal of § 412.230(a)(5)(iii) and the revisions to § 412.230(a)(5)(ii).

d. Impact

In the April 21, 2016 IFC (81 FR 23436 through 23438), we presented the following impact analysis for the IPPS wage index portion of the IFC. We are not making any changes to this IFC impact analysis in this final rule.

We did not conduct an in-depth impact analysis because our revision to the regulatory text is a consequence of court decisions. The *Geisinger* decision invalidated the regulation at § 412.230(a)(5)(iii), effective July 23, 2015, for hospitals in States within the Third Circuit's jurisdiction, and the *Lawrence + Memorial* decision invalidated the regulation at § 412.230(a)(5)(iii), effective February 4, 2016, for hospitals in States within the Second Circuit's jurisdiction. That is, we did not have a choice to maintain the previously uniform regulations at § 412.230(a)(5)(iii) for hospitals in States within the Second and Third Circuits.

Furthermore, we indicated that we do not believe that we could necessarily estimate the national impact of removing the regulation at § 412.230(a)(5)(iii). We noted that of the 3,586 IPPS hospitals listed on wage index Table 2 associated with the proposed rule and available via the Internet on the CMS Web site, 867 hospitals already had an MGCRB reclassification, and 57 hospitals had a reclassification to a rural area under § 412.103. (This table is discussed in the FY 2017 IPPS/LTCH PPS proposed rule and is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2017 IPPS Proposed Rule Home Page''.) We could not estimate how many additional hospitals will elect to apply to the MGCRB by September 1, 2016, for reclassification beginning FY 2018, and we could not predict how many hospitals may elect to retain or acquire § 412.103 urban-to-rural reclassification over and above the hospitals that have already reclassified.

In addition, under § 412.64(e)(1)(ii), (e)(2), and (e)(4), increases in the wage index due to reclassification and other wage index adjustments are implemented in a budget neutral manner (that is, wage index adjustments are made in a manner that ensures that aggregate payments to hospitals are unaffected through the application of a wage index budget neutrality adjustment described more fully in the FY 2017 IPPS/LTCH PPS proposed rule). Therefore, as a result of the Third Circuit's decision in *Geisinger,* even though an urban hospital that may or may not already have a reclassification to another urban area under the MGCRB may be able to qualify for a reclassification to a more distant urban area with an even higher wage index, this would not increase aggregate IPPS payments (although the wage index budget neutrality factor applied to IPPS hospitals could be larger as a result of additional reclassifications occurring to higher wage index areas).

However, we noted in the IFC that there are other Medicare payment provisions potentially impacted by rural status, such as payments to disproportionate share hospitals (DSHs), and non-Medicare payment provisions, such as the 340B Drug Pricing Program administered by HRSA, under which payments are not made in a budget neutral manner. We noted that additional hospitals acquiring rural status under § 412.103 could, therefore, potentially increase Federal expenditures. Nevertheless, taking all of these factors into account, we indicated that we could not accurately determine an impact analysis as a result of the

Third Circuit's decision in *Geisinger* and the Second Circuit's decision in *Lawrence + Memorial.*

Comment: One commenter stated that because the 340B Drug Pricing Program is not a government payment program, Federal expenditures would not be expected to increase as a result of this change to CMS' regulations. The commenter noted that other possible impacts on Federal expenditures would be unrelated to the 340B Drug Pricing Program. The commenter requested that CMS clarify that Federal expenditures would not be increased as a result of the 340B Drug Pricing Program.

Response: We agree with the commenter that because the 340B Drug Pricing Program is not a Federal payment program, Federal expenditures would not be expected to increase as a result of any increased eligibility for the 340B Drug Pricing Program resulting from this change to our regulations.

The Regulatory Flexibility Act (RFA) also requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. MACs are not considered to be small entities. We believe that the provisions of this final rule may have an impact on some small entities, but for the reasons previously discussed in this final rule, we cannot conclusively determine the number of such entities impacted. Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary hospitals. Therefore, we are assuming that all hospitals are considered small entities for the purpose of the RFA. Because we acknowledge that many of the potentially affected entities are small entities, the discussion in this section regarding potentially impacted hospitals constitutes our regulatory flexibility analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a metropolitan statistical area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. For this final rule, no geographically rural hospitals are directly affected because only urban hospitals can reclassify to a rural area under § 412.103. However, we note that with regard to the wage index budget neutrality adjustments applied under § 412.64(e)(1)(ii), (e)(2), and (e)(4), rural IPPS hospitals will be affected to the extent that the reclassification budget neutrality adjustment increases, but this impact is no different than on urban IPPS hospitals, as the same budget neutrality factor is applied to all IPPS hospitals.

3. Other MGCRB Reclassification and Redesignation Issues for FY 2017

a. FY 2017 Reclassification Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280.

At the time this final rule was constructed, the MGCRB had completed its review of FY 2017 reclassification requests. Based on such reviews, there are 265 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2017. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2017, hospitals reclassified beginning in FY 2015 or FY 2016 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 294 hospitals approved for wage index reclassifications in FY 2015 that will continue for FY 2017, and 258 hospitals approved for wage index reclassifications in FY 2016 that will continue for FY 2017. Of all the hospitals approved for reclassification for FY 2015, FY 2016, and FY 2017, based upon the review at the time of this final rule, 817 hospitals are in a MGCRB reclassification status for FY 2017. We note that the number of hospitals with active reclassifications changed between the proposed rule and the final rule because hospitals had the opportunity to withdraw or terminate their reclassification within 45 days of the publication of the FY 2017 proposed rule.

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of a proposed rule. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to 42 CFR 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications, were included in the FY 2008 IPPS final rule (72 FR 47333).

Changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2017 are incorporated into the wage index values published in this FY 2017 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value that redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further, the wage index value for the area from which the hospitals are redesignated/reclassified may be affected.

Comment: One commenter stated that CMS' policy that hospitals must request to withdraw or terminate MGCRB reclassifications within 45 days of the proposed rule is problematic because a hospital could terminate a reclassification based on information in

the proposed rule, and with the publication of the final rule, discover that its original reclassified status was more desirable. The commenter stated that hospitals cannot make informed decisions concerning their reclassification status based on values in a proposed rule that are likely to change and, therefore, recommended that CMS revise its existing policy to permit hospitals to withdraw or terminate their reclassification status within 45 days of the publication of the final rule.

Several other commenters requested that CMS revise group reclassification rules at § 412.234(a)(3)(iv) so that urban county groups would no longer be required to be within the same CSA or CBSA as the desired labor market area.

Response: We did not make any proposals to change any of the reclassification regulations for FY 2017. Any changes to the reclassification regulations would need to be first proposed through notice-and-comment rulemaking. Consequently, we are not making any changes to address the commenters' concerns at this time. We maintain that information provided in the proposed rule constitutes the best available data to assist hospitals in making reclassification decisions. The values published in the final rule represent the final wage index values reflective of reclassification decisions.

b. Requirements for FY 2018 Applications and Revisions Regarding Paper Application Requirements

Applications for FY 2018 reclassifications are due to the MGCRB by September 1, 2016 (the first working day of September 2016). We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2016, via the Internet on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html*, or by calling the MGCRB at (410) 786–1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244–2670.

Under existing regulations at 42 CFR 412.256(a)(1), applications for reclassification must be mailed or delivered to the MGCRB, with a copy to CMS, and may not be submitted through the facsimile (FAX) process or by other electronic means. While existing regulations exclusively require paper applications, we believe this policy to be outdated and overly restrictive. Therefore, to promote ease of application for FY 2018 and subsequent years, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25069), we proposed to revise this policy to require applications and supporting documentation to be submitted via the method prescribed in instructions by the MGCRB, with an electronic copy to CMS. Therefore, we proposed to revise § 412.256(a)(1) to specify that an application must be submitted to the MGCRB according to the method prescribed by the MGCRB, with an electronic copy of the application sent to CMS. We specified that CMS copies should be sent via email to *wageindex@cms.hhs.gov*. We invited public comments on this proposal.

Comment: Commenters supported CMS' proposal to require electronic copies for wage index reclassification materials. Commenters requested that CMS provide email confirmation upon receipt of these copies, and further request CMS to provide additional guidance on how to submit files that may be too large for some email systems.

Response: We appreciate the commenters' support of our proposal, and we are finalizing the regulation change as proposed. We reiterate that MGCRB application requirements will be published separately from this rulemaking process, and paper applications will likely still be required. The MGCRB makes all initial determinations for geographic reclassification requests, but CMS requests copies of all applications to assist in verifying a reclassification status during the wage index development process. We believe that requiring electronic versions would better aid CMS in this process, and would reduce the overall burden upon hospitals. We appreciate the commenters' request for email verification that an application was received in the *wageindex@cms.hhs.gov* mailbox, and we will endeavor to provide such validation in a timely manner. Regarding issues with email size, we believe that a scanned PDF copy of an application should rarely exceed the size limitations of most email systems. In circumstances when this may be an issue, we request that hospitals notify the wage index mailbox to arrange for an alternate delivery method. We also request that all correspondence with the wage index mailbox clearly identify the hospital's CCN (or the county and state for group reclassification requests) in the subject line, and that emails include a name, email address, and phone number of a responsible party at the hospital, should CMS need to contact the hospital to request or clarify certain information.

Comment: Commenters requested additional guidance regarding acceptable materials for a variety of MGCRB application requirements, specifically for documenting proximity requirements.

Response: As discussed previously, MGCRB application instructions are published on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html* separately from the rulemaking process.

We are finalizing our proposal to revise § 412.256(a)(1), without modification, to specify that an application must be submitted to the MGCRB according to the method prescribed by the MGCRB, with an electronic copy of the application sent to CMS. We are specifying that CMS copies should be sent via email to *wageindex@cms.hhs.gov*.

c. Other Policy Regarding Reclassifications for Terminated Hospitals

Under longstanding CMS policy, if a hospital that has an approved reclassification by the MGCRB terminates its CMS certification number (CCN), we terminate the reclassification status for that hospital when calculating the wage index, because the CCN is no longer active, and because the MGCRB makes its reclassification decisions based on CCNs. We believe this policy results in more accurate reclassifications when compiling CBSA labor market wage data, as it is often the case that hospitals that have terminated their CCNs have also terminated operations, and can no longer make timely and informed decisions regarding reclassification statuses, which could have ramifications for various wage index floors and labor market values.

However, as discussed in response to a comment in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49499 through 49500), in the case of a merger or acquisition where the acquiring hospital accepted the Medicare provider agreement of the acquired hospital located in a different market area that has an existing MGCRB reclassification, we do believe that the acquiring hospital should be able to make determinations regarding the reclassification status of the subordinate campus. While the original CCN for the acquired hospital would be considered terminated or ''tied out'' by CMS, in the specific situations where a hospital merges with or acquires another hospital located in a different labor market area to create a ''multicampus''

hospital and accepts the Medicare provider agreement of the acquired hospital, the reclassification status of the subordinate campus remains in effect. The acquired campus (that is, the hospital whose CCN is no longer active) may continue to receive its previously approved reclassification status, and the acquiring hospital is authorized to make timely requests to terminate, withdraw, or reinstate any reclassification for the subordinate campus for any remaining years of the reclassification. We stated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25070) that we believe this policy is consistent with existing regulations regarding reclassification status of ''multicampus'' hospitals at § 412.230(d)(2)(v). We further stated that hospitals should take care to review their status on Table 2 associated with the proposed rule (which is available via the Internet on the CMS Web site) and notify CMS if they believe a reclassification for a hospital was mistakenly terminated by CMS.

We did not receive any public comments on our clarification regarding the treatment of reclassifications of terminated hospitals.

4. Redesignation of Hospitals Under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B)(i) of the Act requires the Secretary to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban MSA to which the greatest number of workers in the county commute if certain adjacency and commuting criteria are met. The criteria utilize standards for designating MSAs published in the **Federal Register** by the Director of the Office of Management and Budget (OMB) based on the most recently available decennial population data. Effective beginning FY 2015, we use the OMB delineations based on the 2010 Decennial Census data to identify counties in which hospitals qualify under section 1886(d)(8)(B) of the Act to receive the wage index of the urban area. Hospitals located in these counties are referred to as ''Lugar'' hospitals and the counties themselves are often referred to as ''Lugar'' counties. The chart for this FY 2017 final rule with the listing of the rural counties containing the hospitals designated as urban under section 1886(d)(8)(B) of the Act is available via the Internet on the CMS Web site.

We refer readers to section III.J.2. of the preamble of this final rule for discussion and the finalization of the April 21, 2016 IFC (CMS–1664–IFC; 81 FR 23428) in which CMS made regulatory changes in order to implement the decisions in *Geisinger Community Medical Center* v. *Secretary, United States Department of Health and Human Services,* 794 F.3d 383 (3d Cir. 2015) and *Lawrence + Memorial Hospital* v. *Burwell,* No. 15–164, 2016 WL 423702 (2d Cir. Feb. 4, 2015) in a nationally consistent manner. Specifically, the IFC revised the regulations at § 412.230(a)(5)(ii) and removed the regulatory provision at § 412.230(a)(5)(iii) to allow hospitals nationwide to reclassify based on their acquired rural status, effective with reclassifications beginning with FY 2018. The IFC also gave hospitals with an existing MGCRB reclassification the opportunity to seek rural reclassification under § 412.103 and keep their existing MGCRB reclassification.

As a consequence of the regulatory changes in the IFC that allow a hospital to have more than one reclassification simultaneously, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25070), we clarified that a hospital with Lugar status may simultaneously receive an urban to rural reclassification under § 412.103. The IFC provides that when there is both a § 412.103 reclassification and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes. Similarly, in the FY 2017 proposed rule, we also clarified that we are treating the wage data of hospitals with simultaneous Lugar status and § 412.103 reclassification as Lugar for wage index calculation and wage index payment purposes. We stated that we believe it is appropriate to apply a similar policy for simultaneous MGCRB reclassification and § 412.103 reclassifications, and simultaneous Lugar and § 412.103 reclassifications, because CMS treats Lugar status as a reclassification for purposes of calculating the wage index in accordance with section 1886(d)(8)(C)(iii) of the Act. (Section 1886(d)(8)(C)(iii) of the Act states that the application of section 1886(d)(8)(B) of the Act or a decision of the MGCRB or the Secretary under section 1886(d)(10) of the Act may not result in the reduction of any county's wage index to a level below the wage index for rural areas in the State in which the county is located.) The wage index associated with the Lugar status, and not the wage index associated with the § 412.103 reclassification, is reflected accordingly in Table 2 associated with this final rule (which is available via the Internet on the CMS Web site). We note that, for payment purposes other than the wage index, a hospital with simultaneous § 412.103 status and Lugar reclassification receives payment as a rural hospital.

Comment: Commenters supported the policy to allow Lugar hospitals to retain their reclassified wage index when they obtain a rural reclassification under § 412.103.

Response: We appreciate the commenters' support.

After consideration of public comments we received, we are again clarifying that a hospital with Lugar status may simultaneously receive an urban to rural reclassification under § 412.103. As discussed above, we are assigning hospitals that qualify under section 1886(d)(8)(B) of the Act while simultaneously maintaining rural status obtained under § 412.103 the wage index associated with their Lugar status.

5. Waiving Lugar Redesignation for the Out-Migration Adjustment

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the DSH payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. (We refer readers to a discussion of DSH payment adjustment under section IV.F. of the preamble of this final rule.)

In addition, we adopted a minor procedural change in that rule that allows a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. Therefore, under the procedural change, a Lugar hospital that requests to waive its urban status in order to receive the rural wage index in addition to the out-migration adjustment would be deemed to have accepted the out-migration adjustment and agrees to be treated as rural for the duration of its 3-year eligibility period, unless, prior to its second or third year of eligibility, the hospital explicitly notifies CMS in writing, within the required period (generally 45 days from the publication of the proposed rule),

that it instead elects to return to its deemed urban status and no longer wishes to accept the out-migration adjustment. If the hospital does notify CMS that it is electing to return to its deemed urban status, it would again be treated as urban for all IPPS payment purposes.

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600) for a detailed discussion of the policy and process for waiving Lugar status for the out-migration adjustment.

We did not receive any public comments on this issue. In the FY 2017 IPPS/LTCH PPS proposed rule, we did not propose a change to the rules regarding waiving Lugar designation for the out-migration adjustment. Therefore, the process remains unchanged at this time. However, as a separate matter, we are taking the opportunity to clarify that a request to waive Lugar status, received within 45 days of the publication of the proposed rule, is valid for the full 3-year period for which the hospital's out-migration adjustment is effective. If a hospital wishes to reinstate Lugar status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of the proposed rule for that particular fiscal year. These requests may be sent electronically to *wageindex@cms.hhs.gov*. CMS will not consider reinstatements of Lugar status for a future fiscal year. For example, if a hospital requests to waive Lugar status for FY 2017 and also to reinstate Lugar status for FY 2018 and 2019, CMS will disregard the reinstatement requests for FY 2018 and FY 2019. Instead, the hospital must request the reinstatement of Lugar status for FY 2018 within 45 days of the FY 2018 IPPS/LTCH PPS proposed rule. If the hospital does this, by default, the hospital would retain Lugar status for FY 2019, although the hospital may once again opt to waive Lugar status for the out-migration adjustment by sending a new request to CMS within 45 days of the FY 2019 IPPS/LTCH PPS proposed rule.

K. Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees for FY 2017

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at the time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new out-migration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-Year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49501), the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment were applicable for FY 2016, and we proposed to use them again for FY 2017. As we stated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25071), we have applied the same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2017. We did not receive any comments on these proposals. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2017, until such time that CMS finalizes out-migration adjustments based on the next Census, the out-migration adjustment continues to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-Year) Microdata. For FY 2017, we did not propose any changes to the methodology or data source that we used for FY 2016 (81 FR 25071). (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).) Table 2 associated with this final rule (which is available via the Internet on the CMS Web site) includes the final out-migration adjustments for the FY 2017 wage index.

L. Notification Regarding CMS ''Lock-In'' Date for Urban to Rural Reclassifications Under § 412.103

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25071 through 25072), under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals.

Hospitals must meet the criteria to be reclassified from urban to rural status under § 412.103, as well as fulfill the requirements for the application process. However, under existing § 412.103(b), there is no timeframe requirement as to when hospitals must apply for the urban to rural reclassification. Therefore, a hospital can apply for the urban to rural reclassification at any time, and under § 412.103(d), the effective date of the hospital's rural status, once approved, is the filing date of the application.

There may be one or more reasons that a hospital applies for the urban to

rural reclassification, and the timeframe that a hospital submits an application is often dependent on those reason(s). Because there are no timeframes for when a hospital must submit its application under § 412.103, it is the hospital's prerogative as to when it files the application with the CMS Regional Office. Because the wage index is part of the methodology for determining the prospective payments to hospitals for each fiscal year, we believe there should be a definitive timeframe within which a hospital should apply for rural status in order for the reclassification to be reflected in the next Federal fiscal year's wage data used for setting payment rates. As hospitals are aware, the IPPS ratesetting process that CMS undergoes each proposed and final rulemaking is complex and labor-intensive, and subject to a compressed timeframe in order to issue the final rule each year within the timeframes for publication. Accordingly, CMS must ensure that it receives, in a timely fashion, the necessary data, including, but not limited to, the list of hospitals that are reclassified from urban to rural status under § 412.103, in order to calculate the wage indexes and other IPPS rates.

Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25071 through 25072), we proposed a date by when we would ''lock in'' the list of hospitals that are reclassified from urban to rural status under § 412.103 in order to include them in the upcoming Federal fiscal year's wage index calculation provided for at § 412.64(h) and budget neutrality calculations provided for at §§ 412.64(e)(1)(ii), (e)(2), and (e)(4) that are part of the ratesetting process. The ratesetting process is described in the Addendum of the annual proposed and final rules and includes the budget neutrality adjustments in accordance with the regulations at §§ 412.64(e)(1)(ii), (e)(2), and (e)(4), as well as adjustments for differences in area wage levels provided for at § 412.64(h). We stated in the proposed rule (81 FR 25072) that we believe this proposal would introduce additional transparency and predictability regarding the timing of accounting for urban or rural status in the IPPS ratesetting each Federal fiscal year. We proposed that this date for ''locking in'' the list of hospitals with rural status achieved under § 412.103 would be the second Monday in June of each year. Therefore, if a hospital is applying for an urban to rural reclassification under § 412.103 for the purpose and expectation that its rural status be reflected in the wage index and budget neutrality calculations for setting payment rates for the next Federal fiscal year, the hospital would need to file its application with the CMS Regional Office not later than 70 days prior to the second Monday in June. Because, under § 412.103(c), the CMS Regional Office must notify the hospital of its approval or disapproval of the application within 60 days of the hospital's filing date (the date it is received by the CMS Regional Office, in accordance with § 412.103(b)(5)), we stated that we would expect that the extra 10 days would provide the CMS Regional Office with sufficient processing and administrative time to notify the CMS Central Office of the reclassification status of the applications by the second Monday in June of each year. This is the latest date that CMS would need the information in order to ensure that reclassified hospitals would be included as such in the wage index and budget neutrality calculations for setting payment rates for the next Federal fiscal year. As discussed in the proposed rule, this does not preclude a hospital from applying for reclassification under § 412.103 earlier or later than the proposed deadline. Nor does the proposed deadline change the fact that the rural reclassification is effective as of its filing date, in accordance with § 412.103(d). However, in order to ensure that a reclassification is reflected in the wage index and budget neutrality calculations for setting payment rates for the next Federal fiscal year, applications must be received by the CMS Regional Office (the filing date) by no later than 70 days prior to the second Monday in June of the current Federal fiscal year. If the CMS Central Office is informed of a reclassification status after the second Monday in June, for wage index and budget neutrality purposes, the reclassification would not be reflected in the payment rates until the following Federal fiscal year; that is, the Federal fiscal year following the next Federal fiscal year. We proposed to revise § 412.103(b) by adding a new paragraph (6) to specify that, in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under §§ 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year, the hospital's filing date must be no later than 70 days prior to the second Monday in June of the current Federal fiscal year and the application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103.

Comment: One commenter believed that the proposal to specify a lock-in date for urban to rural reclassification under § 412.103 for wage index and budget neutrality calculation purposes was reasonable and supported the need to have a ''cutoff'' date. However, the commenter requested clarification that the lock-in date for wage index and ratesetting purposes would have no impact on the timing of payment changes at the hospital-specific level.

Response: We appreciate the commenter's support. We proposed to set a lock-in date by which a hospital must file for urban to rural reclassification under § 412.103 in order to be treated as rural in the upcoming fiscal year's wage index and budget neutrality calculations. Thus, if a hospital wants its rural status to be reflected in the wage index and budget neutrality calculations for setting payment rates for the upcoming fiscal year, the hospital would need to file its reclassification application with the CMS Regional Office not later than 70 days prior to the second Monday in June of the current Federal fiscal year. As we stated in the proposed rule, we did this to introduce additional transparency and predictability regarding the timing of accounting for urban or rural status in the IPPS ratesetting each fiscal year. As the commenter indicated, reclassification under § 412.103 also affects payment at the hospital-specific level. We are clarifying that the lock-in date does not affect the timing of payment changes occurring at the hospital-specific level as a result of reclassification from urban to rural under § 412.103. As we indicated in the proposed rule, this lock-in date does not change the current regulation that allows hospitals that qualify under § 412.103(a) to request, at any time during a cost reporting period, to reclassify from urban to rural. A hospital's rural status and claims payment reflecting its rural status continue to be effective on the filing date of its reclassification application, which is the date the CMS Regional Office receives the application, in accordance with § 412.103(d). The hospital's IPPS claims would be paid reflecting its rural status on the filing date (the effective date) of the reclassification, regardless of when the hospital applies.

After consideration of the public comment we received, we are finalizing, without modification, our proposal that, in order for a hospital that applies for reclassification under § 412.103 to be treated as rural in the wage index and budget neutrality calculations under §§ 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year, the hospital's filing date

must be no later than 70 days prior to the second Monday in June of the current Federal fiscal year and the application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103. We also are finalizing our proposal to add a paragraph (6) to § 412.103 to specify this new lock-in date.

M. Process for Requests for Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files for the proposed FY 2017 wage index were made available on May 15, 2015, and the preliminary CY 2013 occupational mix data files on May 15, 2015, through the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html*.

On January 29, 2016, we posted a public use file (PUF) at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html* containing FY 2017 wage index data available as of January 28, 2016. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October l, 2012 through September 30, 2013; that is, FY 2013 wage data), a tab with the occupational mix data (which includes data from the CY 2013 occupational mix survey, Form CMS–10079), and new for FY 2017, a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 29, 2016 wage data PUF and a tab containing the CY 2013 occupational mix data (if any) of the hospitals deleted from the January 29, 2016 wage data PUF. In a memorandum dated January 21, 2016, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 29, 2016 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2017 Wage Index Timetable.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on our Web site that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS Web site at: *http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html*.

In a memorandum dated April 30, 2015, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the wage index data files and the process and timeframe for requesting revisions (including the specific deadlines listed later in this section). We also instructed the MACs to advise hospitals that these data were also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in May 15, 2015 wage data files and May 15, 2015 occupational mix data files, the hospital was to submit corrections along with complete, detailed supporting documentation to its MAC by September 2, 2015. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the Internet, through the letters sent to them by their MACs.

November 4, 2015 was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. The MACs notified the hospitals by mid-January 2016 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals' revision requests. The MACs also submitted the revised data to CMS by January 22, 2016. CMS published the proposed wage index PUFs that included hospitals' revised wage index data on January 29, 2016. Hospitals had until February 16, 2016, to submit requests to the MACs for reconsideration of adjustments made by the MACs as a result of the desk review, and to correct errors due to CMS' or the MAC's mishandling of the wage index data. Hospitals also were required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 24, 2016. The deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's policy interpretation was April 5, 2016. We note that, as we did for the FY 2016 wage index, for the FY 2017 wage index, in accordance with the FY 2017 wage index timeline posted on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html*, the April appeals have to be sent via mail and email. We refer readers to the wage index timeline for complete details.

Hospitals were given the opportunity to examine Table 2, which is listed in section VI. of the Addendum to the proposed rule and available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html*. Table 2 associated with the proposed rule contained each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2013 data used to construct the proposed FY 2017 wage index. We noted in the proposed rule (81 FR 25073) that the proposed hospital average hourly wages shown in Table 2 only reflected changes made to a hospital's data that were transmitted to CMS by late February 2016.

We posted the final wage index data PUFs on April 21, 2016 on the Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html*. The April 2016 PUFs were made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process previously described (revisions submitted to CMS by the MACs by March 24, 2016).

After the release of the April 2016 wage index data PUFs, changes to the wage and occupational mix data could only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 24, 2016.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 29, 2016 wage index PUFs.
- Requests to revisit factual determinations or policy interpretations

made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2016 final wage index data PUFs, a hospital believed that its wage or occupational mix data were incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital was given the opportunity to notify both its MAC and CMS regarding why the hospital believed an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital was required to send its request to CMS and to the MAC no later than May 23, 2016. Similar to the April appeals, beginning with the FY 2015 wage index, in accordance with the FY 2017 wage index timeline posted on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html*, the May appeals were required to be sent via mail and email to CMS and the MACs. We refer readers to the wage index timeline for complete details.

Verified corrections to the wage index data received timely by CMS and the MACs (that is, by May 23, 2016) were incorporated into the final FY 2017 wage index in this FY 2017 IPPS/LTCH PPS final rule, which is effective October 1, 2016.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2017 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data PUFs by late April 2016, they had the opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2017 wage index by August 2016, and the implementation of the FY 2017 wage index on October 1, 2016. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 23, 2016, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 23, 2016 for the FY 2017 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS Web site prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 23, 2016 deadline for the FY 2017 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 23, 2016 deadline for the FY 2017 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

N. Labor Market Share for the FY 2017 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related

share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share results in a higher payment.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50596 through 50607), we rebased and revised the hospital market basket. We established a FY 2010-based IPPS hospital market basket to replace the FY 2006-based IPPS hospital market basket, effective October 1, 2013. In that final rule, we presented our analysis and conclusions regarding the frequency and methodology for updating the labor-related share for FY 2014. Using the FY 2010-based IPPS market basket, we finalized a labor-related share for FY 2014, FY 2015, and FY 2016 of 69.6 percent. In addition, in FY 2014, we implemented this revised and rebased labor-related share in a budget neutral manner (78 FR 51016). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25074), for FY 2017, we did not propose to make any further changes to the national average proportion of operating costs that are attributable to wages and salaries, employee benefits, contract labor, the labor-related portion of professional fees, administrative and facilities support services, and all other labor-related services. Therefore, for FY 2017, we proposed to continue to use a labor-related share of 69.6 percent for discharges occurring on or after October 1, 2016.

We did not receive any public comments on our proposal and are finalizing our proposal, without modification, to continue to use a labor-related share of 69.6 percent for discharges occurring on or after October 1, 2016.

As discussed in section IV.A. of the preamble of the proposed rule (81 FR 25074) and section IV.A. of the preamble of this final rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2017, we did not propose a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage in the proposed rule (81 FR 25074).

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2017 IPPS/LTCH PPS final rule and available via the Internet on the CMS Web site, reflect the national labor-related share, which is also applicable to Puerto Rico hospitals. For FY 2017, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2017, we are applying the wage index to a labor-related share of 69.6 percent of the national standardized amount.

O. Public Comments on Treatment of Overhead and Home Office Costs in the Wage Index Calculation as a Result of Our Solicitation

Section III.D. of the preamble of this final rule states that the method used to compute the FY 2017 wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012, FY 2013, FY 2014, FY 2015, and FY 2016 final wage indexes without an occupational mix adjustment (76 FR 51591 through 51593, 77 FR 53366 through 53367, 78 FR 50587 through 50588, 79 FR 49967, and 80 FR 49491 through 49492, respectively).

As discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), in ''Step 4'' of the calculation of the unadjusted wage index, for each hospital reporting both total overhead salaries and total overhead hours greater than zero, we allocate overhead costs to areas of the hospital excluded from the wage index calculation. We also compute the amounts of overhead wage-related costs to be allocated to excluded areas. Finally, we subtract the computed overhead salaries, overhead wage-related costs, and hours associated with excluded areas from the total salaries (plus allowable wage-related costs) and hours derived in ''Steps 2 and 3'' of the calculation of the unadjusted wage index. (We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592) for a description of the calculation of the unadjusted wage index.) As stated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25075), we first began to remove from the wage index the overhead salaries and hours allocated to excluded areas beginning with the FY 1999 wage index calculation (63 FR 40971 and 40972). Beginning with the FY 2002 wage index calculation, we estimated and removed overhead wage-related costs allocated to excluded areas in addition to removing overhead salaries and hours allocated to excluded areas (66 FR 39863 and 39864). We began to estimate and remove overhead wage-related costs associated with excluded areas because we realized that without doing so, the formula resulted in large and inappropriate increases in the average hourly wages of some hospitals, particularly hospitals with large overhead and excluded area costs. These findings led us to believe that not all hospitals were fully or consistently allocating their overhead salaries among the lines on Worksheet S–3, Part II, of the hospital cost report for allowable wage-related costs (Worksheet S–3, Part II, lines 13 and 14 on CMS Form 2552–96, and lines 17 and 18 on CMS Form

2552–10), and nonallowable wage-related costs associated with excluded areas (Worksheet S–3, Part II, line 15 on CMS Form 2552–96 and line 19 on CMS Form 2552–10, OMB Control Number 0938–0050). Therefore, we determined that it was necessary to estimate and remove overhead wage-related costs allocated to excluded areas, and we have been doing so in ''Step 4'' of the unadjusted wage index calculation since FY 2002.

With the implementation of CMS Form 2552–10, Worksheet S–3, Part IV was added to the cost report on which hospitals are required to itemize their wage-related costs (formerly reported on Exhibit 6 of CMS Form–339). The total amount of wage-related costs reported on Worksheet S–3, Part II, lines 17 through 25 (CMS Form 2552–10) must correspond to the total core wage-related costs on Worksheet S–3, Part IV, line 24. (We refer readers to the instructions for line 17 of Worksheet S–3, Part II, which state: ''Enter the core wage-related costs from Worksheet S–3, Part IV, line 24.'') Hospitals report wage-related costs associated with excluded areas of the hospital on Worksheet S–3, Part II, line 19. We stated in the proposed rule (81 FR 25075) that we understand that hospitals use an allocation methodology to allocate total wage-related costs to each of lines Worksheet S–3, Part II, lines 17 through 25 respectively, typically based on the ratio of individual line costs to total wage-related costs on lines 17 through 25. Alternatively, we understand that hospitals use the ratio of full-time equivalent (FTE) hours of an individual line to total FTE hours for those lines 17 through 25. Because the wage-related costs of employees who work in overhead areas of the hospital are included in the wage-related costs of the hospital reported on Worksheet S–3, Part IV, and in turn, on Worksheet S–3, Part II, it is possible to conclude that hospitals' own allocation methodologies are properly allocating an accurate amount of wage-related costs for both direct cost centers and overhead areas to line 19 for the excluded areas. Accordingly, the question has been raised whether it continues to be necessary for CMS to estimate and remove the overhead wage-related costs associated with excluded areas from the unadjusted wage index calculation.

We have tested the effect on the average hourly wages of hospitals if we would not estimate and remove the overhead wage-related costs associated with excluded areas from the unadjusted wage index calculation. The results show that the problem manifested in the formula prior to FY 2002 continues to be a concern; that is, while the average hourly wages of all hospitals with excluded areas are impacted, hospitals that have particularly large excluded areas experience large and inappropriate increases to their average hourly wages. For example, one hospital with an excluded area percentage of 95 percent that has an average hourly wage of approximately $32 under our current methodology would have an average hourly wage of $128 under the formula in effect prior to FY 2002 (that is, *without* removal of excluded area overhead wage-related costs). Accordingly, as stated in the proposed rule (81 FR 25075), we believe that, at this point, there is a need for CMS to continue to estimate and remove the overhead wage-related costs associated with excluded areas from the unadjusted wage index calculation. However, in an effort to improve consistency in hospital cost reporting practices and to improve the accuracy of the wage index, we indicated in the proposed rule that we are considering the possibility of future rulemaking or cost reporting changes, or a combination of both, where hospitals would apply a single allocation methodology between Worksheet S–3, Part IV and Worksheet S–3, Part II, lines 17 through 25. For example, one possibility is the modification and expansion of Worksheet S–3, Part IV to add columns that would correspond to each line 17 through 25 of Worksheet S–3, Part II. In addition, Worksheet S–3, Part IV could employ one or two standard statistical allocation methods, facilitating a direct flow of the allocated amounts to each line 17 through 25 of Worksheet S–3, Part II.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25075), we solicited comments from stakeholders to gain a better understanding of the nature of hospitals' reporting of wage-related costs on Worksheet S–3, Part IV, statistical allocation methods that hospitals typically use to allocate their wage-related costs, the treatment of direct versus overhead employee wage-related costs, and suggestions for possible modifications to Worksheet S–3, Parts II and IV respectively, which would preempt the need for CMS to estimate and remove overhead wage-related costs associated with excluded areas from the unadjusted wage index.

Comment: One commenter stated that CMS' ''Step 4'' process for estimating and removing overhead wage-related costs associated with excluded areas is fair and equitable for all hospitals and should continue, as it is clear that in most, if not all cases, hospitals are not self-identifying and removing the excluded area amounts. The commenter noted that while current cost report instructions for line 17 of Worksheet S–3, Part II instruct hospitals that wage-related costs associated with excluded areas be removed, the cost report instructions do not state that hospitals should remove *overhead* wage-related costs associated with excluded areas from Line 17 (CMS emphasis added). The commenter believed that any plan to require hospitals to perform their own calculation to estimate and remove excluded area overhead could create inconsistent results unless very specific cost report instructions are provided and adhered to.

Response: We agree with the commenter that, at this point, there is a need for CMS to continue to estimate and remove the overhead wage-related costs associated with excluded areas from the unadjusted wage index calculation. As we stated in the proposed rule (81 FR 25075), we have tested the effect on the average hourly wages of hospitals if we would not estimate and remove the overhead wage-related costs associated with excluded areas from the unadjusted wage index calculation. The results show that the problem manifested in the formula prior to FY 2002 continues to be a concern; that is, while the average hourly wages of all hospitals with excluded areas are impacted, hospitals that have particularly large excluded areas experience large and inappropriate increases to their average hourly wages. While we believe that existing cost report instructions for lines 17 and 18 for wage-related costs state clearly that lines 17 and 18 must ''not include wage-related costs applicable to the excluded areas reported on lines 9 and 10; instead, these costs are reported on line 19,'' we may consider further specifying that hospitals must also not include on lines 17 and 18 *overhead* wage-related costs applicable to excluded areas. When revising the cost report instructions, we will consider whether more precise and uniform instructions for estimating and removing overhead wage-related costs should be incorporated directly into the cost report for hospitals to complete, rather than CMS estimating and removing the overhead wage-related costs associated with excluded areas from the unadjusted wage index calculation.

Comment: In regard to CMS' solicitation of comments related to reporting of wage-related costs on lines 17 through 25 of Worksheet S–3, Part II, one commenter believed that most hospitals allocate their wage-related cost

on lines 17 through 25 based on salaries, and therefore, this should be the preferred allocation method. The commenter stated that if a hospital wishes to use a wage-related cost allocation method other than one based on salaries, the hospital should be required to document to the MAC that an alternative method would be more accurate than salaries. The commenter added that if CMS chooses to pursue building the ''Step 4'' overhead allocation into the cost report, CMS should simultaneously add lines to the cost report that perform the complete average hourly wage calculation that CMS uses to calculate the unadjusted wage index. The commenter pointed out that the addition of these lines to the cost report should not require extra administrative burden because all the additional data elements would be drawn from existing lines on Worksheet S–3, Parts II and III. However, the commenter noted that the disadvantage to incorporating the complete average hourly wage calculation into the cost report is that the cost report would need to be updated if the wage index calculation is revised.

Response: We appreciate the information provided by the commenter that most hospitals allocate their wage-related cost on lines 17 through 25 based on salaries. We also appreciate the commenter's suggestion regarding adding lines to Worksheet S–3, Part III to incorporate the complete unadjusted average hourly wage calculation (meaning, the average hourly wage unadjusted for occupational mix). We will consider these suggestions further in future rulemaking and/or cost report revisions as appropriate.

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25075 through 25076), another issue about which we are concerned and for which we solicited public comments in the proposed rule relates to inconsistent reporting of home office salaries and wage-related costs. Worksheet S–2, Part I, line 140, requires hospitals to complete Worksheet A–8–1 if they have any related organization or home office costs claimed as defined in the Provider Reimbursement Manual, CMS Pub. 15–1, Chapter 10, Section 1002, and 42 CFR 413.17. Then, line 14 of Worksheet S–3, Part II instructs hospitals to enter the salaries and wage-related costs paid to personnel who are affiliated with a home office and/or related organization, who provide services to the hospital, and whose salaries are *not* included on Worksheet A, Column 1. Because home office salaries and wage-related costs are not included on Worksheet A, Column 1, we are concerned that hospitals are not including home office costs on Worksheet A, Column 2 or Column 6 in the appropriate cost centers on lines 4 through 17, adjusted from Worksheet A–8 or Worksheet A–8–1.[22] Another concern is a hospital's inadvertent inclusion on line 14 of the home office salaries or wage-related costs associated with excluded areas on Worksheet S–3, Part II, lines 9 or 10. In addition, we are concerned about the amalgam of personnel costs that hospitals report on line 14, particularly when another more precise line exists for those personnel costs to be reported. For example, if cafeteria services are provided through the home office, those wages and hours should not be reported on line 14, but instead should be reported on the more specific cost center for Cafeteria, Worksheet S–3, Part II, line 36 (corresponding to Cafeteria on Worksheet A, line 11 [23]). We note that, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967), we reiterated our requirement that all hospitals must document salaries, wages, and hours for the purpose of reporting this information on Worksheet S–3, Part II, lines 32, 33, 34, and/or 35 (for either directly employed housekeeping and dietary employees on lines 32 and 34, and contract labor on lines 33 and 35). We have learned of instances where housekeeping or dietary services are provided through the home office, and the hospital reported those wages and hours on line 14. This is inconsistent with other hospitals' reporting of housekeeping and dietary services on lines 32 through 35. As stated in the FY 2015 IPPS/LTCH PPS final rule, we have instructed the MACs to impute housekeeping or dietary wages and hours when hospitals have not properly completed those lines 32 through 35. Hospitals whose housekeeping or dietary services (either direct or under contract) are provided through their home office are not exempt from this requirement to report wages and hours on the specific cost centers for housekeeping and dietary. Hospitals should also take care to report housekeeping and dietary services in the appropriate cost centers on Worksheet A, lines 9 and 10 respectively. As stated in the proposed rule (81 FR 25076), because the nature of services provided by home office personnel are for general management or administrative services related to the provision of patient care (CMS Pub. 15–1, Chapter 21, Section 2150), and may be provided to multiple areas of the hospital, we are considering ending reporting of home office costs on line 14 of Worksheet S–3, Part II, and instead we may require reporting of home office costs as part of the overhead lines, possibly by adding lines or columns, or subscripting existing line 27 (Administrative & General), and line 28 (Administrative & General for contract labor). In the FY 2017 proposed rule (81 FR 25076), we solicited public comments to gain a better understanding of hospitals' reporting of home office salaries and wage-related costs for possible future revisions to the cost report instructions and lines.

Comment: One commenter recognized the problem of inconsistent reporting of home office salaries and wage-related costs, and supported the idea of reporting these costs in the overhead lines, as long as the home office salaries and wage-related cost are delineated separately from other overhead costs. The commenter stated that it is important to retain transparency on home office costs versus other hospital-specific overhead costs, and that CMS should also explore the possibility of penalties for the filing of incomplete or inconsistent cost reports to increase compliance.

Response: We appreciate the commenter's support, and acknowledge that it may be useful to separately track home office wages and hours from other overhead wages and hours. We are in favor of measures to increase transparency and accuracy of cost reporting, which we are attempting to do as part of the solicitation of public comments to gain a better understanding of hospitals' reporting practices regarding overhead and home office costs and hours. We will consider the commenter's suggestions in the future as appropriate.

Comment: One commenter stated that most hospitals report home office salaries on Worksheet A–8–1 with an appropriate adjustment in Column 6 of Worksheet A. In addition, the commenter believed that most hospitals report their entire home office salary and hour allocation on line 14 Worksheet S–3 Part II without removing an amount for excluded areas. The

[22] CMS Pub. 15–2, Chapter 40, Section 4013, Worksheet A instructions for column 6: ''Enter on the appropriate lines in column 6 the amounts of any adjustments to expenses indicated on Worksheet A–8, column 2,'' and the note for line 12 of Worksheet A–8, section 4016: ''Worksheet A–8–1 represents the detail of the various cost centers on Worksheet A which must be adjusted.''

[23] CMS Pub. 15–2, Chapter 40, Section 4013, Worksheet A instructions under Line Descriptions: ''The trial balance of expenses is broken down into general service, inpatient routine service, ancillary service, outpatient service, other reimbursable, special purpose, and nonreimbursable cost center categories *to facilitate the transfer of costs to the various worksheets. The line numbers on Worksheet A are used on subsequent worksheets* . . . .'' (emphasis added).

commenter recommended that if CMS decides that an allocation is needed to remove overhead cost associated with excluded areas contained within the home office costs, CMS subscript line 14 into overhead and nonoverhead cost and hours. The overhead portion could then be allocated in the same manner that the hospital overhead cost is currently allocated.

Response: We appreciate the information provided by the commenter, although we are disconcerted to learn that the commenter believes that most hospitals report their entire home office salary and hour allocation on line 14 of Worksheet S–3, Part II, without performing an allocation to remove costs and hours associated with excluded areas. This means that hospitals are inappropriately including wages and hours associated with excluded areas in the wage index. We will take these comments into consideration for future rulemaking and/or cost report revisions as appropriate.

Comment: One commenter disagreed with CMS' suggestion in the proposed rule that it may require reporting of home office cost as part of the overhead lines, instead of line 14 of Worksheet S–3, Part II, because the nature of services provided by home office personnel are for general management or administrative services related to the provision of patient care (81 FR 25076). The commenter stated that the cost report instructions (CMS Pub. 15–2, Chapter 40, Section 4005.2) for Worksheet S–3, Part II, Line 14 do not specify that the home office and/or related party organizations costs need to only be administrative and general costs. The commenter stated that, as a hospital system with multiple hospitals, it reports ancillary services such as physical, occupational, and speech therapy personnel costs on line 14 of Worksheet S–3, Part II, because they are related organizational costs that are not reported on Worksheet A, Column 1 and are adjusted on Worksheet A–8–1. The commenter asserted that because line 14 of Worksheet S–3, Part II, can include costs not related to general management or administrative services, these costs should not be reported on overhead lines.

Response: We appreciate the feedback provided by the commenter. In the proposed rule, we listed several concerns regarding hospitals' reporting on line 14, such as inclusion on line 14 of the home office salaries or wage-related costs associated with excluded areas on Worksheet S–3, Part II, lines 9 or 10, and inclusion of an amalgam of personnel costs, particularly when another more precise line exists for those personnel costs to be reported (81 FR 25076). We acknowledge that, currently, the cost report instructions for line 14 of Worksheet S–3, Part II, do not specify that the home office and/or related party organizations costs need to only be administrative and general costs. However, the fact that the commenter, a hospital system with multiple hospitals, stated that it reports ancillary services such as physical, occupational, and speech therapy personnel costs on Worksheet S–3, Part II, line 14, is evidence of the inconsistent and disparate types of services that hospitals are reporting on line 14. It seems apparent that hospitals are treating line 14 as they would an overhead cost center, supporting the need for CMS to consider ending reporting of home office costs on line 14 and to instead require reporting of home office costs as part of the overhead lines 27 and 28 (Administrative & General). By incorporating the home office costs into new lines that are part of the overhead cost centers, we could systematically remove costs and hours associated with excluded areas from the wages, wage-related costs, and hours associated with home office, as we currently do in ''Step 4'' of the calculation of the unadjusted wage index described above and in the proposed rule (81 FR 25075). We intend to consider such measures for future cost report revisions.

Comment: One commenter suggested that any change in the wage index calculation be evaluated after the additional information is gathered, similar to CMS efforts in relation to the solicitation of comments regarding the overhead allocation. The commenter stated that CMS should disclose its findings and any proposed changes to the wage index calculation through notice-and-comment rule making.

Response: We will take the commenter's suggestions into consideration as appropriate.

Because we did not make specific proposals in the proposed rule regarding treatment of overhead and home office costs in the wage index calculation, that is, we only solicited comments to gain a better understanding of hospitals' reporting practices, we are not making any changes at this time. However, we will take the comments into consideration for future cost reporting changes and/or rulemaking as appropriate.

IV. Other Decisions and Changes to the IPPS for Operating Costs and Direct Graduate Medical Education (GME) and Indirect Medical Education (IME) Costs

A. Changes to Operating Payments for Subsection (d) Puerto Rico Hospitals as a Result of Section 601 of Public Law 114–113

Prior to January 1, 2016, Puerto Rico hospitals were paid with respect to operating costs of inpatient hospital services for inpatient hospital discharges based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As a result of the amendment made by section 601 of Public Law 114–113, on February 4, 2016, we issued Change Request 9523 which updated the payment rates for subsection (d) Puerto Rico hospitals for discharges occurring on or after January 1, 2016. Change Request 9523 can be downloaded from the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2016-Transmittals-Items/R3449CP.html*.

For operating costs for inpatient hospital discharges occurring in FY 2017 and subsequent fiscal years, consistent with the provisions of section 1886(d)(9)(E) of the Act as amended by section 601 of Public Law 114–113, subsection (d) Puerto Rico hospitals will continue to be paid based on 100 percent of the national standardized amount.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25076), we proposed to make conforming changes to the regulations at 42 CFR 412.204 to reflect the current law that is effective for discharges occurring on or after January 1, 2016. Specifically, we proposed to add a new paragraph (e) to § 412.204 to reflect that, beginning January 1, 2016, subsection (d) Puerto Rico hospitals are paid based on 100 percent of the national standardized amount. We also proposed to revise paragraph (d) of § 412.204 to specify that subsection (d) Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount for discharges occurring through December 31, 2015.

We did not receive any public comments on our proposed changes to the regulations at § 412.204 and, therefore, are finalizing these proposed changes without modification in this final rule.

B. Changes in the Inpatient Hospital Update for FY 2017 (§ 412.64(d))

1. FY 2017 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25076 through 25077), for FY 2017, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2016. Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to—

(a) A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act;

(b) A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act;

(c) An adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment); and

(d) An additional reduction of 0.75 percentage point as required by section 1886(b)(3)(B)(xii) of the Act.

Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2017 adjustment of 0.75 percentage point may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50596 through 50607), we replaced the FY 2006-based IPPS operating and capital market baskets with the revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2014. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49993 through 49996) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49508 through 49511), we continued to use the FY 2010-based IPPS operating and capital market baskets for FY 2015 and FY 2016 and the labor-related share of 69.6 percent, which was based on the FY 2010-based IPPS market basket. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25077), for FY 2017, we proposed to continue using the FY 2010-based IPPS operating and capital market baskets and a proposed labor-related share of 69.6 percent, which was based on the FY 2010-based IPPS market basket. We did not receive any public comments on these proposals and, therefore, for FY 2017, will continue to use the FY 2010-based IPPS operating and capital markets and the labor-related share of 69.6 percent.

Based on the most recent data available for the FY 2017 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we proposed to base the FY 2017 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Insight, Inc.'s (IGI's) first quarter 2016 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through fourth quarter 2015, which was estimated to be 2.8 percent (81 FR 25077). We proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket and the MFP adjustment), we would use such data, if appropriate, to determine the FY 2017 market basket update and the MFP adjustment in the final rule.

Based on the most recent data available for this FY 2017 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2016 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through first quarter 2016), we estimate that the FY 2017 market basket update used to determine the applicable percentage increase for the IPPS is 2.7 percent.

For FY 2017, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount. Based on the most recent data described above, we determined final applicable percentage increases to the standardized amount for FY 2017, as specified in the table that appears later in this section.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509), beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using the revised series developed by IGI to proxy the aggregate capital inputs. Specifically, in order to generate a forecast of MFP, IGI forecasts BLS aggregate capital inputs using a regression model. A complete description of the MFP projection methodology is available on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.* As discussed in the FY 2016 IPPS/LTCH PPS final rule, if IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25077), for FY 2017, we proposed an MFP adjustment of 0.5 percentage point. Similar to the market basket update, for the proposed rule, we used the most recent data

available to compute the MFP adjustment. As noted previously, we proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2017 market basket update and MFP adjustment for the final rule. Based on the most recent data available for this final rule, we have determined an MFP adjustment of 0.3 percentage point for FY 2017.

We did not receive any public comments on our proposal to use the most recent available data to determine the final market basket update and the MFP adjustment. Therefore, for this final rule, we are finalizing a market basket update of 2.7 percent and an MFP adjustment of 0.3 percentage point based on the most recent available data.

Based on the most recent data available for this final rule, as described previously, we have determined four applicable percentage increases to the standardized amount for FY 2017, as specified in the following table:

FY 2017 Applicable Percentage Increases for the IPPS

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.025	0.0	−2.025
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.3	−0.3	−0.3	−0.3
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Applicable Percentage Increase Applied to Standardized Amount	1.65	−0.375	0.975	−1.05

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25078), we proposed to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law for the FY 2017 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we proposed to add a new paragraph (vii) to § 412.64(d)(1) to reflect the applicable percentage increase to the FY 2017 operating standardized amount as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less an MFP adjustment and less an additional reduction of 0.75 percentage point.

We did not receive any public comments on our proposed changes to the regulations at § 412.64(d)(1) and, therefore, are finalizing these proposed changes without modification in this final rule.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. We note that section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017).

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25078), for FY 2017, we proposed the updates to the hospital-specific rates applicable to SCHs and MDHs based on IGI's first quarter 2016 forecast of the FY 2010-based IPPS market basket update and the MFP adjustment. We proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such data, if appropriate, to determine the update for SCHs and MDHs in the final rule. We did not receive any public comments with regard to our proposal. Therefore, we are finalizing the proposal to determine the update to the hospital-specific rates for SCHs and MDHs in this final rule using the most recent data available.

For this final rule, based on most recent available data, we are finalizing the following updates to the hospital-specific rates applicable to SCHs and MDHs using IGI's second quarter 2016 forecast of the FY 2010-based IPPS market basket update and the MFP adjustment (as described previously in this section): An update of 1.65 percent for a hospital that submits quality data and is a meaningful EHR user; an update of −0.375 percent for a hospital that submits quality data and is not a meaningful EHR user; an update of 0.975 percent for a hospital that fails to submit quality data and is a meaningful EHR user; and an update of –1.05 percent for a hospital that fails to submit quality data and is not a meaningful EHR user.

2. FY 2017 Puerto Rico Hospital Update

As discussed in section IV.A. of the preamble of this final rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to determine an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this final rule. Accordingly, in the proposed rule (81 FR 25078), for FY

2017, we determined a proposed applicable percentage increase of 1.55 percent to the standardized amount for hospitals located in Puerto Rico. We note that we did not receive any public comments with regard to our proposal. Based on the most recent data available for this final rule (as discussed in section IV.B.1. of the preamble of this final rule), we are finalizing an applicable percentage increase of 1.65 percent to the standardized amount for hospitals located in Puerto Rico.

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2017.

C. Rural Referral Centers (RRCs): Annual Updates to Case-Mix Index and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive some special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in Subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (c)(5) and the September 30, 1988 **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The national median CMI value for FY 2017 is based on the CMI values of all urban hospitals nationwide, and the regional median CMI values for FY 2017 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These values are based on discharges occurring during FY 2015 (October 1, 2014 through September 30, 2015), and include bills posted to CMS' records through March 2016.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25079), we proposed that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2016, they must have a CMI value for FY 2015 that is at least—

- 1.6125 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region were set forth in a table in the proposed rule (81 FR 25079). We stated in the proposed rule that we intended to update the CMI values in the FY 2017 final rule to reflect the updated FY 2015 MedPAR file, which would contain data from additional bills received through March 2016.

Based on the latest available data (FY 2015 bills received through March 2016), in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2016, they must have a CMI value for FY 2015 that is at least:

- 1.6111; or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The final CMI values by region are set forth in the following table.

Region	Case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.3633

Region	Case-mix index value
2. Middle Atlantic (PA, NJ, NY)	1.4409
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV) ..	1.5079
4. East North Central (IL, IN, MI, OH, WI)	1.5331
5. East South Central (AL, KY, MS, TN)	1.4472
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.5946
7. West South Central (AR, LA, OK, TX)	1.64525
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.6944
9. Pacific (AK, CA, HI, OR, WA)	1.6165

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25079), we proposed to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2014 (that is, October 1, 2013 through September 30, 2014), which were the latest cost report data available at the time the proposed rule was developed. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule, we proposed that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2016, must have, as the number of discharges for its cost reporting period that began during FY 2014, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2017 IPPS/LTCH PPS proposed rule at 81 FR 25079.) In the proposed rule, we stated that we intended to update these numbers in the FY 2017 final rule based on the latest available cost report data.

Based on the latest discharge data available at this time, that is, for cost reporting periods that began during FY 2015, the final median number of discharges for urban hospitals by census region are set forth in the following table:

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,090
2. Middle Atlantic (PA, NJ, NY)	10,270
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV) ..	10,309
4. East North Central (IL, IN, MI, OH, WI)	8,090
5. East South Central (AL, KY, MS, TN)	8,359
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,748
7. West South Central (AR, LA, OK, TX)	5,167
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,605
9. Pacific (AK, CA, HI, OR, WA)	8,651

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, under this final rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

We did not receive any public comments on our proposals.

D. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital that is paid under IPPS beginning in FY 2005, and the low-volume hospital payment policy is set forth in the regulations at 42 CFR 412.101. Sections 3125 and 10314 of the Affordable Care Act provided for a temporary change in the low-volume hospital payment policy for FYs 2011 and 2012. Specifically, the provisions of the Affordable Care Act amended the qualifying criteria for low-volume hospitals to specify, for FYs 2011 and 2012, that a hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A during the fiscal year. In addition, the statute as amended by the Affordable Care Act, provides that the low-volume hospital payment adjustment (that is, the percentage increase) is determined using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year. We revised the regulations governing the low-volume hospital payment adjustment policy at § 412.101 to reflect the changes to the qualifying criteria and the calculation of the payment adjustment for low-volume hospitals according to the provisions of the Affordable Care Act in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414).

The temporary changes to the low-volume hospital qualifying criteria and the payment adjustment originally provided for by the Affordable Care Act have been extended by subsequent legislation as follows: Through FY 2013, by the American Taxpayer Relief Act of 2012 (ATRA), Public Law 112–240; through March 31, 2014, by the Pathway for SGR Reform Act of 2013, Public Law 113– 167; through March 31, 2015, by the Protecting Access to Medicare Act of 2014 (PAMA), Public Law 113–93; and most recently through FY 2017, by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10. For additional details on the implementation of the previous extensions of the temporary changes to the low-volume hospital qualifying criteria and payment adjustment originally provided for by the Affordable Care Act, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS notice (78 FR 14689 through 14691); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50611 through 50612); the FY 2014 IPPS interim final rule with comment period (79 FR 15022 through 15025); the FY 2014 IPPS notice (79 FR 34444 through 34446); the FY 2015 IPPS/LTCH PPS final rule (79 FR 49998 through 50001); and the FY 2016 IPPS interim final rule with comment period (80 FR 49594 through 49595).

2. Low-Volume Hospital Definition and Payment Adjustment for FY 2017

Under section 1886(d)(12) of the Act, as amended by section 204 of the MACRA, the temporary changes in the low-volume hospital payment policy originally provided by the Affordable Care Act and extended through subsequent legislation, are effective through FY 2017. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25080 through 25081), consistent with our historical approach, we proposed to update the discharge data source used to

identify qualifying low-volume hospitals and calculate the payment adjustment (percentage increase) for FY 2017. Under § 412.101(b)(2)(ii), for the applicable fiscal years, a hospital's Medicare discharges from the most recently available MedPAR data, as determined by CMS, are used to determine if the hospital meets the discharge criteria to receive the low-volume payment adjustment in the current year and to determine the applicable low-volume percentage increase for qualifying hospitals. The applicable low-volume percentage increase for FY 2017 is determined using a continuous linear sliding scale equation that results in a low-volume hospital payment adjustment ranging from an additional 25 percent for hospitals with 200 or fewer Medicare discharges to a zero percent additional payment adjustment for hospitals with 1,600 or more Medicare discharges. For FY 2017, consistent with our historical policy, we proposed that qualifying low-volume hospitals and their payment adjustment would be determined using the most recently available Medicare discharge data, which at the time of the proposed rule was from the December 2015 update of the FY 2015 MedPAR file, as these data were the most recent data available at that time. Table 14 listed in the Addendum of the proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) listed the ''subsection (d)'' hospitals with fewer than 1,600 Medicare discharges based on the claims data from the December 2015 update of the FY 2015 MedPAR file and their potential proposed low-volume hospital payment adjustment for FY 2017. Consistent with past practice, we noted in the proposed rule that the list of hospitals with fewer than 1,600 Medicare discharges in Table 14 did not reflect whether or not the hospital meets the mileage criterion. Eligibility for the low-volume hospital payment adjustment for FY 2017 also is dependent upon meeting the mileage criterion specified at § 412.101(b)(2)(ii); that is, the hospital must be located more than 15 road miles from any other IPPS hospital. In other words, eligibility for the low-volume hospital payment adjustment for FY 2017 also is dependent upon meeting (in the case of a hospital that did not qualify for the low-volume hospital payment adjustment in FY 2016) or continuing to meet (in the case of a hospital that did qualify for the low-volume hospital payment adjustment in FY 2016) the mileage criterion specified at § 412.101(b)(2)(ii). Consistent with historical practice, we proposed that if more recent Medicare discharge data became available, we would use that updated data to determine qualifying low-volume hospitals and their payment adjustment in the final rule, and update Table 14 to reflect that updated data.

In order to receive a low-volume hospital payment adjustment under § 412.101 for FY 2017, consistent with our previously established procedure, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25080 through 25081), we proposed that a hospital must notify and provide documentation to its MAC that it meets the discharge and mileage criteria under § 412.101(b)(2)(ii). Specifically, for FY 2017, we proposed that a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2016, in order for the applicable low-volume hospital payment adjustment to be applied to payments for its FY 2017 discharges occurring on or after October 1, 2016. Under this procedure, a hospital that qualified for the low-volume hospital payment adjustment in FY 2016 may continue to receive a low-volume hospital payment adjustment for FY 2017 without reapplying if it continues to meet the Medicare discharge criterion established for FY 2017 and the mileage criterion. However, we proposed that the hospital must send written verification that is received by its MAC no later than September 1, 2016, stating that it continues to be located more than 15 miles from any other subsection (d) hospital. This written verification could be a brief letter to the MAC stating that the hospital continues to meet the low-volume hospital mileage criterion as documented in a prior low-volume hospital status request. We also proposed that if a hospital's written request for low-volume hospital status for FY 2017 is received after September 1, 2016, and if the MAC determines that the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the applicable low-volume hospital payment adjustment to determine the payment for the hospital's FY 2017 discharges effective prospectively within 30 days of the date of its low-volume hospital status determination, consistent with past practice. (For additional details on our established process for the low-volume hospital payment adjustment, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53408) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50000 through 50001).)

Comment: Commenters supported the actions taken by CMS related to the extension of the modified criteria to qualify for the low-volume hospital adjustment through FY 2017. Commenters also expressed their support for legislative action that would make permanent the criteria that a hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to or enrolled for benefits under Medicare Part A.

Response: We appreciate the commenters' support of our implementation of the low-volume hospital payment adjustment for FY 2017, which is consistent with the statutory provisions under section 1886(d)(12) of the Act.

After consideration of the public comments we received, we are finalizing our proposals, without modification. Consistent with our proposal to use the most recent Medicare discharge data available for the final rule, we are using data from the March 2016 update of the FY 2015 MedPAR files to determine qualifying low-volume hospitals and their payment adjustment in this final rule, and updating Table 14 to reflect these updated data. Accordingly, Table 14 listed in the Addendum of this final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the ''subsection (d)'' hospitals with fewer than 1,600 Medicare discharges based on the claims data from the March 2016 update of the FY 2015 MedPAR file and their potential low-volume hospital payment adjustment for FY 2017. Consistent with past practice, we note that this list of hospitals with fewer than 1,600 Medicare discharges in Table 14 does not reflect whether or not the hospital meets the mileage criterion. Eligibility for the low-volume hospital payment adjustment for FY 2017 also is dependent upon meeting the mileage criterion specified at § 412.101(b)(2)(ii); that is, the hospital must be located more than 15 road miles from any other IPPS hospital. In other words, eligibility for the low-volume hospital payment adjustment for FY 2017 also is dependent upon meeting (in the case of a hospital that did not qualify for the low-volume hospital payment adjustment in FY 2016) or continuing to meet (in the case of a hospital that did qualify for the low volume hospital payment adjustment in FY 2016) the mileage criterion specified at § 412.101(b)(2)(ii). As we proposed, in

order to receive a low-volume hospital payment adjustment under § 412.101 for FY 2017, consistent with our previously established procedure, a hospital must notify and provide documentation to its MAC that it meets the discharge and mileage criteria under § 412.101(b)(2)(ii). Specifically, for FY 2017, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2016, in order for the applicable low-volume hospital payment adjustment to be applied to payments for its FY 2017 discharges occurring on or after October 1, 2016. Under this procedure, a hospital that qualified for the low-volume hospital payment adjustment in FY 2016 may continue to receive a low-volume hospital payment adjustment for FY 2017 without reapplying if it continues to meet the Medicare discharge criterion established for FY 2017 and the mileage criterion. However, as we proposed, the hospital must send written verification that is received by its MAC no later than September 1, 2016, stating that it continues to be located more than 15 miles from any other subsection (d) hospital. This written verification could be a brief letter to the MAC stating that the hospital continues to meet the low-volume hospital mileage criterion as documented in a prior low-volume hospital status request. Also, as we proposed, if a hospital's written request for low-volume hospital status for FY 2017 is received after September 1, 2016, and if the MAC determines that the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine the payment for the hospital's FY 2017 discharges effective prospectively within 30 days of the date of its low-volume hospital status determination, consistent with past practice. (As noted above, for additional details on our established process for the low-volume hospital payment adjustment, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53408) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50000 through 50001).)

We note that, in an interim final rule with comment period (IFC) in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49595), we revised the regulations at § 412.101 to conform the text to the provisions of section 204 of the MACRA, which extended the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals through FY 2017 (that is, through September 30, 2017). We are finalizing the provisions of that IFC without modification, as discussed in section IV.N. of this final rule.

E. Indirect Medical Education (IME) Payment Adjustment Factor for FY 2017 (§ 412.105)

1. IME Adjustment for FY 2017

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2017, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2017 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident to bed ratio.

Comment: One commenter requested that CMS take into consideration IME costs across all provider settings and correspondingly increase the IPPS payment to account for higher indirect patient costs. The commenter requested that CMS not eliminate or decrease the formula modifier for the FY 2017 IME adjustment.

Response: The IME adjustment factor is set by statute. Therefore, we do not have discretion to make any changes to the formula multiplier.

2. Other Policies Related to IME

We refer readers to section IV.I. of the preamble of this final rule for a discussion of the finalized policy changes for FY 2017 relating to medical residency training programs (specifically, rural training tracks) at urban hospitals that also affect payments for IME.

F. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2017 and Subsequent Years (§ 412.106)

1. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the DSH statutory references (under section 1886(d)(5)(F) of the Act) to ''days'' apply only to hospital acute care inpatient days. Regulations located at § 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the

Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this final rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

As provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a subsection (d) hospital that would otherwise receive DSH payments made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to the Congress. We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for each fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FYs 2014 through 2017, 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, determined by comparing the percent of such individuals who were uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment), and the percent of individuals who were uninsured in the most recent period for which data are available (as so calculated) minus 0.1 percentage point for FY 2014, and minus 0.2 percentage point for FYs 2015 through 2017. For FYs 2014 through 2017, the baseline for the estimate of the change in uninsurance is fixed by the most recent estimate of the Congressional Budget Office before the final vote on the Health Care and Education Reconciliation Act of 2010, which is contained in a March 20, 2010 letter from the Director of the Congressional Budget Office to the Speaker of the House. (The March 20, 2010 letter is available for viewing on the following Web site: *http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf.*)

For FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019. Therefore, for FY 2018 and subsequent fiscal years, the statute provides some greater flexibility in the choice of the data sources to be used for the estimate of the change in the percent of uninsured individuals.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.''

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which were established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care

payments, or the periods selected in order to develop such estimates.

2. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As indicated earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50006), we specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. We refer readers to those two final rules for a detailed discussion of our policies. In summary, we specified the following:

• *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50623 and 79 FR 50006).

• *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50007), effective January 1, 2014, the State of Maryland elected to no longer have Medicare pay Maryland hospitals in accordance with section 1814(b)(3) of the Act and entered into an agreement with CMS that Maryland hospitals will be paid under the Maryland All-Payer Model. However, under the Maryland All-Payer Model, Maryland hospitals still are not paid under the IPPS. Therefore, they remain ineligible to receive empirically justified Medicare DSH payments or uncompensated care payments under section 1886(r) of the Act.

• *SCHs that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).

• *MDHs* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10, enacted April 16, 2015, extended the MDH program for discharges on or after April 1, 2015, through September 30, 2017. Because MDHs are paid based on the IPPS Federal rate, for FY 2017, MDHs will continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent. We will apply the same process to determine MDHs' eligibility for empirically justified Medicare DSH and uncompensated care payments, as we do for all other IPPS hospitals, through September 30, 2017. Moreover, we will continue to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). Our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year. In addition, as we do for all IPPS hospitals, we calculate a numerator for Factor 3 for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator for Factor 3 will be based on the uncompensated care data from the hospitals that we have projected to be eligible for Medicare DSH payments during the fiscal year.

• *IPPS hospitals that have elected to participate in the Bundled Payments for Care Improvement initiative* continue to be paid under the IPPS (77 FR 53342) and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments (78 FR 50625 and 79 FR 50008).

• *Hospitals participating in the Rural Community Hospital Demonstration Program* under section 410A of the Medicare Modernization Act do not receive DSH payments and, therefore, are excluded from receiving empirically justified Medicare DSH payments and uncompensated care payments under the new DSH payment methodology (78 FR 50625 and 79 FR 50008). There are 14 hospitals currently participating in the program; 10 will continue to participate through the end of FY 2016, and 4 will continue to participate through the scheduled end of the program on December 31, 2016. Once a hospital's participation in the demonstration program ends, the hospital will be treated like a subsection (d) hospital and subject to the IPPS. Therefore, once their participation ends, these hospitals could be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments and, if so, will be treated accordingly for interim and final payments. We will apply the same process for determining their eligibility as we do for all other IPPS hospitals, and will make interim and final DSH and uncompensated care payments accordingly.

3. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising MACs to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html*.

4. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. Below we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2016, and our proposed and final policies for FY 2017.

a. Calculation of Factor 1 for FY 2017

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between (1) the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

As we did for FY 2016, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25084), in order to determine Factor 1 in the uncompensated care payment formula for FY 2017, we proposed to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act. These estimates will not be revised or updated after we know the final Medicare DSH payments for FY 2017.

Therefore, in order to determine the two elements of Factor 1 for FY 2017 (Medicare DSH payments *prior* to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments *after* application of section 1886(r)(1) of the Act), for the proposed rule, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary using the most recently filed Medicare hospital cost report with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File.

For purposes of calculating Factor 1 and modeling the impact of the FY 2017 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's March 2016 Medicare DSH estimates, which are based on data from the December 2015 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2016 IPPS/LTCH PPS final rule IPPS Impact file, published in conjunction with the publication of the FY 2016 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the March 2016 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals participating in the Maryland All-Payer Model that do not receive DSH payments were also excluded from the Office of the Actuary's Medicare DSH estimates. Because the Rural Community Hospital Demonstration program is scheduled to end on December 31, 2016, hospitals that were participating in the program were included in this estimate for FY 2017. However, for the proposed rule, we excluded 25 percent of our estimate of DSH payments that would otherwise be made to the 4 hospitals whose participation in the program will continue through December 31, 2016, as

these hospitals will be excluded from receiving DSH payments until that time. The estimate included the total DSH payments that would be made to the 10 hospitals whose participation in the Rural Community Hospital Demonstration program will continue only through September 30, 2016.

For the proposed rule, using the data sources discussed above, the Office of the Actuary used the most recently submitted Medicare cost report data to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the IPPS Impact File, and applied inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The March 2016 Office of the Actuary estimate for Medicare DSH payments for FY 2017, without regard to the application of section 1886(r)(1) of the Act, was approximately $14.227 billion. This estimate excluded Maryland hospitals participating in the Maryland All-Payer Model, SCHs paid under their hospital-specific payment rate, and 25 percent of DSH payments to the 4 hospitals whose participation in the Rural Community Hospital Demonstration program will continue through December 31, 2016. Therefore, based on the March 2016 estimate, the estimate for empirically justified Medicare DSH payments for FY 2017, with the application of section 1886(r)(1) of the Act, was approximately $3.556 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2017). Under § 412.l06(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, in the proposed rule, we proposed that Factor 1 for FY 2017 was $10,670,529,595.84, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2017 ($14,227,372,794.46 minus $3,556,843,198.62).

We invited public comments on our proposed calculation of Factor 1 for FY 2016.

Comment: A number of commenters requested greater transparency in the methodology used by the OACT to estimate aggregate DSH payments that would have been paid absent implementation of the Affordable Care Act, particularly with respect to the calculation of estimated DSH payments for purposes of determining Factor 1. The commenters urged CMS to clarify the methodology and provide additional information on the assumptions used to make these projections. The commenters also requested that this information be provided in advance of the publication of the FY 2017 IPPS/LTCH PPS final rule and in future proposed rules each year. The commenters stated that hospitals do not have sufficient information to understand or replicate the relevant projections and estimates for Factor 1.

Many commenters stated that there is variability in the ''Other'' factors that are used to estimate Medicare DSH expenditures and requested full disclosure of the methodology and the various components used to estimate the catch-all ''Other'' column, such as the factor for Medicaid expansion due to the Affordable Care Act. Specifically, the commenters expressed concern that the value in the ''Other'' column for FY 2016 changed from 1.045 in the FY 2016 IPPS/LTCH PPS final rule to 0.9993 in the FY 2017 IPPS/LTCH PPS proposed rule. Commenters were concerned that such a discrepancy also appeared in the FY 2016 IPPS/LTCH PPS final rule, when CMS used the exact same 0.9993 factor from the ''Other'' column for FY 2014, the first year of the Medicaid expansion; they expressed concern that they believed this was updated to 1.04795 without explanation in the version of the table that appeared in the FY 2017 IPPS/LTCH PPS proposed rule. The commenters requested that CMS provide clarification regarding these changes.

Some commenters asked CMS to explain how Medicaid and CHIP expansion is accounted for in the ''Other'' column used to determine the Factor 1 estimate. The commenters stated that CMS appears to have applied internally inconsistent assumptions as to the effect of Medicaid expansion on Factor 1, with no explanation or support. One commenter stated that the effect of Medicaid expansion on the agency's projection of what the traditional DSH payment would have been for FY 2014, absent of the Affordable Care Act, has varied erratically in the agency's successive rulemakings for FYs 2014 through 2017. Another commenter noted that the most recent Congressional Budget Office report showed a 32-percent increase in Medicaid/CHIP enrollment as a result of Medicaid expansion, and expected that this increase in enrollment would result in a substantial increase in reported DSH payments that is not reflected in OACT's DSH estimate for Factor 1. A second commenter provided its own estimates of how the Medicaid expansion would affect DSH payments, and noted that these estimates do not align with CMS' figures.

Commenters objected to CMS' statement from prior rulemaking that ''the increase due to Medicaid expansion is not as large as commenters contended due to the actuarial assumption that the new enrollees are healthier than the average Medicaid recipient, and, therefore, use fewer hospital services.'' Commenters noted that this assumption has the effect of reducing the estimate of total Medicare DSH spending under prior law, which in turn reduces the estimates of both the empirically justified amount and the amount available to be distributed as uncompensated care payments. Some commenters asserted that there is no solid evidentiary basis for the assumption that new Medicaid enrollees are healthier, and requested that CMS reconsider and discontinue use of this assumption. Some commenters asserted that CMS should by now have accurate information regarding States that have expanded Medicaid, and that CMS should utilize the available enrollment and/or utilization information from Medicaid expansion programs either to support or refute the assumption that the Medicaid expansion population is healthier than the average Medicaid recipient. One commenter stated that, in the FY 2015 IPPS/LTCH PPS final rule, CMS provided a table comparing pre-Affordable Care Act versus post-Affordable Care Act Medicaid enrollment and the corresponding estimated percentage increase in Medicare DSH, but those data were not provided in the FY 2016 IPPS/LTCH PPS proposed and final rule or the FY 2017 IPPS/LTCH PPS proposed rule.

Several commenters believed there was incomplete information in the FY 2017 IPPS/LTCH PPS proposed rule regarding the ''completion factor'' and requested further detail. These commenters suggested that CMS publish the ''completion factor'' used to adjust the FY 2014 and FY 2015 claims data for purposes of the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25085). In addition, the commenters suggested that CMS publish information on the ''preliminary data for 2016'' used by the OACT to determine the discharge figure for FY 2016, as well as the ''assumptions'' used to determine the FY 2017 discharge figure. The commenters requested that CMS also share detailed calculations of the discharge and case-mix values as well as the inflation factor update used for FY 2014 through FY 2017. One commenter noted that, according to the FY 2017 IPPS/LTCH PPS proposed rule, the data source for the change in 2015 case-mix is actual data adjusted for a completion factor, but the value is the same for 2016 and 2017 based on the 2010–2011 Medicare Technical Review Panel

report. The commenter questioned whether a more current data source could be used for this calculation.

Several commenters expressed concern about the sustainability of continued reductions to aggregate uncompensated care payments. The commenters noted that, as insurance coverage increases, the aggregate amount available for uncompensated care payments will decline and thus reduce the amount of payments to be distributed which they believe will help cover the cost of uncompensated care. These commenters believed that it would be appropriate to adjust the ''Other'' column in a manner that supports safety-net hospitals in order to reflect the growing number of hospitals that are becoming eligible for DSH payments. Furthermore, commenters noted that hospitals in States that have not expanded Medicaid are not experiencing a decrease in uncompensated care costs and that reductions in Medicare DSH payments are detrimental to these hospitals. Some commenters noted the reductions in payments they would experience due to CMS' uncompensated care proposal in totality and observed that the hospitals that are disproportionately impacted may not have the resources necessary to successfully transform care, maintain high quality care, and continue in the commitment to meet the needs of patients and communities.

Response: We thank the commenters for their input. As in previous years, we would like to clarify that Factor 1 is not estimated in isolation. The Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rule are generally consistent with those used for the Midsession Review of the President's Budget. For additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget Web site at: *https://www.whitehouse.gov/omb/budget.* For additional information on the specific economic assumptions used in the Midsession Review of the President's FY 2017 Budget, we refer readers to the ''Midsession Review of the President's FY 2017 Budget'' available on the Office of Management and Budget Web site at: *https://www.whitehouse.gov/omb/budget/MSR.* For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS Web site at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html?redirect=/reportstrustfunds/* under ''Downloads.''

As we did in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49519), later in this section, we provide additional information regarding the data sources, methods, and assumptions employed by the actuaries in determining the OACT's updated estimate of Factor 1 for FY 2017. We believe that this discussion addresses the methodological concerns raised by commenters regarding the various assumptions used in the estimate, including the ''Other'' and ''Discharges'' assumptions and also provides additional information regarding how we address the Medicaid and CHIP expansion. However, we note that, with regard to the commenters' questions and concerns on the completion factor, the OACT assumed a discharge completion factor of 99 percent for FY 2014 and 98 percent for FY 2015. Similarly, the OACT assumed that case-mix was stabilized at the time of the estimate and no additional completion factor adjustment was needed. These assumptions are consistent with historical patterns of completion factors that were determined for discharge and case-mix numbers.

Regarding the commenters' assertion that Medicaid expansion is not adequately accounted for in the ''Other'' column, we note that, based on data from the Midsession Review of the President's Budget, the OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be 50 percent of the average per capita of the pre-expansion Medicaid beneficiary due to the better health of these beneficiaries. This assumption is consistent with recent internal estimates of Medicaid per capita spending pre-expansion and post-expansion.

In response to the commenters who requested that we adjust the ''Other'' assumption to reflect the growing number of disproportionate share hospitals in a manner that supports safety-net hospitals, particularly in States that do not have a Medicaid or CHIP expansion, we note that our proposed methodology includes assumptions regarding how DSH payments will increase in aggregate, regardless of how many hospitals qualify for DSH payments. The statute is clear that the computation of Factor 1 begins with an aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. In our view, the most appropriate way to estimate this amount is to project, to the best of our ability, how DSH payments will change in aggregate, based on the programs and policies that will be in effect during the fiscal year, rather than focusing on changes in payments to specific hospitals. Thus, there is no need to adjust our estimate of the ''Other'' factors to reflect new DSH hospitals. Furthermore, in response to concerns about the decrease in the amount available to make uncompensated care payments, we believe that the intent of the statute is to reduce the amount available to make uncompensated care payments to reflect the decline in the number of uninsured individuals and the corresponding decrease in the amount of uncompensated care costs.

Comment: In addition to requesting that the methodology and assumptions used for Factor 1 be made public before the publication of the final rule and with the proposed rule each subsequent year, commenters requested that CMS furnish interested parties with advance opportunity to comment on new calculations based on the more recent data that CMS intends ultimately to use for the final rule. One commenter believed that CMS' rulemaking is flawed because different data and calculations are used in the final rule without any opportunity for the hospitals to comment. This commenter requested that CMS make clear that it will use different or updated data to determine DSH payments for uncompensated care in the final rule. The commenter believed that the proposal to determine the amount of hospitals' new DSH payment based on data first released with the final rule and on which hospitals will have no meaningful opportunity to comment violates notice-and-comment rulemaking requirements. As discussed above, several commenters noted the variability in the values of the ''Other'' column as well as in the factor applied to account for Medicaid expansion; one of the commenters called on CMS to explain why these values were allowed to change from one rulemaking to the next when the agency has otherwise taken the position that the estimates used to determine uncompensated care payments should be fixed when made and not be reconciled with data that become available later.

Response: We believe that stakeholders had notice and a full opportunity to comment on methodology that would be used to

determine uncompensated care payments, including the data sources that would be used. As a result, commenters had a full opportunity to raise any concerns regarding the appropriateness of the data generally, even if the actual data were not yet available, consistent with the requirements for notice and comment under the Administrative Procedure Act. With respect to concerns about the variability of the factors used to estimate Factor 1, we note that, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50630), using the discretion afforded in the statute to estimate the aggregate amount of DSH payments that would be made in the absence of section 1886(r) of the Act, we finalized a policy of defining the methodology for calculating Factor 1 using the OACT's biannual Medicare DSH payment projections, which are typically available in February of each year (based on data from December of the previous year) as part of the President's Budget, and in July (based on data from June) as part of the Midsession Review of the President's Budget.

Comment: Some commenters requested that, in light of their concerns about the data sources and methods used to estimate Factor 1, CMS adopt a process of reconciling the initial estimates of Factor 1 with actual data for the payment year in conjunction with the final settlement of hospital cost reports for the applicable year. The commenters believed that a ''true-up approach'' would ensure that Medicare DSH payments are determined using the best data.

Response: We continue to believe that applying our best estimates prospectively is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010; and 80 FR 49518). As we noted in the FY 2014 IPPS/LTCH PPS final rule, we do not know the aggregate Medicare DSH payment amount that would be paid for each Federal fiscal year until the time of cost report settlements, which occur several years after the end of the fiscal year. Furthermore, the statute provides that Factor 1 shall be determined based on estimates of the aggregate amount of DSH payments that would be made in the absence of section 1886(r) of the Act and the aggregate amount of empirically justified DSH payments that are made under section 1886(r)(1) of the Act. We believe that, in affording the Secretary the discretion to estimate the amount of these payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability in payments and sought to avoid a situation in which the uncompensated care payments would be subject to change over a period of a number of years. Accordingly, we do not agree with the commenters that we should establish a process for reconciling our estimates of Factor 1. We note that, in reviewing the OACT's prior estimates for DSH payments compared to more updated estimate and/or actual experience, from FY 2005 to FY 2017, the original estimates have been higher than either the more updated estimates and/or actual experience for 7 of the 13 years and lower than actual experience in only 6 years.

Comment: Commenters indicated that the estimated DSH payments do not account for the impact of the D.C. Circuit Court decision in *Allina* by excluding Medicare Advantage days from the SSI ratio and including dual eligible Medicare Advantage days in the Medicaid fraction. The commenters believed that this understates the estimate of Factor 1. The commenters stated that CMS cannot use prior year data for its calculations without adjusting that data to reflect what it should have been under binding D.C. Circuit precedent.

Response: We do not believe the *Allina* decision has any bearing on our estimate of Factor 1 for FY 2017. The holding in *Allina* addresses traditional DSH payments made to a group of providers between 2004 and 2010. The *Allina* decision did not address the FY 2014 IPPS/LTCH PPS final rule (78 FR 50614 through 50620) in which we readopted the policy of counting Medicare Advantage days in the SSI ratio for FY 2014 and all subsequent fiscal years. In its estimate of Factor 1 for FY 2017 for the FY 2017 IPPS/LTCH PPS proposed rule, the Office of the Actuary was making an estimate of difference between the aggregate amount of DSH payments that would be made under section 1886(d)(5)(F) of the Act in FY 2017 if section 1886(r) of the Act did not apply and the aggregate amount of empirically justified DSH payments that will be made to hospitals in FY 2017 under section 1886(r)(1) of the Act. Thus, although the Office of the Actuary used the December 2015 update of the Medicare Hospital Cost Report Information System (HCRIS) in making this estimate, it also applied inflation adjustments and assumptions regarding future changes in utilization and case-mix in order to estimate Medicare DSH payments for FY 2017. Because Medicare Advantage days will be counted in the SSI fraction in FY 2017 for purposes of determining empirically justified DSH payments, we believe it is more appropriate to use data that also include Medicare Advantage days in the SSI fraction when determining Factor 1 for FY 2017. Accordingly, consistent with § 412.106(b)(2), as readopted in the FY 2014 IPPS/LTCH PPS final rule, in estimating DSH payments for FY 2017, the OACT did not remove patients enrolled in Medicare Advantage plans from SSI ratios or make any other adjustments to the hospital cost report data from the December 2015 update of the HCRIS database. We believe this methodology is consistent with the statute and our regulations.

After consideration of the public comments we received, we are finalizing, as proposed, the methodology for calculating Factor 1 for FY 2017. Using this methodology, we discuss the resulting Factor 1 amount for FY 2017 below.

To determine Factor 1 and to model the impact of this provision for FY 2017, we used the Office of the Actuary's June 2016 Medicare DSH estimates based on data from the March 2016 update of 2013 cost report data included in the HCRIS and the Impact File published in conjunction with the publication of the FY 2016 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the June 2016 Medicare DSH estimates. Furthermore, because Maryland hospitals participating in the Maryland All-Payer Model do not receive DSH payments, these hospitals also are excluded from the OACT's Medicare DSH estimates. Because the Rural Community Hospital Demonstration program is scheduled to end on December 31, 2016, hospitals that are participating in the program are included in this estimate for FY 2017. However, for this final rule, we are excluding 25 percent of our estimate of DSH payments that would otherwise be made to the 4 hospitals whose participation in the program will continue through December 31, 2016, as these hospitals will be excluded from receiving DSH payments until that time. The estimate includes the total DSH payments that would be made to the 10 hospitals whose participation in the Rural Community Hospital Demonstration program will continue only through September 30, 2016.

For this final rule, using the data sources discussed above, the Office of the Actuary used the most recently submitted Medicare cost report data for 2013 to identify Medicare DSH

payments and the most recent Medicare DSH payment adjustments provided in the Impact File published in conjunction with the publication of the FY 2016 IPPS/LTCH PPS final rule, and applied inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The June 2016 Office of the Actuary estimate for Medicare DSH payments for FY 2017, without regard to the application of section 1886(r)(1) of the Act, is approximately $14,396,635,710.16 billion. This estimate excludes Maryland hospitals participating in the Maryland All-Payer Model, SCHs paid under their hospital-specific payment rate, and 25 percent of DSH payments for the 4 hospitals whose participation in the Rural Community Hospital Demonstration program will continue through December 31, 2016. Therefore, based on the June 2016 estimate, the estimate for empirically justified Medicare DSH payments for FY 2017, with the application of section 1886(r)(1) of the Act, is approximately $3,599,158,927.54 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2017). Under § 412.l06(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, in this final rule, Factor 1 for FY 2017 is $10,797,476,782.62, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2017 ($14,396,635,710.16 minus $3,599,158,927.54).

The Office of the Actuary's final estimates for FY 2017 began with a baseline of $12.277 billion in Medicare DSH expenditures for FY 2013. The following table shows the factors applied to update this baseline through the current estimate for FY 2017:

FACTORS APPLIED FOR FY 2014 THROUGH FY 2017 TO ESTIMATE MEDICARE DSH EXPENDITURES USING 2013 BASELINE

FY	Update	Discharge	Case-Mix	Other	Total	Estimated DSH payment (in billions)
2014	1.009	0.9553	1.015	1.0586	1.035688	$12.715
2015	1.014	0.9897	1.005	1.0705	1.079678	13.738
2016	1.009	0.9868	1.025	0.9999	1.020471	14.009
2017	1.0015	1.0084	1.005	1.0125	1.027649	14.397

In this table, the discharge column shows the increase in the number of Medicare FFS inpatient hospital discharges. The figures for FYs 2014 and 2015 are based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2016 is based on preliminary data for 2016. The discharge figure for FY 2017 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The case-mix column shows the increase in case-mix for IPPS hospitals. The case-mix figures for FYs 2014 and 2015 are based on actual data adjusted by a completion factor. The FY 2016 increase is based on preliminary data adjusted by a completion factor. The FY 2017 increases are based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The ''Other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy). In addition, the ''Other'' column includes a factor for the Medicaid expansion due to the Affordable Care Act.

The table below shows the factors that are included in the ''Update'' column of the above table:

FY	Market basket percentage	Affordable Care Act payment reductions	Multifactor productivity adjustment	Documentation and coding	Total update percentage
2014	2.5	−0.3	−0.5	−0.8	0.9
2015	2.9	−0.2	−0.5	−0.8	1.4
2016	2.4	−0.2	−0.5	−0.8	0.9
2017	2.7	−0.75	−0.3	−1.5	0.15

Note: All numbers are based on Midsession Review of FY 2017 President's Budget projections.

b. Calculation of Factor 2 for FY 2017

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Specifically, section 1886(r)(2)(B)(i) of the Act provides that, for each of FYs 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, as determined by comparing the percent of such individuals (1) who were uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and (2) who are uninsured in the most recent period for which data are available (as so calculated), minus 0.1 percentage point for FY 2014 and minus 0.2 percentage point for each of FYs 2015, 2016, and 2017.

Section 1886(r)(2)(B)(i)(I) of the Act further indicates that the percent of individuals under 65 without insurance in 2013 must be the percent of such individuals who were uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary

based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment). The Health Care and Education Reconciliation Act (Pub. L. 111–152) was enacted on March 30, 2010. It was passed in the House of Representatives on March 21, 2010, and by the Senate on March 25, 2010. Because the House of Representatives was the first House to vote on the Health Care and Education Reconciliation Act of 2010 on March 21, 2010, we have determined that the most recent estimate available from the Director of the Congressional Budget Office ''*before* a vote in either House on the Health Care and Education Reconciliation Act of 2010 . . .'' (emphasis added) appeared in a March 20, 2010 letter from the director of the CBO to the Speaker of the House. Therefore, we believe that only the estimates in this March 20, 2010 letter meet the statutory requirement under section 1886(r)(2)(B)(i)(I) of the Act. (To view the March 20, 2010 letter, we refer readers to the Web site at: *http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf*.)

In its March 20, 2010 letter to the Speaker of the House of Representatives, the CBO provided two estimates of the ''post-policy uninsured population.'' The first estimate is of the ''Insured Share of the Nonelderly Population Including All Residents'' (82 percent) and the second estimate is of the ''Insured Share of the Nonelderly Population Excluding Unauthorized Immigrants'' (83 percent). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50631), we used the first estimate that includes all residents, including unauthorized immigrants. We stated that we believe this estimate is most consistent with the statute, which requires us to measure ''the percent of individuals under the age of 65 who are uninsured'' and provides no exclusions except for individuals over the age of 65. In addition, we stated that we believe that this estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than the estimate that reflects only legal residents. The March 20, 2010 CBO letter reports these figures as the estimated percentage of individuals with insurance. However, because section 1886(r)(2)(B)(i) of the Act requires that we compare the percent of individuals who are uninsured in the most recent period for which data are available with the percent of individuals who were uninsured in 2013, in the FY 2014 IPPS/LTCH PPS final rule, we used the CBO insurance rate figure and subtracted that amount from 100 percent (that is the total population without regard to insurance status) to estimate the 2013 baseline percent of individuals without insurance. Therefore, for FYs 2014 through 2017, our estimate of the uninsurance percentage for 2013 is 18 percent.

Section 1886(r)(2)(B)(i) of the Act requires that we compare the baseline uninsurance rate to the percent of such individuals who are uninsured in the most recent period for which data are available (as so calculated). In the FY 2014, FY 2015, and FY 2016 IPPS/LTCH PPS final rules (78 FR 50634, 79 FR 50014, and 80 FR 49522, respectively), we used the same data source, CBO estimates, to calculate this percent of individuals without insurance. In response to public comments, we also agreed that we should normalize the CBO estimates, which are based on the calendar year, for the Federal fiscal years for which each calculation of Factor 2 is made (78 FR 50633). Therefore, for the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24486), we used the most recently available estimate of the uninsurance rate, which was based on the CBO's March 2015 estimates of the effects of the Affordable Care Act on health insurance coverage (which are available at *http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2014-04-ACAtables2.pdf*). The CBO's March 2015 estimate of individuals under the age of 65 with insurance in CY 2016 was 89 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2016 was 11 percent (that is, 100 percent minus 89 percent.) Similarly, the CBO's March 2015 estimate of individuals under the age of 65 with insurance in CY 2017 was 90 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2017 available for the proposed rule was 10 percent (that is, 100 percent minus 90 percent.)

The calculation of the proposed Factor 2 for FY 2017, employing a weighted average of the CBO projections for CY 2016 and CY 2017, was as follows:

- CY 2016 rate of insurance coverage (March 2015 CBO estimate): 89 percent.
- CY 2017 rate of insurance coverage (March 2015 CBO estimate): 90 percent.
- FY 2017 rate of insurance coverage: (89 percent * .25) + (90 percent * .75) = 89.75 percent.
- Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent.
- Percent of individuals without insurance for FY 2017 (weighted average): 10.25 percent.

$1 - |((0.1025 - 0.18)/0.18)| = 1 - 0.4306 = 0.5694$ (56.94 percent)

0.5694 (56.94 percent) − .002 (0.2 percentage points for FY 2017 under section 1886(r)(2)(B)(i) of the Act) = 0.5674 or 56.74 percent

0.5674 = Factor 2

Therefore, we proposed that Factor 2 for FY 2017 would be 56.74 percent.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25046), we stated that the FY 2017 Proposed Uncompensated Care amount was $\$10,670,529,595.84 \times 0.5674 = \$6,054,458,492.68$.

Comment: A number of commenters expressed concern about the accuracy and transparency of the methodology used to calculate Factor 2. The commenters questioned whether CMS has accounted for factors that affect the percentage of insured individuals, such as the Supreme Court's ruling on Medicaid expansion in *National Federation of Independent Business* v. *Sebelius*, which resulted in some States not expanding their Medicaid programs. One commenter specifically asserted that CMS' methodology for the uncompensated care component of the Medicare DSH calculation does not account for those States that have not yet expanded Medicaid, resulting in an overstated percentage of insured individuals. Another commenter supported using the most recently available CBO estimates for the uninsured, including any revised estimates issued before the final rule. A third commenter believed the CBO estimates to be within reason. This commenter suggested that CMS true-up the factors based on actual data in order to yield the most accurate determination of the factors and the amount available to make uncompensated care payments.

Response: In the FY 2014 IPPS/LTCH PPS final rule, we finalized a policy to employ the most recent available CBO estimate of the rate of uninsurance in the calculation of Factor 2 for FY 2014. We stated that we believe that this approach is consistent with the language of section 1886(r)(2)(B)(i)(II) of the Act. In addition, it is preferable from a statistical point of view to calculate the percent change in the rate of insurance over time using a consistent data source (78 FR 50632). We also used the most recent CBO estimates in the calculation of Factor 2 for FY 2015 and FY 2016, and we continue to believe

that the CBO projections of the insurance coverage are the most appropriate and consistent basis on which to calculate Factor 2 for FY 2017. We note that CBO's coverage projections for CY 2016 and CY 2017 reflect changes in the rate of uninsurance arising from participation in the health insurance exchanges, Medicaid and CHIP enrollment, and changes in employer-sponsor, nongroup, and other insurance coverage. In addition, the estimate reflects other individuals who choose to remain uninsured, despite being eligible for Medicaid or having access to coverage through an employer, the exchange, or from an insurer. Therefore, the CBO estimates do take into account some uncertainties under the Affordable Care Act, including the decisions by States as to whether to expand their Medicaid programs, the different outcomes of Medicaid expansions and changes in insurance coverage status over time. For detailed explanations outlining the methodology and assumptions used by CBO, we refer readers to the CBO Web site and particularly in the Appendix of the March 2016 Updated Budget Projections: 2016–2026 (which are available at *https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/51384-MarchBaseline.pdf*).

With respect to the commenter's concern about employing actual data to reconcile the projections employed to determine Factor 2, in the FY 2014 IPPS/LTCH PPS final rule, we stated that employing actual data would impose an unacceptable delay in the final determination of uncompensated care payments (78 FR 50632). Actual data on the rates of insurance and uninsurance do not become available until several years after the payment year, and the initial data for a year will continue to be adjusted for several years after that as further data become available. Furthermore, by stating that the Secretary's calculations should be based on ''estimates'' provided by the CBO, the statute clearly contemplates the use of such estimates on a prospective basis without reconciliation. Accordingly, we continue to believe that determining Factor 2 prospectively is consistent with the statute and conducive to administrative efficiency, finality, and predictability in payments.

Comment: Several commenters requested that CMS work with Congress to take steps to mitigate the effect of the reduction in the overall amount available to make uncompensated care payments for FY 2017. Some commenters requested that CMS use its authority to decrease the magnitude of the proposed reduction in uncompensated care payments. One commenter requested that CMS maintain the percentage of uninsurance that it had applied in the 2015 calculation until more accurate projections can be made, accounting for those States that have not yet expanded Medicaid. Several commenters asked CMS to ensure the payment methodology does not harm access to care in rural areas.

Response: We thank the commenters for their alternative suggestions. The statute requires us to implement the uncompensated care payment methodology in its entirety for FY 2014 and each subsequent fiscal year. Therefore, we do not believe there is a statutory basis to delay or modify the implementation of Factor 2. The statute also does not provide us with a basis to use the percentage of uninsurance we applied for FY 2015 because section 1886(r)(2)(B)(i)(II) requires us to use the data on the percent of individuals who are uninsured in the most recent period for which data are available, and such data are available for FY 2017. Finally, although we understand the commenters' concerns regarding access to care in rural areas, the statute does not include any exception to the methodology for computing uncompensated care payments for hospitals by geographic location or geographic classification. Therefore, hospitals in rural areas are subject to the same reductions as hospitals elsewhere in the country.

Comment: Several commenters requested that any proposed changes to the methodology that will be used to calculate Factor 2 for FY 2018 and subsequent years be transparent and open for comment in next year's proposed rule. One commenter asked CMS to elaborate on future changes and questioned whether using the CBO's projections of the rate of uninsurance would still be a viable option for determining Factor 2 for future years.

Response: The statute permits the use of a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. Because we did not make a proposal to change the Factor 2 methodology for FY 2018 and subsequent years in the FY 2017 IPPS/LTCH PPS proposed rule, we do not believe it is appropriate to discuss any potential changes to the methodology or the viability of potential alternative data sources in this final rule. We plan to address this issue in the FY 2018 IPPS/LTCH PPS proposed rule.

After consideration of the public comments we received, we calculated the final Factor 2 as follows:

For this FY 2017 IPPS/LTCH PPS final rule, we used the most recently available estimate of the uninsurance rate, which is based on the CBO's March 2016 estimates of the effects of the Affordable Care Act on health insurance coverage (which are available at *http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2014-04-ACAtables2.pdf*). The CBO's March 2016 estimate of individuals under the age of 65 with insurance in CY 2016 is 90 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2016 is 10 percent (that is, 100 percent minus 90 percent.) The CBO's March 2016 estimate of individuals under the age of 65 with insurance in CY 2017 is also 90 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2017 available for the final rule is 10 percent (that is, 100 percent minus 90 percent.)

The calculation of the final Factor 2 for FY 2017, employing a weighted average of the CBO projections for CY 2016 and CY 2017, is as follows:

- CY 2016 rate of insurance coverage (March 2016 CBO estimate): 90 percent.
- CY 2017 rate of insurance coverage (March 2016 CBO estimate): 90 percent.
- FY 2016 rate of insurance coverage: (90 percent * .25) + (90 percent * .75) = 90 percent.
- Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent.
- Percent of individuals without insurance for FY 2017 (weighted average): 10 percent.

$1 - |((0.10–0.18)/0.18)| = 1 - 0.4444 =$ 0.5555 (55.56 percent)

0.5556 (55.56 percent) − .002 (0.2 percentage points for FY 2017 under section 1886(r)(2)(B)(i) of the Act) = 0.5536 or 55.36 percent

0.5536 = Factor 2

Therefore, the final Factor 2 for FY 2017 is 55.36 percent.

The FY 2017 Final Uncompensated Care Amount is: $10,797,476,782.62 × 0.5536 = $5,977,483,146.86.

FY 2017 Uncompensated Care Total Available	$5,977,483,146.86

c. Calculation of Factor 3 for FY 2017

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents

the quotient of (1) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of each hospital and determined that Worksheet S–10 of the Medicare cost report potentially provides the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on the Worksheet S–10 and the completeness of these data, we did not propose to use data from the Worksheet S–10 to determine the amount of uncompensated care for FY 2014, the first year this provision was in effect, or for FY 2015 and FY 2016. We instead employed the utilization of insured low-income patients, defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in § 412.106(b)(4) and § 412.106(b)(2)(i) of the regulations, respectively, to determine Factor 3. We believed that these alternative data, which are currently reported on the Medicare cost report, would be a better proxy for the amount of uncompensated care provided by hospitals. We also indicated that we were expecting reporting on the Worksheet S–10 to improve over time and remained convinced that the Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3. In section IV.F.4.d. of the preamble of the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25089), we explained our belief that since the introduction of the uncompensated care payment in FY 2014, hospitals have been submitting more accurate and consistent data through Worksheet S–10 on the Medicare cost report (OMB control number 0938–0050) and that it would be appropriate to begin incorporating Worksheet S–10 data for purposes of calculating Factor 3 starting in FY 2018. As discussed in greater detail in section IV.F.4.d. of the preamble of the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25089) and in section IV.F.4.d. of this final rule, we proposed a methodology and timeline for incorporating Worksheet S–10 data and invited public comments on that proposal. We address the public comments we received on the proposal to incorporate Worksheet S–10 data for purposes of determining Factor 3 starting in FY 2018 in that section of this final rule.

In the FY 2017 IPPS/LTCH PPS proposed rule, we stated that we believe it remains premature to propose the use of Worksheet S–10 data for purposes of determining Factor 3 for FY 2017 because hospitals were not on notice that Worksheet S–10 would be used for purposes of computing uncompensated care payments prior to FY 2014, which could affect the accuracy and completeness of the information reported on Worksheet S–10. As described more fully below regarding the time period of the data used to calculate Factor 3, for FY 2017, we are using data from hospital cost reports that precede FY 2014 to determine Factor 3 of the uncompensated care payment methodology. Therefore, we indicated that, for FY 2017, we remain concerned about the accuracy and consistency of the data reported on Worksheet S–10 and proposed to continue to employ the utilization of insured low-income patients (defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in § 412.106(b)(4) and § 412.106(b)(2)(i), respectively) to determine Factor 3 (81 FR 25087). We also proposed to continue the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers for FY 2017 and subsequent fiscal years (81 FR 25087).

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25087), we also proposed to make a change to the data that will be used to calculate Factor 3 for Puerto Rico hospitals. We received a comment in response to the FY 2016 IPPS/LTCH PPS proposed rule requesting that CMS create a proxy for the SSI days used in the Factor 3 calculation for Puerto Rico hospitals (80 FR 49526). Specifically, commenters were concerned that residents of Puerto Rico are not eligible for SSI benefits. Although we did not have logical outgrowth to adopt any change for FY 2016, we indicated that we planned to address this issue in the FY 2017 IPPS/LTCH PPS proposed rule if we also proposed to continue using inpatient days of Medicare SSI patients as a proxy for uncompensated care in FY 2017. We stated in the proposed rule that because we were proposing to continue using insured low-income patient days as a proxy for uncompensated care in FY 2017, we believed it was important to consider the commenter's request regarding the data used to calculate Factor 3 for Puerto Rico hospitals. Accordingly, we proposed to create a proxy for SSI days for Puerto Rico hospitals for use in the Factor 3 calculation. The commenter specifically mentioned the use of inpatient days for Medicare beneficiaries receiving Medicaid as this proxy. We examined this concept but were unable to identify a systematic source for these data for

Puerto Rico hospitals. Specifically, we noted that inpatient utilization for Medicare beneficiaries entitled to Medicaid is not reported by hospitals on the Medicare cost report. Therefore, we sought an alternative method using publicly available Medicare data for determining a proxy to account for the fact that residents of Puerto Rico are not eligible for SSI, and therefore Puerto Rico hospitals have a relatively low number of Medicare SSI days in the Factor 3 computation. We stated that we believe it is appropriate to use data from the Medicare cost report to develop a Puerto Rico Medicare SSI days proxy because they are publicly available, used for payment purposes, and subject to audit. However, we acknowledged that there are other data sources that could be included to develop such a proxy, in particular the SSI ratios posted on the Medicare DSH Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*, and therefore solicited public comment on their use.

To develop a Puerto Rico Medicare SSI days proxy using data from the Medicare cost report, our Office of the Actuary examined data from 2013 cost reports and analyzed the relationship between Medicare SSI days (estimated using SSI ratios on the cost report and Medicare days from the same cost report) and Medicaid days (reported by the hospitals in accordance with § 412.106(b)(4)). Nationally, excluding Puerto Rico, the Office of the Actuary found that, on average and across States, for every 100 Medicaid inpatient days, hospitals had 14 Medicare SSI days. In other words, the relationship between Medicare SSI days and Medicaid days reported by hospitals in States, excluding Puerto Rico, was approximately 14 percent. We believe it would be appropriate to extrapolate this relationship to Puerto Rico hospitals to approximate how many patient days for these hospitals would be Medicare SSI days if Puerto Rico residents were eligible to receive SSI. Therefore, to calculate Factor 3 for FY 2017, we proposed to use a proxy for Medicare SSI days for each Puerto Rico hospital equal to 14 percent (or 0.14) of its Medicaid days. In other words, for each Puerto Rico hospital, we would compute a value that is equal to 14 percent of its Medicaid days, where Medicaid days are determined in accordance with § 412.106(b)(4). Because this is a proposed proxy for the Puerto Rico hospital's Medicare SSI days, we stated that this value would replace whatever value would otherwise be computed for the hospital under § 412.106(b)(2)(i). Specifically, we would first remove any Medicare SSI days that a Puerto Rico hospital has from our calculation for purposes of determining the numerator of Factor 3 for the hospital and, if the hospital is projected to be eligible for DSH payments in FY 2017, the denominator of Factor 3. Second, we would add the proxy to the hospital's Medicaid days for purposes of determining the numerator of Factor 3 for the hospital and, if the hospital is projected to be eligible for DSH payments in FY 2017, the denominator of Factor 3. We noted that we continue to encourage Puerto Rico hospitals to report uncompensated care costs on Worksheet S–10 of the Medicare cost report completely and accurately in light of our proposal to begin incorporating data from Worksheet S–10 in the computation of hospitals' uncompensated care payments starting in FY 2018, as described in more detail in section IV.F.4.d. of the preamble of the proposed rule.

In summary, we invited public comments on the proposal to continue to use insured low-income days (that is, to use data for Medicaid and Medicare SSI patient days determined in accordance with § 412.106(b)(2)(i) and (b)(4) as a proxy for uncompensated care, as permitted by statute, including a proxy for Medicare SSI days for Puerto Rico hospitals), to determine Factor 3 for FY 2017. We proposed to codify these proposals in our regulations at § 412.106(g)(1)(iii)(C). We also invited public comments on our proposal to continue the policies concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers.

Comment: Several commenters objected to the proposal to calculate Factor 3 for FY 2017 based on a hospital's share of total Medicaid days and Medicare SSI days as a proxy for measuring a hospital's share of uncompensated care costs. These commenters believed that this method is significantly inaccurate as a measure of a hospital's uncompensated care burden. In particular, the commenters asserted that the low-income insured days proxy does not capture the extent to which low-income patients make up a hospital's overall patient population; that the use of only inpatient days does not capture the significant amount of care hospitals provide to low-income patients in the outpatient setting; and that the use of only inpatient days does not account for the full variation in the amount of resources required to treat low-income patients. One commenter suggested that CMS consider modifications to the low-income insured days proxy that the commenter believed would more accurately measure each hospital's uncompensated care burden. The commenter suggested CMS weight each hospital's SSI and Medicaid days in relation to its total patient days, rather than using the SSI and Medicaid days without any weights.

In addition, many commenters who objected to the proposal to use the low-income insured days proxy for FY 2017 believed that its continued use rewards providers in States where Medicaid has expanded, and it is thus inappropriate as a proxy for uncompensated care costs. One commenter stated that using Medicaid and Medicare SSI days to calculate Factor 3 harms hospitals in States with lower Medicaid income eligibility limits and high uncompensated care costs. As an example, this commenter stated that hospitals in Wisconsin have comparably lower Medicaid days, as the State government lowered Medicaid income eligibility limits to 100 percent of the Federal poverty level, yet losses associated with uninsured or underinsured patients remain high. Another commenter stated that, in using low-income insured days to determine a hospital's disproportionate patient percentage, most of the dollars in empirically justified Medicare DSH payments are distributed to hospitals with high Medicaid shares because in the commenter's view Medicaid days are much more common than Medicare SSI days. The commenter stated that there will be no direct payments for uncompensated care costs in FY 2017 because Medicaid and Medicare SSI days will continue to be used as a proxy for uncompensated care costs. The commenter asserted that the net result is that the Medicare Part A Trust Fund will, in effect, provide significant payments for treating Medicaid patients, which are more numerous in Medicaid expansion States.

Some commenters who opposed the low-income insured days proxy believed that using data from Worksheet S–10, coupled with selective auditing, would lead to better estimates of uncompensated care costs than the low-income insured days proxy. These commenters asserted that the use of Worksheet S–10 to distribute uncompensated care payments, coupled with distributing traditional DSH payments based on the disproportionate patient percentage formula, would create more balance between Medicare support of Medicaid patients and Medicare support of the uninsured. Some commenters recommended that

CMS transition as soon as possible away from the low-income insured days proxy and towards the use of Worksheet S–10 data to determine uncompensated care costs, as any delay would perpetuate current inaccuracies and inequities. However, several commenters who disagreed with the use of the low-income insured days proxy for FY 2017 were also not comfortable using data from Worksheet S–10 until CMS changes the form and instructions to improve the accuracy and consistency of the data it collects. Several commenters who disagreed with continued use of the low-income insured days proxy recommended that CMS use a new data source for obtaining data on uncompensated care costs. Potential data sources identified by commenters included a federally administered DSH survey and proxy data from the Bureau of Labor Statistics.

Response: For the reasons we stated in the FY 2014, FY 2015, and FY 2016 IPPS/LTCH PPS final rules, we believe that data on utilization for insured low-income patients are a reasonable proxy for the treatment costs of uninsured patients in FY 2017. Moreover, due to the concerns that continue to be expressed by a large majority of commenters regarding the accuracy and consistency of the data reported on the Worksheet S–10 in its current form, we continue to believe that these alternative data on utilization for insured low-income patients, which are currently reported on the Medicare cost report, remain a better proxy for the amount of uncompensated care provided by hospitals in FY 2017. However, we remain convinced that Worksheet S–10 can ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3, as discussed in section IV.F.4.d of the preamble of this final rule.

As discussed in the FY 2016 IPPS/LTCH PPS final rule, in using Medicaid and Medicare SSI days as a proxy for uncompensated care, we recognize it would be possible for hospitals in States that choose to expand Medicaid to receive higher uncompensated care payments because they may have more Medicaid patient days than hospitals in a State that does not choose to expand Medicaid. We note that the earliest Medicaid expansions pursuant to the Affordable Care Act began in 2014. The data that will be used to determine Factor 3 for FY 2017 are from 2011, 2012, and 2013, and therefore do not reflect the effects of these Medicaid expansions. Thus, for the reasons discussed above, we believe that data on insured low-income days remain the best proxy for uncompensated care costs currently available to determine Factor 3 for FY 2017.

Comment: One commenter requested that CMS consider using a proxy for Puerto Rico hospitals' SSI days in computing the empirically justified DSH payment amount, or 25 percent of the amount that would have been paid for Medicare DSH prior to implementation of Section 3133 of the Affordable Care Act. The commenter stated that the use of a proxy in the traditional Medicare DSH formula is a logically and naturally derived conclusion of the proposal to use the overall national average ratio of Medicare SSI days to Medicaid days as a proxy for SSI days in the calculation of Factor 3 for Puerto Rico hospitals. The commenter stated that there is sufficient precedent and legal support for CMS to use a proxy for SSI days for empirically justified Medicare DSH payments to Puerto Rico. Specifically, the commenter stated that the law requires CMS to apply the formula in the same manner and to the same extent in each jurisdiction. The commenter asserted that by not addressing the ineligibility of beneficiaries in the Territories, including Puerto Rico, to receive SSI, the empirically justified DSH payment formula and its resulting payments are not consistent with the requirement to make these payments in the same manner and to same extent as they apply to subsection (d) hospitals. The commenter stated that the result is that the jurisdiction with the highest proportion of low income beneficiaries gets the lowest disproportionate share payment, within the context of the empirically justified DSH payment.

Another commenter believed that the use of a proxy for SSI days to calculate Factor 3 for Puerto Rico hospitals should be accompanied by a corresponding increase in Factor 1. The commenter stated that the increase in Factor 1 is long overdue. The commenter noted that traditional Medicare DSH payments are based in part on the Medicare/SSI fraction, established under 42 U.S.C. 1395ww(d)(5)(D)(vi)(I), which is the percentage of a hospital's inpatients who were entitled to Medicare Part A benefits and were also entitled to Supplemental Security Income (SSI) benefits under Title XVI of the Social Security Act when they were receiving inpatient services at the hospital. The commenter asserted that the problem for Puerto Rico is that it does not have an SSI program, as Congress did not extend that program to Puerto Rico when enacting the Title XVI SSI program. The commenter further suggested that Congress had addressed Puerto Rico's lack of an SSI program in 42 U.S.C. 1395ww(d)(9)(D), which they interpreted to provide that Puerto Rico hospitals are paid DSH ''in the same manner and to the extent'' as hospitals in the 50 States, and as such, inpatient days should be included for Puerto Rico Medicare beneficiary residents who would qualify for SSI benefits if they were residents of a State. The commenter concluded that CMS' interpretation that only Title XVI SSI program days ''count'' when calculating the DSH payment for Puerto Rico hospitals turns the provision at 42 U.S.C. 1395ww(d)(9)(D) from one that was intended to provide for a DSH payment to Puerto Rico hospitals into one that prohibits such a payment.

Response: In the FY 2017 IPPS/LTCH PPS proposed rule, we did not propose to adopt a proxy for Puerto Rico hospitals' SSI days in the calculation of the empirically justified Medicare DSH payment. Therefore, we consider this comment to be outside the scope of the proposed rule. We note, however, that while section 1886(r)(2)(C)(i) of the Act allows for the use of alternative data as a proxy to determine the costs of subsection (d) hospitals for treating the uninsured for purposes of determining uncompensated care payments, section 1886(r)(1) of the Act requires the Secretary to pay an empirically justified DSH payment that is equal to 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(d)(5)(F)(vi) of the Act, which prescribes the disproportionate patient percentage used to determine empirically justified Medicare DSH payments, specifically calls for the use of SSI days in the Medicare fraction and does not allow the use of alternative data, we disagree with the commenter that there is legal support for CMS to use a proxy for Puerto Rico hospitals' SSI days in the calculation of the empirically justified Medicare DSH payment. As a result, there is also no basis for us to change our estimate of Factor 1.

Comment: Several commenters supported the proposal to use 14 percent of Medicaid days as a proxy for Medicare SSI days for Puerto Rico Hospitals. These commenters stated that they appreciated the attention and effort of CMS to develop a fair and appropriate method to estimate SSI days for Puerto Rico, as the SSI program is statutorily unavailable to U.S. citizens residing in the Territories. One commenter believed, however, that using a 50 State average ratio of Medicare SSI days to Medicaid days did

not constitute an appropriate proxy in light of Puerto Rico's current economic crisis.

One commenter recognized the Puerto Rico proxy as a positive step taken by CMS, but reiterated its view that Puerto Rico hospitals have been undercompensated since the beginning of the Medicare program in 1986. This commenter noted that the use of SSI eligibility as an indicator of low-income Medicare patients effectively extends the statutory exclusion of Puerto Rico from the SSI program to other Federal programs from which U.S. citizens residing in the Territories are clearly not excluded by statute. This commenter recommended that CMS examine data to evaluate future proxy alternatives, such as using data for Medicare beneficiaries with Medicaid eligibility (dual beneficiaries). The commenter proposed that CMS initiate a plan to work with hospitals in Puerto Rico to formally review and define cost report data for recent years in relation to the documentation of hospital days for dual beneficiaries. As a second step, the commenter recommended that CMS allow hospitals in Puerto Rico to resubmit the pertinent worksheets of the cost reports for past years, to appropriately document the hospital days for dual beneficiaries, including those in the integrated Medicare Platino program that works through membership in the Medicare Advantage program.

Response: We appreciate the support for our proposal to use 14 percent of a Puerto Rico hospital's Medicaid days as a proxy for SSI days. Because we are continuing to use insured low-income patient days as a proxy for uncompensated care in FY 2017 and residents of Puerto Rico are not eligible for SSI benefits, we believe it is important to create a proxy for SSI days for Puerto Rico hospitals in the Factor 3 calculation. Regarding the comment recommending that we use inpatient days for Medicare beneficiaries receiving Medicaid as this proxy, we have examined this concept and have been unable to identify a systematic source for these data for Puerto Rico hospitals. Specifically, we note that inpatient utilization for Medicare beneficiaries entitled to Medicaid is not reported by hospitals on the Medicare cost report, either within or outside Puerto Rico. We may further address issues related to estimating the amount of uncompensated care for hospitals in Puerto Rico in future rulemaking.

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with the FY 2017 IPPS/LTCH PPS proposed rule, we published on the CMS Web site a table listing Factor 3 for all hospitals that we estimate would receive empirically justified Medicare DSH payments in FY 2017 (that is, hospitals that we projected would receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a Medicare DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. This table also contained a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. Hospitals had 60 days from the date of public display of the FY 2017 IPPS/LTCH PPS proposed rule to review this table and notify CMS in writing of any inaccuracies. Comments could be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov.* We have addressed these comments as appropriate in the table that we are publishing on the CMS Web site in conjunction with the publication of this FY 2017 IPPS/LTCH final rule. Hospitals will have until August 31, 2016, to review and submit comments on the accuracy of the table. Comments can be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov* through August 31, 2016, and any changes to Factor 3 will be posted on the CMS Web site prior to October 1, 2016.

Comment: Some commenters provided detailed information regarding specific merger situations involving their hospitals and requested that CMS consider these mergers in determining Factor 3 for FY 2016. One commenter expressed appreciation for the actions CMS took in the FY 2015 rulemaking to combine the low-income insured days of hospitals that merged, where the surviving hospital has accepted assignment of the provider agreement of the retired provider.

Response: We thank the commenters for their input. We have updated our list of mergers based on information submitted by the MACs as of June 2016. In addition, we have reviewed the commenters' submissions of mergers not previously identified in the proposed rule and have updated our list accordingly.

The statute also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for such hospital *for a period selected by the Secretary.* Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act *for such period.* In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50018), we finalized a policy of using the most recent available full year of Medicare cost report data for determining Medicaid days and the most recently available SSI ratios to calculate Factor 3. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49528), we held constant the cost reporting years used to determine Medicaid days in the calculation of Factor 3. That is, instead of calculating the numerator and the denominator of Factor 3 for hospitals based on the most recently available full year of Medicare cost report data with respect to a Federal fiscal year, we used data from the more recent of the cost report years (2012/2011) used to determine Medicaid days in FY 2015. We made this change in order to refine the balance between the recency and accuracy of the data used in the Factor 3 calculation. Because we make prospective determinations of the uncompensated care payment without reconciliation, we believed this change would increase the accuracy of the data used to determine Factor 3, and accordingly each eligible hospital's allocation of the overall uncompensated care amount by providing hospitals with more time to submit these data before they are used in the computation of Factor 3. As in prior years, if the more recent of the two cost reporting periods did not reflect data for a 12-month

period, we used data from the earlier of the two periods so long as that earlier period reflected data for a period of 12 months. If neither of the two periods reflected 12 months, we used the period that reflected a longer amount of time. We also finalized a proposal to continue to extract Medicaid days from the most recent HCRIS database update and to use Medicare SSI days from the most recent SSI ratios available to us during the time of rulemaking to calculate Factor 3. In the FY 2016 IPPS/LTCH PPS final rule, we stated that, for subsequent fiscal years, if we propose and finalize a policy of using insured low-income days in computing Factor 3, we would continue to use the most recent HCRIS database extract at the time of the annual rulemaking cycle, and to use the subsequent year of cost reports (that is, to advance the 12-month cost reports by 1 year). In addition, we stated that for any subsequent fiscal years in which we finalize a policy to use insured low-income days to compute Factor 3, our intention would be to continue to use the most recently available SSI ratio data at the time of annual rulemaking to calculate Factor 3. We believed that it was appropriate to state our intentions regarding the specific data we would use in the event Factor 3 was determined on the basis of low-income insured days for subsequent years to provide hospitals with as much guidance as possible so they may best consider how and when to submit cost report information in the future. We noted that we would make proposals with regard to our methodology for calculating Factor 3 for subsequent fiscal years through notice-and-comment rulemaking.

Since the publication of the FY 2016 IPPS/LTCH PPS final rule, we have learned that some members of the hospital community have been disadvantaged by our policy of using only one cost reporting period to determine their share of uncompensated care. Specifically, many hospitals have reported unpredictable swings and anomalies in their low-income insured days between cost reporting periods. These hospitals expressed concern that the use of only one cost reporting period is a poor predictor of their future uncompensated care burden and results in inadequate payments. We stated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25089) that, because the data used to make uncompensated care payment determinations are not subject to reconciliation after the end of the fiscal year, we believe that it would be appropriate to expand the time period for the data used to calculate Factor 3 from one cost reporting period to three cost reporting periods. We stated that using data from more than one cost reporting period would mitigate undue fluctuations in the amount of uncompensated care payments to hospitals from year to year and smooth over anomalies between cost reporting periods. Moreover, we believed this policy would have the benefit of supplementing the data of hospitals that filed cost reports that are less than 12 months, such that the basis of their uncompensated care payments and those of hospitals that filed full-year 12-month cost reports would be more equitable. We stated that we believe that computing Factor 3 using data from three cost reporting periods would best stabilize hospitals' uncompensated care payments while maintaining the recency of the data used in the Factor 3 calculation. We indicated that we believe using data from two cost reporting periods would not be as stable while using data from more than three cost reporting periods could result in using overly dated information.

Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25089), we proposed to use an average of data derived from three cost reporting periods instead of one cost reporting period to compute Factor 3 for FY 2017. That is, we would calculate a Factor 3 for each of the three cost reporting periods and calculate the average. We would calculate the average by adding these amounts together, and dividing the sum by three, in order to calculate Factor 3 for FY 2017. Consistent with the policy adopted in the FY 2016 IPPS/LTCH PPS final rule, we proposed to advance the most recent cost report years used to obtain Medicaid days and Medicare SSI days in FY 2017 by one year and to continue to extract Medicaid days data from the most recent update of HCRIS. We note that, in the FY 2017 IPPS/LTCH PPS proposed rule, we inadvertently stated that the most recent update of HCRIS would be the March 2015 update of HCRIS. We clarify here that the most recently available data for purposes of determining Factor 3 for FY 2017 is from the March 2016 update of HCRIS. If the hospital does not have data for one or more of the three cost reporting periods, we proposed to compute Factor 3 for the periods available and average those. In other words, we would divide the sum of the individual Factor 3s by the number of cost reporting periods for which there are data. If two hospitals have merged, we would combine data from both hospitals for the cost reporting periods in which the merger is not reflected in the surviving hospital's cost report data to compute Factor 3 for the surviving hospital. Moreover, to further reduce undue fluctuations in a hospital's uncompensated care payments, if a hospital filed multiple cost reports beginning in the same fiscal year, we proposed to combine data from the multiple cost reports so that a hospital may have a Factor 3 calculated using more than one cost report within a cost reporting period. We invited public comments on this proposal, which we describe more fully below.

For the FY 2016 IPPS/LTCH PPS final rule, we used the most recent of hospitals' 12-month 2012 or 2011 cost reports and 2012 cost report data submitted to CMS by IHS hospitals to obtain the Medicaid days to calculate Factor 3. In addition, we used Medicare SSI days from the FY 2013 SSI ratios published on the following CMS Web site to calculate Factor 3: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*.

Under our proposal to calculate Factor 3 for FY 2017 using data from three cost reporting periods, we proposed to use data from hospitals' FY 2011, FY 2012, and FY 2013 cost reporting periods extracted from the most recent update of the hospital cost report data in the HCRIS database and the FY 2011 and FY 2012 cost report data submitted to CMS by IHS hospitals to obtain the Medicaid days to calculate Factor 3. (We note that, starting with the FY 2013 cost reports, data for IHS hospitals will be included in the HCRIS database and will no longer be submitted separately.) In addition, to calculate Factor 3 for FY 2017, we anticipated that, under our proposal discussed earlier to use the most recent available 3 years of data on Medicare SSI utilization, we would obtain Medicare SSI days from the FY 2012, FY 2013, and FY 2014 SSI ratios (or, for Puerto Rico hospitals, substitute Medicare SSI days with a proxy as described earlier). We indicated that we expected the FY 2014 SSI ratios to be published on the CMS Web site when available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*. Under this proposal, we would calculate Factor 3 as follows:

Step 1: Calculate Factor 3 for FY 2011 by summing a hospital's FY 2011 Medicaid days and FY 2012 SSI days and dividing by all DSH eligible hospitals' FY 2011 Medicaid days and FY 2012 SSI days.

Step 2: Calculate Factor 3 for FY 2012 by summing a hospital's FY 2012 Medicaid days and FY 2013 SSI days

and dividing by all DSH eligible hospitals' FY 2012 Medicaid days and FY 2013 SSI days.

Step 3: Calculate Factor 3 for FY 2013 by summing a hospital's FY 2013 Medicaid days and FY 2014 SSI days and dividing by all DSH eligible hospitals' FY 2013 Medicaid days and FY 2014 SSI days.

Step 4: Sum the Factor 3 calculated for FY 2011, FY 2012, and FY 2013 and divide by the number of cost reporting periods with data to compute an average Factor 3.

For illustration purposes, in Table 18 associated with the FY 2017 IPPS/LTCH PPS proposed rule (which is available via the Internet on the CMS Web site), we computed Factor 3 using hospitals' FY 2011, FY 2012, and FY 2013 cost reports from the December 2015 update of HCRIS to obtain Medicaid days and the FY 2012 and FY 2013 SSI ratios published on the following CMS Web site to determine Medicare SSI days: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*. As discussed in the proposed rule (81 FR 25089), the FY 2014 SSI ratios were not available in time to be used in the proposed rule. Therefore, for the proposed rule, we computed Factor 3 for FY 2013 using FY 2013 Medicaid days and FY 2013 SSI days. However, we noted that we expected the FY 2014 SSI ratios to be available to calculate Factor 3 for the FY 2017 IPPS/LTCH PPS final rule.

For subsequent years, we proposed to continue to use the most recent HCRIS database extract at the time of the annual rulemaking cycle and to advance the three cost reporting periods used to determine Factor 3 by 1 year as appropriate. For instance, if we were to finalize a proposal to continue using the proxy in FY 2018, we would use FY 2012, FY 2013, and FY 2014 cost reports from the most recent available extract of HCRIS for Medicaid days and FY 2013, FY 2014, and FY 2015 SSI ratios to obtain the Medicare SSI days and follow the same methodology outlined earlier to determine Factor 3. However, we also stated that we believed that it would be possible to begin incorporating data from Worksheet S–10 into the computation of Factor 3 starting in FY 2018 and outlined a proposal for doing so using data from three cost reporting periods in section IV.F.4.d. of the preamble of the proposed rule.

Comment: Many commenters supported the proposal to expand the time period for the data used to calculate hospitals' Medicaid and Medicare Supplemental Security Income (SSI) inpatient days from one year to three years, and specifically to use an average of data derived from three cost reporting periods instead of one cost reporting period to compute Factor 3 for FY 2017. The commenters believed that using 3 years of data would provide assurance that hospitals' uncompensated care payments remain stable and predictable, and would not be subject to unpredictable swings and anomalies in a hospital's low-income insured days.

Response: We thank the commenters for their input. We appreciate the commenters' support for the use of a 3-year blend in the low-income insured days proxy methodology.

Comment: Several commenters expressed concern about the method CMS has proposed to attribute data to each year when performing the calculation of Factor 3 in the three-year proxy model for FY 2017. Commenters noted that the proposed methodology could pose a problem for some hospitals that file multiple cost reports in a single fiscal year. One commenter stated, for example, that a hospital might file a 6-month cost report and an 18-month cost report as the result of a merger midway through the cost reporting period. The commenter noted that this keeps the data separate for the individual and merged facilities but also enables them to preserve the surviving hospital's cost-reporting period in the future. The commenter believed that, in such an instance, the proposed methodology would attribute 2 years of data to a single year and no data to the following year. Thus, the commenter asserted that, under the 3-year average methodology, the hospital's data would be overstated because 3 years of data would be used to calculate two Factor 3s that would then be averaged together to determine the final Factor 3. Conversely, the commenter noted that if a hospital has only a short cost reporting period beginning in a year, the hospital could be disadvantaged by the calculation. This commenter asked CMS to modify its proposal to appropriately attribute portions of the cost reporting period to the period for which it is calculating a Factor 3.

Another commenter opposed the use of multiple cost reporting periods if it would result in a hospital having more than 12 months of data in the Factor 3 calculation for a year, and recommended that CMS prorate the data down to a 12-month period. Similarly, commenters recommended that CMS annualize cost report data for any cost reporting period that is less than 12 months that began during the fiscal year from which the data is taken. One commenter suggested that if a hospital has two cost reporting periods that began during the same fiscal year and one of those cost reporting periods is a 12-month cost reporting period, only the 12-month cost reporting period should be utilized.

One commenter questioned whether the rules pertaining to ''New Hospitals'' adopted in previous rules apply to FY 2017. This commenter asked specifically whether new hospitals will be paid through an alternative methodology if full 12-month cost reports are not available for one or more of the three cost reporting periods used to calculate Factor 3. The commenter believed that using a partial cost reporting period under this averaging methodology will harm new facilities, and suggested that for new hospitals a partial cost reporting year should be removed from the calculation. The commenter stated that this methodology would be the most consistent with the payment it has received through the Medicare Cost Report filing calculations related to ''New Hospitals'' in the past.

Response: We appreciate the commenters raising these data concerns and areas of needed clarification. We are finalizing our proposal to calculate Factor 3 for FY 2017 using the average of data from three cost reporting periods. To further reduce undue fluctuations in a hospital's uncompensated care payments, if a hospital filed multiple cost reports beginning in the same fiscal year, we also are finalizing our proposal to combine data from the multiple cost reports so that a hospital may have a Factor 3 calculated using more than one cost report within a cost reporting period. We are clarifying that if the hospital does not have data for one or more of the three cost reporting periods, we will compute Factor 3 for the periods available and average those. In other words, we will divide the sum of the individual Factor 3s by the number of cost reporting periods for which there are data. For new hospitals that do not have data for any of the three cost reporting periods used in the proposed Factor 3 calculation, we will apply the new hospital policy finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50643). That is, the hospital will not receive either interim empirically justified Medicare DSH payments or interim uncompensated care payments; however, if it is later determined to be eligible to receive empirically justified Medicare DSH payments based on its FY 2017 cost report, the hospital will also receive an uncompensated care payment calculated using a Factor 3, where the numerator is the sum of Medicaid days and Medicare SSI days

reported on the hospital's FY 2017 cost report. We did not make a proposal to annualize cost reports to calculate Factor 3 in the FY 2017 IPPS/LTCH PPS proposed rule. We note that section 1886(r)(2)(c) of the Act specifies that Factor 3 is equal to the percent that represents the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data) divided by the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under this subsection for such period (as so estimated). In implementing this provision, we believe it is appropriate to first select the period—in this case, 3 separate years of data—and then to utilize data from all cost reports that align with these periods. However, we acknowledge that the situations presented by commenters, including both long and short cost reporting periods, pose unique challenges in the context of estimating Factor 3. As a result, this is an issue that we intend to consider further and may address in future rulemaking.

Comment: One commenter expressed concern about our policy of distributing uncompensated care payments as a per-discharge add-on. The commenter believed this policy is problematic because the per-discharge add-on varies widely from hospital to hospital. The commenter noted that the variability of the add-on payments in turn distorts the MS–DRG prices and creates problematic incentives for MA plans. Therefore, the commenter believed that it would be better to make a uniform interim add-on payment to all DSH hospitals in a county, and any underpayments or overpayments to an individual hospital could be corrected at year-end settlement or on an interim basis during the year (as is already necessary under the current system). Alternatively, the commenter suggested that DSH payments be distributed to hospitals on a periodic basis for their FFS and MA patients.

Response: We consider this comment to be outside the scope of the proposed rule, as we did not propose any revision in our method of making interim payments for uncompensated care. However, we would like to make two observations in response to this recommendation. The first observation is that we have received very few comments from the hospital industry indicating that the problem cited by this commenter actually exists. We would expect that, if hospitals were truly disadvantaged in the manner cited by these commenters by our methodology for making interim payment uncompensated care payments, we would have received many more comments to that effect. The second observation is that adopting the recommendation may pose, for some hospitals, serious problems that may conceivably exceed the problem that the recommendation is designed to solve. For example, reducing the interim uncompensated care payments to high DSH hospitals to a countywide average payment might cause serious cash flow problems during the period before the interim payments could be adjusted or settled. Similarly, low DSH hospitals might receive significantly higher interim payments than would be warranted by their actual uncompensated care data. As a result, these hospitals would have to take financial management steps to ensure that they are capable of making significant repayments when interim payments are adjusted or settled.

Comment: One commenter stated that some of the participants in the *Allina* litigation have been advised to include beneficiaries that are enrolled in Medicare Part C and eligible for Medicaid on their cost report as Medicaid days. However, the commenter noted that, rather than reporting dually eligible MA days as Medicaid days in their cost report, some providers are protesting these days and are not including them when they file their filed cost reports. The commenter believed that those providers who are protesting these days rather than including them as Medicaid days are being harmed compared to the providers that include them. The commenter requested that CMS clarify its policy and adjust the days that are reported on Worksheet S–2 as necessary for use in uncompensated care payment calculations. The commenter asserted that hospitals are not being fairly paid for uncompensated care because some providers are including dually eligible MA days in their Medicare cost report.

Response: If hospitals are inappropriately reporting dually eligible MA claims in the cost report as Medicaid days, the commenter is correct that, absent review and/or adjustment by the MAC, it would result in Factor 3 overstating the amount of uncompensated care provided by those hospitals relative to other hospitals. We reiterate our policy that MA beneficiaries who are also eligible for Medicaid are patients entitled to Medicare Part A. Accordingly, their patient days are included in the Medicare SSI ratio and therefore should not be reported in the cost report as Medicaid days. Hospitals that exclude the MA days of patients who are also eligible for Medicaid from Worksheet S–2 are reporting these days appropriately.

After consideration of the public comments we received, we continue to believe that using low-income insured days as a proxy for uncompensated care costs provides a reasonable basis to determine Factor 3 for FY 2017, as we work to improve Worksheet S–10 to accurately and consistently capture uncompensated care costs. Accordingly, in this final rule, we are finalizing for FY 2017 the policy that we originally adopted in the FY 2014 IPPS/LTCH PPS final rule, of employing the utilization of insured low-income patients, defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in § 412.106(b)(4) and § 412.106(b)(2)(i), respectively, to determine Factor 3 for FY 2017. We also are finalizing our proposal to use 14 percent of Medicaid days as a proxy for SSI days for Puerto Rico hospitals when determining Factor 3 for FY 2017; our proposal to continue the policies concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers; our proposal to expand the time period of the data used to determine Factor 3 from one cost reporting period to three cost reporting periods as well as the accompanying methodology; and our proposal to combine cost reports for hospitals with more than one cost report within a cost reporting period. We are codifying these changes for FY 2017 by amending the regulation at § 412.106(g)(1)(iii)(C).

d. Calculation of Factor 3 for FY 2018 and Subsequent Years

(1) Background

In response to commenters' requests for a timeline and transition for introducing Worksheet S–10 data into the calculation of Factor 3 (for example, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49524)), in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25089 through 25094), we discussed our proposed plans for how to begin incorporating hospitals' Worksheet S–10 data into the calculation of Factor 3, in order to allocate payments based on a hospital's share of overall uncompensated care costs reported on Worksheet S–10. When we first discussed using Worksheet S–10 to allocate hospitals' shares of uncompensated care costs in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we explained why we believed that it was premature to use uncompensated care costs reported on Worksheet S–10 for FY 2014. Specifically, at that time, the most recent available cost reports would have

been from FYs 2010 and 2011, which were submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. We believed that ''[c]oncerns about the standardization and completeness of the Worksheet S–10 data could be more acute for data collected in the first year of the Worksheet's use'' (78 FR 50635). In addition, we believed that it would be most appropriate to use data elements that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes) to determine the amount of uncompensated care for purposes of Factor 3 (78 FR 50635). At the time we issued the FY 2014 IPPS/LTCH PPS final rule, we did not believe that the available data regarding uncompensated care from Worksheet S–10 met these criteria and, therefore, we believed they were not reliable enough to use for determining FY 2014 uncompensated care payments. Accordingly, for FY 2014, we concluded that utilization of insured low-income patients would be a better proxy for the costs of hospitals in treating the uninsured. For FYs 2015, 2016, and 2017, the cost reports used for calculating uncompensated care payments (that is, FYs 2011, 2012, and 2013) were also submitted prior to the time that hospitals were on notice that Worksheet S–10 could be the data source for calculating uncompensated care payments. Therefore, we believe it is also appropriate to use proxy data to calculate Factor 3 for these years.

We stated in the proposed rule that we believe that, for FY 2018, many of these concerns would no longer be relevant. That is, as described more fully below regarding the use of Worksheet S–10 from FY 2014, hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Hospitals' cost reports from FY 2014 have been publically available for some time now. Furthermore, MedPAC has provided analyses that found that current Worksheet S–10 data are a better proxy for predicting audited uncompensated care costs than Medicaid/Medicare SSI days. Specifically, MedPAC submitted a public comment discussed in the FY 2016 IPPS/LTCH PPS final rule that cited its 2007 analysis of data from the Government Accountability Office (GAO) and data from the American Hospital Association (AHA), which suggests that Medicaid days and low-income Medicare days are not a good proxy for uncompensated care costs (80 FR 49525). Analysis performed by MedPAC showed that the correlation between audited uncompensated care data from 2009 and the data from the FY 2011 Worksheet S–10 was over 0.80, as compared to a correlation of approximately 0.50 for 2011 Medicare SSI and Medicaid days. MedPAC concluded that use of Worksheet S–10 data was already better than using Medicare SSI and Medicaid days as a proxy for uncompensated care costs, and that the data on Worksheet S–10 would improve over time as the data are actually used to make payments.

As we discussed in the FY 2017 IPPS/LTCH PPS proposed rule, we also have undertaken an extensive analysis of the Worksheet S–10 data, benchmarking it against the data on uncompensated care costs reported to the Internal Revenue Service (IRS) on Form 990 by not-for-profit hospitals. The purpose of this analysis, performed by Dobson DaVanzo & Associates, LLC, under contract to CMS, was to determine if Worksheet S–10 uncompensated care data are becoming more stable over time. (This analysis, included in a report entitled ''Improvements to Medicare Disproportionate Share Hospital (DSH) Payments Report: Benchmarking S–10 Data Using IRS Form 990 Data and Worksheet S–10 Trend Analyses,'' is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html* under the Downloads section.) Although we acknowledge that the analysis was limited to not-for-profit hospitals, we believe it is relevant to our assessment of the overall quality of the data reported on Worksheet S–10. Because many not-for-profit hospitals are eligible for empirically justified Medicare DSH payments and, therefore, uncompensated care payments, they represent a suitable standard of comparison. We conducted an analysis of 2010, 2011, and 2012 Worksheet S–10 data and IRS Form 990 data from the same years. Using IRS Form 990 data for tax years 2010, 2011, and 2012 (the latest available years) as a benchmark, we compared key variables derived from Worksheet S–10 and IRS Form 990 data, such as charity care and bad debt. The analysis was completed using data from hospitals that had completed both Worksheet S–10 and IRS Form 990 across all study years, yielding a sample of 788 not-for-profit hospitals (representing 668 unique Taxpayer Identification Numbers). Because Factor 3 is used to determine the Medicare uncompensated care payment amount for each hospital, we calculated the amounts for Factor 3 for the matched hospitals using charity care and bad debt, and compared the Factor 3 distributions calculated using data from IRS Form 990 and Worksheet S–10. Key findings indicate that the amounts for Factor 3 derived using the IRS Form 990 and Worksheet S–10 data are highly correlated. In addition, the correlation coefficient between the amounts for Factor 3 calculated from the IRS Form 990 and Worksheet S–10 has increased over time, from 0.71 in 2010 to 0.80 in 2012, suggesting some convergence in the data sources over time. In the proposed rule, we stated that this strong correlation indicates that Worksheet S–10 data would be a statistically valid source to use as part of the calculation of the uncompensated care payments in FY 2018.

Accordingly, because hospitals have been on notice since the FY 2014 rulemaking that CMS intended eventually to use Worksheet S–10 as the data source for calculating uncompensated care payments, and in light of growing evidence that Worksheet S–10 data are improving over time, at the time of development of the proposed rule, we believed it would be appropriate to use Worksheet S–10 as a data source for determining Factor 3 starting in FY 2018. We discuss below our proposed methodology for how we would begin to incorporate Worksheet S–10 data into the calculation of Factor 3 of the uncompensated care payment methodology.

(2) Data Source and Time Period for FY 2018 and Subsequent Years, Including Methodology for Incorporating Worksheet S–10 Data

For the reasons explained in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR25090), we believed that it would be appropriate to begin to incorporate Worksheet S–10 data into the computation of Factor 3 and the allocation of uncompensated care payments, starting with Worksheet S–10 data reported for FY 2014. Below is a description of the proposal set forth in the proposed rule. Specifically, we proposed to continue to use low-income insured patient days as a proxy for uncompensated care for cost reporting periods before FY 2014 and to use Worksheet S–10 data for FY 2014 and subsequent fiscal years to calculate uncompensated care payments for FY 2018 and subsequent fiscal years, which, when combined with our proposal to use data from three cost reporting periods to calculate Factor 3 starting in FY 2017, would have the effect of transitioning toward exclusive

use of Worksheet S–10 data. Under this proposed approach, we would use only Worksheet S–10 data to calculate Factor 3 for FY 2020 and subsequent fiscal years.

As discussed previously, for FY 2017, we proposed and are finalizing a policy of calculating a hospital's share of uncompensated care based on the proxy of its share of low-income insured days using a time period that includes three cost reports (that is, FY 2011, FY 2012, and FY 2013 cost reports). For the reasons we described earlier, we believe it would not be appropriate to use Worksheet S–10 data for periods prior to FY 2014. For cost reporting periods prior to FY 2014, we believe it is appropriate to continue to use low-income insured days for the reasons we have previously described. Accordingly, to determine Factor 3 for FY 2018, with a time period that includes three cost reporting periods consisting of FY 2014 and two preceding periods, we proposed to use Worksheet S–10 data for the FY 2014 cost reporting period and the low-income insured days proxy data for the two earlier cost reporting periods, drawing three sets of data from the most recently available HCRIS extract. That is, for FY 2018, to compute Factor 3, we proposed to continue to advance the 3-year time period we are using by 1 year and therefore to use FY 2012, FY 2013, and FY 2014 cost report data from the most recent update of HCRIS. In addition, for FY 2018, we proposed to use Medicaid days from FY 2012 and FY 2013 cost reports and FY 2014 and FY 2015 SSI ratios. We stated our belief that this approach would have a transitioning effect of incorporating data from Worksheet S–10 into the calculation of Factor 3 starting in FY 2018.

Consistent with our proposal to determine Factor 3 using data over a period of 3 cost reporting periods, we proposed to calculate a Factor 3 for each of the three cost reporting periods. Specifically, we proposed to calculate Factor 3 for FY 2018 based on an average of Factor 3 calculated using low-income insured days (proxy data) determined using Medicaid days from FY 2012 and FY 2013 cost reports and FY 2014 and FY 2015 SSI ratios, and Factor 3 calculated using uncompensated care data based on FY 2014 Worksheet S–10. We proposed to compute this average for each hospital by—

- Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2012 cost report data and the FY 2014 SSI ratio;
- Step 2: Calculating Factor 3 using the insured low-income days proxy based on FY 2013 cost report data and the FY 2015 SSI ratio;
- Step 3: Calculating Factor 3 based on the FY 2014 Worksheet S–10 data; and
- Step 4: Averaging the Factor 3 values that are computed in Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2012, FY 2013, and FY 2014 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3.

The denominator would be the sum of the averages of the FY 2012, FY 2013, and FY 2014 amounts from Step 4 for each hospital that is estimated to be eligible for Medicare DSH payments in FY 2018. For example, assuming there are only three hospitals in the IPPS and Hospitals A and B are estimated to be eligible for Medicare DSH payments in FY 2018, while Hospital C is estimated as ineligible for Medicare DSH payments in FY 2018, each hospital's proposed share of the overall amount available for uncompensated care payments would be calculated as follows:

[(Hospital A FY 2012 Factor 3 proxy) + (Hospital A FY 2013 Factor 3 proxy) + (Hospital A FY 2014 Factor 3 S–10)]/3 = X

[(Hospital B FY 2012 Factor 3 proxy) + (Hospital B FY 2013 Factor 3 proxy) + (Hospital B FY 2014 Factor 3 S–10)]/3 = Y

[(Hospital C FY 2012 Factor 3 proxy) + (Hospital C FY 2013 Factor 3 proxy) + (Hospital C FY 2014 Factor 3 S–10)]/3 = Z

Hospital A's Factor 3 or proposed share of the overall uncompensated care amount in FY 2018 would be equal to (X)/(X+Y).

Hospital B's Factor 3 or proposed share of the overall uncompensated care amount in FY 2018 would be equal to (Y)/(X+Y).

Hospital C's Factor 3 or proposed share of the overall uncompensated care amount in FY 2018 would be equal to (Z)/(X+Y).

We noted that, under this proposal, the methodology for calculating Factor 3 for each subsequent year would remain unchanged (such as using all cost reports for eligible hospitals that begin during the relevant cost reporting years, including cost reporting periods that are not 12 months in length, and using a proxy for Medicare SSI days for hospitals in Puerto Rico, as described earlier for the calculation of Factor 3 for FY 2017). With regard to FY 2019 and subsequent years, we stated our belief that it would continue to be appropriate to advance the 3-year time period used to compute Factor 3 by one year. Accordingly, we proposed to use FY 2013, FY 2014, and FY 2015 cost report data from the most recent available update of HCRIS to compute Factor 3 and allocate uncompensated care payments for FY 2019. As we stated earlier, with regard to the data used to compute Factor 3, we believed that it would be appropriate to use Worksheet S–10 data from FY 2014 and subsequent periods to calculate Factor 3 and hospitals' uncompensated care payments for FY 2018 and subsequent fiscal years. Because we proposed to use FY 2013, FY 2014, and FY 2015 cost reports to determine Factor 3 for FY 2019, we proposed to calculate Factor 3 with a proxy calculated based on FY 2013 cost report data and FY 2015 SSI ratios and based on Worksheet S–10 uncompensated care costs from FY 2014 and FY 2015 cost reports. We proposed to calculate Factor 3 for FY 2019 based on an average of Factor 3 amounts calculated using data from the three cost reporting periods in the manner described earlier for FY 2018. For FY 2020, we proposed to continue to advance the three cost reports used by 1 year, and we proposed to calculate Factor 3 using only data from the Worksheet S–10, from cost reports from FY 2014, FY 2015, and FY 2016. For FY 2021 and subsequent fiscal years, we proposed to continue to base our estimates of the amount of hospital uncompensated care on uncompensated care costs, using three cost reporting periods from the most recently available HCRIS database, and in each fiscal year, the cost reporting periods would be advanced forward by 1 year (for example, for FY 2021, FY 2015, FY 2016, and FY 2017 cost reports would be used). We solicited comments on the proposed data sources, time periods, and method for calculating uncompensated care costs in FY 2018 and subsequent years.

Although we proposed to calculate Factor 3 for FY 2018 based on an average of the Factor 3 amounts calculated using 2 years of proxy data and 1 year of data from the FY 2014 Worksheet S–10, we stated that readers might find it useful to review a file posted on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html* under the Downloads section, which shows preliminary uncompensated care costs calculated by hospital using only Worksheet S–10 data from FY 2014 cost reports extracted from the December 2015 update of HCRIS. To the extent that hospitals had either not submitted

a Worksheet S–10 with their FY 2014 cost report or found errors on a submitted Worksheet S–10, we encouraged hospitals to work with MACs to complete and revise, as appropriate, their FY 2014 Worksheet S–10 as soon as possible.

Comment: A few commenters supported CMS' proposal to transition to the use of Worksheet S–10 to derive uncompensated care costs for the calculation of Factor 3. MedPAC stated that using Worksheet S–10 data, in conjunction with select auditing of cost reports of hospitals reporting the highest levels of uncompensated care, would lead to better estimates of uncompensated care costs than the continued use of the current proxy of Medicaid and SSI days. Several commenters including MedPAC supported using Worksheet S–10 beginning in FY 2018 with a 3-year phase in. Other commenters recommended accelerating the timeline for implementation of Worksheet S–10, for example, beginning the transition in FY 2017 or shortening the phase in period. These commenters noted that the metrics from Worksheet S–10 appear to provide a better assessment of a hospital's uncompensated care costs than the current metrics used, which assess low-income insured days.

Response: We appreciate the support for our proposal to begin to incorporate Worksheet S–10 data into the computation of Factor 3 for FY 2018. However, as explained in more detail in response to comments below, after considering the overwhelming amount of comments urging additional delay in implementation of Worksheet S–10 data, we are not finalizing our proposal to begin to incorporate Worksheet S–10 data into the computation of Factor 3 for FY 2018. Instead, we believe it is important that we have the opportunity to consider further the concerns raised by commenters regarding the use of Worksheet S–10 data to determine Factor 3. We expect to re-propose a policy of incorporating Worksheet S–10 data into the computation of Factor 3 no later than FY 2021, as explained further below.

Comment: Many commenters opposed the use of Worksheet S–10 to compute Factor 3 and allocate uncompensated care costs beginning in FY 2018. Commenters believed that the form does not measure the amount of uncompensated care that section 3133 of the Affordable Care Act is designed to compensate. These commenters stated that in their view, data from Worksheet S–10 are not presently a reliable and accurate reflection of uncompensated care costs. Many commenters expressed concern about the lack of accurate and consistent data being reported on Worksheet S–10, primarily due to what they perceive as a lack of clear and concise line level instructions. Commenters stated that significant modifications should be made to Worksheet S–10 and the corresponding instructions as to how to report information for each line to clarify the intent.

Commenters also called for audits of Worksheet S–10 and audit guidelines for charity care and bad debt. These commenters supported the transition through a phase-in approach once CMS ensures the accuracy and consistency of the data from Worksheet S–10. One commenter noted that CMS may wish to monitor changes in hospital-specific data from Worksheet S–10 from year to year to determine if further guidance is needed regarding how to accurately complete the form and monitor Worksheet S–10 data for accuracy.

Many commenters cited the report from Dobson DaVanzo, ''Improvements to Medicare Disproportionate Share Hospital (DSH) Payments Report: Benchmarking S–10 Data Using IRS Form 990 Data and Worksheet S–10 Trend Analyses,'' which concluded that hospitals are doing a better job of reporting their uncompensated care data on Worksheet S–10 than they did a few years ago. However, these commenters disagreed with CMS about the significance of this observation. One commenter stated that even if it is true in the aggregate that hospitals are reporting data more accurately on Worksheet S–10, the zero-sum nature of the calculation of uncompensated care payments is such that the remaining inaccuracy and lack of uniformity in the data reported can have a very large impact on hospitals. The commenter asserted that if hospitals, for whatever reason, over-report their uncompensated care, they benefit financially from doing so, while those that do not aggressively report suffer financial harm. The commenter concluded that, for this reason, the possibility that some hospitals are generally ''doing better'' with reporting data is not good enough. All hospitals must do better, and until they do, the commenter believed that data from Worksheet S–10 are not accurate enough for public policymaking purposes. Other commenters asserted that the Dobson/DaVanzo study does not illustrate or even evaluate whether data from Worksheet S–10 are a reasonable proxy for the costs hospitals incur in providing care to the uninsured. These commenters pointed out that their own analyses indicate that the most notable aberrations in Worksheet S–10 data reporting occur among public hospitals, which do not file a Form 990 and are therefore missing from the Dobson/DaVanzo analysis.

Many commenters shared observations regarding concerns and anomalies they identified in data from Worksheet S–10. A number of commenters shared their own analyses that looked at the small proportion of hospitals receiving a large share of uncompensated care payments, and the proportion of hospitals that reported aberrant data relating to uncompensated care costs. Along those lines, some commenters noted that the current Worksheet S–10 can result in negative uncompensated care values for some hospitals.

One commenter noted that it has been monitoring how hospitals have been reporting data from Worksheet S–10 for the last 5 years and has concluded that there is no single, uniform manner in which hospitals report their uncompensated care. The commenter stated that the aberrant numbers reported by some hospitals illustrate some combination of misinterpretation of Worksheet S–10 instructions, the lack of clarity of those instructions, and the possible attempts from providers to maximize their Medicare DSH dollars.

Because many commenters were concerned that unclear reporting instructions on Worksheet S–10 would result in inconsistent and inaccurate reporting of data, commenters overwhelmingly requested that, after more precise instructions are provided, CMS apply a strict auditing process for information reported on the Worksheet S–10 before it is used to determine uncompensated care costs. They believed that simply tying information reported on Worksheet S–10 to payment and requiring its regular use will not improve the accuracy of the data. Other commenters indicated that if CMS finalizes a FY 2018 start date, audits with the existing instructions and interpretation would need to commence immediately. In addition, commenters requested that CMS ensure that its contractors administer an auditing process consistently and make the instructions for such an audit public. Some commenters requested that instructions be provided to MACs on how to update hospitals' 2014 Worksheet S–10 data, and that CMS provide guidance and documentation to MACs clarifying that CMS expects MACs to accept amended and/or corrected cost reports. They suggested that CMS look to the process used to audit and review the data used for the Medicare wage index annually.

Specifically, the commenters requested that CMS develop timetables for the cut-off of submissions or changes to the data; validate reporting against hospital policies; create a separate audit protocol for all-inclusive rate providers (AIRPs) in order to ensure uncompensated care costs are adequately captured; address the appropriateness of reporting variability from year to year; and that MACs be engaged to audit these data to ensure validity. A commenter also suggested that CMS institute a fatal edit in the cost report audit process for negative or zero uncompensated care costs, or consider including Level 1 cost report edit checks in the cost report software to flag unusual and missing data. Similarly, commenters requested that CMS provide hospitals with FAQs and host educational events to ensure proper cost reporting, while also providing a means to appeal adjustments to the Worksheet S–10.

One commenter added that, currently, there are no published audit instructions for Medicare contractors to follow when reviewing non-Medicare charity care and non-Medicare bad debt. The commenter stated that it had undergone ''meaningful use audits'' in which the Medicare contractor disallowed charity care costs, and that, based on its experience, this commenter believed that an FY 2018 start date would not provide sufficient time for hospitals to improve their Worksheet S–10 reporting. In addition, commenters recommended that CMS perform an in-depth review of the FY 2014 data for a limited number of hospitals to identify key issues for a full review of FY 2015 and later data. The commenters believed that such a review should be performed by a single MAC for consistency and should include: hospitals with unusual data on Worksheet S–10, including CCRs and different charges as compared to Worksheet C; selective auditing of cost reports of hospitals reporting the highest levels of uncompensated care; and a random mix of other hospitals by type location, or other criteria as applicable.

Commenters requested that CMS implement a process for providing hospitals an opportunity to comment on proposed revisions to clarify the instructions for the completion of Worksheet S–10 to ensure that hospitals receive clear guidance on how to report uncompensated care costs. One commenter suggested that CMS institute a supplemental data collection because CMS chose to use a time period that already has passed as the Worksheet S–10 reporting period for the Factor 3 calculation for FY 2018.

Another commenter suggested that CMS change the instruction for line 22 of Worksheet S–10 from ''Enter payments received or expected for services delivered during this cost report period'' to ''Payments received during the period covered by the cost report.''

Response: In previous rulemaking cycles, commenters both in favor of and opposed to use of a proxy for calculation of Factor 3, requested that CMS provide a timeline and implementation process for when and how the Worksheet S–10 would be used for determining uncompensated care costs (for example, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49524)). In response to those requests, and based on what appeared to be growing evidence that Worksheet S–10 was improving over time, and based on the fact that hospitals were made aware as of FY 2014 that Worksheet S–10 could eventually become the data source for computing Factor 3, we proposed starting to incorporate Worksheet S–10 data from FY 2014 cost reports into the calculation of Factor 3 for FY 2018. Specifically, using a timeframe that includes three cost reports (that is, FY 2012, FY 2013, and FY 2014) to compute Factor 3 for FY 2018 based on a 3-year average, we proposed to use low-income insured patient days from FY 2012 and FY 2013 cost reports as a proxy for uncompensated care costs, and Worksheet S–10 data from the FY 2014 cost report. We stated that this averaging approach would have a transitioning effect by incorporating data from Worksheet S–10 into the calculation of Factor 3 starting in FY 2018 (81 FR 25091).

However, after reviewing and considering all comments, we believe it would be appropriate to institute certain additional quality control and data improvement measures prior to moving forward with incorporating Worksheet S–10 data into the calculation of Factor 3. Consequently, we are not finalizing our proposal to begin to incorporate Worksheet S–10 data into the computation of Factor 3 for FY 2018 at this time. Instead, our intent is to begin to incorporate Worksheet S–10 data into the computation of Factor 3 once these additional measures are in place, and no later than FY 2021. We believe additional time may be needed to make certain modifications and clarifications to the cost report instructions for Worksheet S–10, as well as explore suggestions made by the commenters for ensuring universal submission of Worksheet S–10 by hospitals when filing their cost reports (such as software edits to flag negative, unusual, or missing data or a missing worksheet S–10). As commenters recommended, we will consider issuance of FAQs and hosting of educational seminars for hospitals and MACs as appropriate, coinciding with the issuance of revised cost report instructions. We also intend to explore development of more specific instructions and more uniform review protocols for Worksheet S–10 data. We believe that postponing the final decision as to how and when to incorporate Worksheet S–10 data into the calculation of Factor 3 is necessary, given the significant concerns expressed by commenters regarding the Worksheet S–10 data. Substantive cost report changes may not realistically be implemented in time for FY 2018, as originally proposed. Furthermore, after we complete the substantive work to revise and issue cost report revisions and attending policy clarifications, we would prefer to provide sufficient time for hospitals to report data using the revised instructions and for the results of cost report changes and MAC reviews to be reflected in the data reported on Worksheet S–10. Under normal circumstances, commenters are aware that there is typically a 3- to 4-year lag between the ratesetting year and the cost report data that CMS is using to develop those rates. For example, to develop the FY 2017 wage index, we are using FY 2013 cost report data. Accordingly, there could be a 4-year lag before prospective changes to Worksheet S–10 would result in data that could be used to calculate Factor 3. That is, we would need time to draft and implement cost report revisions, hospitals would need time to file cost reports reflecting those new cost report revisions, and the MACs would need time to review those cost reports. While some cost report clarifications could apply retroactively, some revisions to Worksheet S–10 must apply prospectively to ensure consistent application to other policies impacted by Worksheet S–10, such as EHR or Medicare bad debt payments. Accordingly, we believe that cost reporting periods beginning during FY 2017 would be the first cost reports available that would reflect revised Worksheet S–10 data. Thus, we anticipate that the revised Worksheet S–10 data, as first reflected for cost reporting periods starting during FY 2017, would be available for use in determining uncompensated care costs no later than in FY 2021. We will consider further whether the current Worksheet S–10 data or a proxy should be used to calculate Factor 3 for years

between FY 2017 and FY 2021 in future rulemaking.

With regard to the commenters' request for additional information about the review process that we will instruct the MACs to institute, it may not be identical to the annual desk review process for the IPPS wage index that many commenters have recommended, but we intend to provide standardized instructions to the MACs to guide them in determining when and how often a hospital's Worksheet S–10 should be reviewed. Although it may be relatively simple to provide guidance to MACs to flag and review negative or missing data on the Worksheet S–10, we intend to give consideration to establishment of measures to identify ''aberrant'' data for further review, such as, but not necessarily limited to, hospitals with unusual data on Worksheet S–10, including different CCRs and charges as compared to Worksheet C. In addition, we will consider the commenters' recommendation that we instruct MACs to audit selectively the cost reports of hospitals reporting the highest levels of uncompensated care, as well as a random mix of other hospitals by type location or other criteria as appropriate. Accordingly, the instructions for the MACs for review of Worksheet S–10 will include not only general guidance for review, but also, where appropriate, special instructions for review of certain unique categories of hospitals, such as the All Inclusive Rate Providers (AIRPs), and other mostly government-owned hospitals with unique charity care or charging practices (CMS Pub 15–1, Section 2208.1 describes AIRPs as ''hospitals having an all-inclusive rate (one charge covering all services) or a no-charge structure,'' for whom the ''approved methods for apportioning allowable cost between Medicare and non-Medicare patients'' are not readily adaptable, and therefore, provides for ''alternative methods of apportionment'' for these facilities.). However, we will not make the MACs' review protocol public, as commenters have requested. All CMS desk review and audit protocols are confidential and are for CMS and MAC use only. We also refer readers to Change Request 9648, Transmittal 1681, titled ''The Supplemental Security Income (SSI)/ Medicare Beneficiary Data for Fiscal Year 2014 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCH),'' issued on July 15, 2016 (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2016-Transmittals-Items/R1681OTN.html*). In this transmittal, as a first step in the process of ensuring complete submission of Worksheet S–10 by all eligible DSH hospitals, we instruct MACs to accept amended Worksheets S–10 of FY 2014 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none have been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal states that, for revisions to be considered, hospitals must submit their amended FY 2014 cost report containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than September 30, 2016.

The issuance of these special instructions in CR 9648 is one of multiple steps we intend to take over the next several years to ensure more accurate and uniform reporting of uncompensated care costs on Worksheet S–10. As a result of taking these steps and instituting Worksheet S–10 modifications, clarifications, and MAC reviews, we believe that revised Worksheet S–10 data will be available for use in the calculation of Factor 3 in the near future, and no later than FY 2021. With regard to how Factor 3 will be computed in FY 2018 and subsequent years, we intend to explore whether there is an appropriate proxy for uncompensated care that could be used to calculate Factor 3 until we determine that data from the revised Worksheet S–10 can be used for this purpose. We will undertake notice-and-comment rulemaking to address the issue of the appropriate data to use to determine Factor 3 for FY 2018 and subsequent fiscal years. We also anticipate proposing to continue to use data from three cost reports, as we are doing to calculate Factor 3 for FY 2017, which would have a transitioning effect as we described in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25091).

Comment: Many commenters stated that the proposed 3-year phase in period for Worksheet S–10 is not long enough, and requested that CMS consider alternative lengths. Commenters suggested a variety of lengths for a transition, such as 5 years or 10 years, to mitigate wide swings in hospital payments from year to year and to allow hospitals more time to ensure accurate reporting based on any revised instructions CMS may issue.

Some commenters suggested alternative schedules and methods for the phase in of data from Worksheet S–10 to calculate Factor 3. Summaries that illustrate the breadth of commenters' suggestions for alternative schedules and methods for transitioning to Worksheet S–10 are presented below.

- Commenters cited the 10-year transition to the capital PPS, the 4-year transition for indirect medical education reduction in the Balanced Budget Act, and the 5-year transition of certain data elements out of the wage index calculation as examples that could be used as a model for the transition to Worksheet S–10 data.
- One commenter suggested a 5-year phase in period in which S–10 data would be used to allocate 20 percent of the payments in 2018, 40 percent in 2019, 60 percent in 2020, 80 percent in 2021, and would account for 100 percent of payments in 2022. This transition would involve using 3 years of Medicare SSI days and Medicaid days in each year, and transitioning to using 3 years of S–10 data over the 5-year phase-in. Specifically, under a 5-year phase-in approach, 2018 would use 2014 S–10 cost report data, 2019 would use 2014 and 2015 S–10 cost report data, 2020 would use 2014, 2015, and 2016, and so forth.
- Another commenter suggested a 6-year transition beginning in FY 2019 with Worksheet S–10 data accounting for 5 percent of the Factor 3 for each hospital in FY 2019, and then doubling each year, to 10, 20, 40, and 80 percent, and finally full adoption of Worksheet S–10 data in 2024. The commenter argued that this transition would allow time for initial revisions to the Worksheet S–10 form and instructions and further revisions based on reporting and audit experience before the Worksheet S–10 data become the sole source for the Factor 3 calculation. The commenter added that it would also provide States more time to expand their Medicaid programs.
- Several commenters suggested adopting a stop-loss policy that mitigates losses to those most negatively impacted by the incorporation of Worksheet S–10 data, using percentiles or other statistical measures to define and cap losses to certain hospitals in a budget-neutral manner.
- One commenter suggested CMS consider a series of transition policies such that no hospital sees more than a 5-percent change in overall uncompensated care payments in any given year, and one commenter requested that CMS implement a maximum cap of 10 percent on any redistribution of uncompensated care funds for a minimum of 10 years.
- One commenter stated that CMS should commit to smoothing variability by using no fewer than 2 years' worth of Worksheet S–10 data, as opposed to

beginning the Worksheet S–10 data phase-in by combining 1 year of Worksheet S–10 data with 2 years of patient-day data.

Several commenters suggested that CMS consider using a hybrid methodology that includes both a hospital's low-income insured days and uncompensated care costs from Worksheet S–10 to calculate Factor 3. For example, one commenter recommended that, beginning in FY 2020, when CMS proposed to transition entirely to Worksheet S–10 data, CMS instead use a weighted average of low-income insured days and uncompensated care costs from Worksheet S–10, with the low-income insured days weighted 25 percent and the Worksheet S–10 data weighted 75 percent. Other commenters urged CMS to consider a permanent blend of the current proxy of Medicaid days and SSI days, and Worksheet S–10 data, weighted equally in the calculation of Factor 3 for distribution of uncompensated care payments to begin at a future date.

Several commenters believed that there is a need to develop alternative methods or data sources for calculating Factor 3. One commenter suggested a new Factor 3 calculation that would be equal to the quotient of a hospital's cost-adjusted discharges attributable to uninsured patients for a base year divided by the average cost-adjusted discharges in the base year for all hospitals eligible for Medicare DSH uncompensated care payments in the payment year. The commenter believed that this approach would create a single, auditable data source for determining hospitals' uncompensated care for use in calculating hospitals' Medicare DSH uncompensated care payments. This commenter also stated that this would require revising Worksheet S–10 to require hospitals to report the number of discharges and outpatient visits attributable to uninsured individuals. The commenter added that the revised form would require hospitals to report four values associated with services delivered to this population: The number of discharges, outpatient claims, charges, and payments. This information would be reported separately for patients who are and who are not covered by State or local indigent care programs. The commenter believed that the new Factor 3 would be equal to the quotient of a hospital's cost-adjusted discharges attributable to uninsured patients for a year divided by the average cost-adjusted discharges in the base year for all hospitals eligible for Medicare DSH uncompensated care payments in the payment year. The commenter stated that its suggested 10-step process to determine hospitals' Medicare DSH uncompensated care payments would offer four advantages over the proposed regulation for FY 2018: It would maintain the incentives under the IPPS for the efficient and high-quality delivery of health care services; it would avoid the use of CCRs; it would better align Medicare and Medicaid DSH; and it would better reflect the costs for which the Factor 3 data are intended to be a proxy, as defined in the statute.

Response: We appreciate the comments regarding alternative transition timelines to incorporating Worksheet S–10 data into the calculation of Factor 3 and alternative methods for computing proxies for uncompensated care costs. However, as we have noted above, we are not finalizing our proposal to begin to incorporate Worksheet S–10 data into the computation of Factor 3 in FY 2018 at this time. Instead, we expect to begin to incorporate Worksheet S–10 data into the computation of Factor 3 by FY 2021 once we have taken certain quality control and data improvement measures and also implemented an audit process, as we described above. We believe that postponing our decision regarding when to begin incorporating data from the Worksheet S–10 is necessary to allow us time to consider what changes to the cost report may be necessary and to implement an audit process. When we have determined that it is appropriate to use Worksheet S–10 data, we anticipate proposing to continue to use data from three cost reports, as we are doing for the calculation of Factor 3 for FY 2017, which would have a transitioning effect as we described in the proposed rule (81 FR 25091). At this time, we do not expect that a longer transition will be necessary. With regard to how Factor 3 will be computed in FY 2018 and the intervening years until data from the revised Worksheet S–10 are available, we intend to explore whether there is an appropriate proxy for uncompensated care that could be used to calculate Factor 3 until we determine that revised Worksheet S–10 data can be used for this purpose. We will undertake further notice-and-comment rulemaking to address the issue of the appropriate data to use to determine Factor 3 for FY 2018 and subsequent fiscal years.

Comment: As noted previously, several commenters expressed concern over the proposal to combine data from the multiple cost reports so that a hospital may have a Factor 3 calculated using more than one cost report that begins during a given Federal fiscal year. One commenter found that 39 hospitals included Worksheet S–10 data from multiple cost reporting periods within their FY 2014 Worksheet S–10 data. Some of these cost reporting periods represent more than 12 months of data. In the commenter's view, individual hospital data on the Worksheet S–10 need to represent a 12-month period so that the data are evenly weighted among all DSH hospitals for purposes of determining Factor 3. The commenter believed that inconsistencies in the length of cost report periods would result in erroneous uncompensated care payment allocations. The commenter suggested that, to resolve this, CMS could prorate the data down to an equivalent 12-month period.

Response: As we stated in the proposed rule (81 FR 25089), we believe that using data from more than one cost reporting period, instead of prorating short or long cost report data to 12 month equivalents, mitigates undue fluctuations in the amount of uncompensated care payments to hospitals from year to year and provides a stabilizing effect from one year to the next. In addition, as discussed above in the section related to the calculation of Factor 3 for FY 2017, in the instance where a hospital has more than one cost reporting period starting within a fiscal year, we are finalizing our proposal to combine data from multiple cost reports so that a hospital would have a Factor 3 calculated using more than one cost report starting within the fiscal year, as doing so would provide the most complete dataset for the hospital for that fiscal year, and would smooth out fluctuations in the data. At this point, we expect to propose to continue to use three cost reports of data to calculate Factor 3 in FY 2018 and subsequent years, although we may reevaluate this approach if warranted.

In summary, we are not finalizing our proposal to begin to incorporate Worksheet S–10 data into the computation of Factor 3 for FY 2018, and we are not finalizing the proposed regulations text changes at § 412.106(g)(C)(*4*) through (*7*) regarding FY 2018 and subsequent fiscal years. In light of the significant concerns expressed by commenters, we are postponing the decision regarding when to begin incorporating data from Worksheet S–10 and proceeding with revisions to the cost report instructions to address the commenters' concerns in an appropriate manner. We believe that revised Worksheet S–10 data will be available to use in the calculation of Factor 3 in the near future, and no later than FY 2021. With regard to how Factor 3 will be computed in FY 2018

and subsequent years, we intend to explore whether there is an appropriate proxy for uncompensated care that could be used to calculate Factor 3 until we determine that data from the revised Worksheet S–10 data can be used for this purpose. We will undertake further notice-and-comment rulemaking to address the issue of the appropriate data to use to determine Factor 3 for FY 2018 and subsequent fiscal years. We also anticipate proposing to continue to use data from three cost reports to calculate Factor 3, as we are doing for the calculation of Factor 3 for FY 2017, which would have a transitioning effect as we described in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25091).

(3) Definition of Uncompensated Care for FY 2018 and Subsequent Fiscal Years

In the FY 2014 IPPS/LTCH PPS rulemaking, we considered three potential definitions of uncompensated care: Charity care; charity care + bad debt; and charity care + bad debt + Medicaid shortfalls. As we explained in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50634), we considered proposing to define the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and considered potential data sources for those costs. We examined the literature on uncompensated care and the concepts of uncompensated care used in various public and private programs, and considered input from stakeholders and public comments in various forums, including the national provider call that we held in January 2013. Our review of the information from these sources indicated that there is some variation in how different States, provider organizations, and Federal programs define ''uncompensated care.'' However, a common theme of almost all these definitions is that they include both ''charity care'' and ''bad debt'' as components of ''uncompensated care.'' Therefore, a definition that incorporates the most commonly used factors within uncompensated care as reported by stakeholders would include charity care costs and bad debt costs. Worksheet S–10 employs the definition of charity care plus non-Medicare bad debt. Specifically:

Cost of charity care ..... + Cost of non-Medicare bad debt expense.	(line 23) (line 29)
Cost of non-Medicare uncompensated care.	(line 30)

Where:

- Cost of charity care = Cost of initial obligation of patients approved for charity care (line 21) minus partial payment by patients approved for charity care (line 22).
- Cost of non-Medicare bad debt expense = Cost to charge ratio (line 1) times non-Medicare and nonreimbursable bad debt expense (line 28).

As we stated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25092), we believe a definition that incorporates the most commonly used factors within uncompensated care as reported by stakeholders would include charity care costs and non-Medicare bad debt costs which correlates to line 30 of Worksheet S–10. Therefore, we proposed that, for purposes of calculating Factor 3 and uncompensated care costs beginning in FY 2018, ''uncompensated care'' would be defined as the amount on line 30 of Worksheet S–10, which is the cost of charity care and the cost of non-Medicare bad debt.

In the FY 2017 IPPS/LTCH PPS proposed rule, we discussed that we have received many comments and questions from hospitals and hospital associations regarding whether Medicaid payment shortfalls should be included in the definition of uncompensated care. Some stakeholders argue that such payment shortfalls are unreimbursed care for low-income patients and that the definition of uncompensated care should be consistent across Medicare and Medicaid (where the longstanding Medicaid definition of uncompensated care used for Medicaid hospital-specific DSH limits includes Medicaid payment shortfalls). Proponents of including Medicaid shortfalls advance two arguments:

- Medicaid payment shortfalls represent noncovered care; therefore, hospitals have unmet costs when treating these patients.
- The goal of Medicare DSH payments is to provide partial relief from charity care that is provided to (primarily) low-income patients. Because Medicaid enrollees are low-income persons, the underpayments associated with their care are a form of charity care.

In contrast, there are several arguments to support excluding Medicaid shortfalls from the definition of uncompensated care:

- Several government agencies and key stakeholders define uncompensated care as bad debt plus charity care, without consideration for Medicaid payment shortfalls. Specifically, MedPAC, GAO, and the AHA exclude Medicaid underpayments from the definition of uncompensated care.
- Including Medicaid shortfalls in the calculation of Medicare uncompensated care payments would represent a form of cross-subsidization from Medicare to cover Medicaid costs. In the past, CMS and MedPAC have not supported such action.
- Excluding Medicaid shortfalls from the uncompensated care definition allows Medicare DSH payments to better target hospitals with a disproportionate share of uncompensated care for patients with no insurance coverage.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25092), we stated that we believe these arguments for excluding Medicaid shortfalls from the definition of uncompensated care are compelling. In addition, we stated that we believe that it is advisable to adopt a definition that is used by several government agencies and key stakeholders. Therefore, we proposed that, for purposes of calculating Factor 3 and the amount of uncompensated care for a hospital beginning in FY 2018, ''uncompensated care'' would be defined as the cost of charity care and the cost of non-Medicare bad debt. We also proposed to exclude Medicaid shortfalls reported on Worksheet S–10 from the definition of uncompensated care for purposes of calculating Factor 3. We proposed to codify this definition in the regulation at § 412.106(g)(1)(iii)(C) and invited public comment on our proposed definition. We stated that we believe that uncompensated care costs as reported on line 30 of Worksheet S–10 best reflect our proposed definition of uncompensated care, but we welcomed public input on this issue.

Comment: Many commenters provided a broad range of detailed suggestions related to reporting requirements for specific lines of Worksheet S–10. Commenters suggested the following general modifications to the manner in which uncompensated care costs are captured on Worksheet S–10:

- A number of commenters observed that the instructions for Worksheet S–10 are inconsistent with generally accepted accounting principles (GAAP) and differ from the accounting practices of the majority of hospitals. Therefore, the commenters requested that CMS amend the cost reporting instructions to require hospitals to report amounts based on GAAP. Commenters suggested that the Worksheet S–10 instructions be amended to require hospitals to report the same bad debt and charity care amounts they report on their financial

statements, which are GAAP appropriate.

• Commenters noted that because Worksheet S–10 is derived from data reported on the Medicare cost report, charges and payments for physician services are currently excluded. However, the commenters stated that hospitals provide physician services to patients with little or no access to private physicians. They noted that safety-net hospitals in low-income communities particularly provide these services. The commenters believed that establishing an uncompensated care cost methodology that takes these services into account would encourage providers to furnish these services.

• Commenters requested clarification of whether charity care charges should be reported for inpatient hospital services, outpatient hospital services, or both. They requested the ability to report these charges on separate lines and to apply separate CCRs to these separate sets of costs.

• Commenters noted that the instructions for line 26 include Medicare bad debts for services provided beyond the inpatient and outpatient setting, and interpreted this to mean that hospitals should include non-Medicare bad debts for services provided in the following settings for which expenses are included on the hospital cost report: Skilled nursing beds (both swing beds and distinct part facilities), distinct part inpatient rehabilitation units, distinct part LTCHs, distinct part psychiatric units, dialysis centers, CMHCs, RHCs and FQHCs. The commenters asked CMS to confirm in the final rule that this interpretation is correct.

• Similarly, commenters requested that CMS define any additional distinct part units or services that are not listed in the instructions for line 26 but should be included in that line when reporting non-Medicare bad debt. As an example, one commenter noted that there is no cost sharing for home health services in the Medicare benefit design and therefore it is not listed as an item/service to include in line 26. However, if CMS truly intends for the bad debt expense to represent the ''entire hospital complex,'' the commenter stated that distinct part home health agencies should be included, as a hospital could still accrue related bad debt from home health services furnished to the uninsured or underinsured.

• Commenters advised requiring Medicaid DSH payments and Medicaid supplemental payment information to be reported on separate lines, and to offset all of these payments against Medicaid costs reported on Worksheet S–10. Commenters requested separate reporting of a number of payments, including direct payments to hospitals, Medicaid DSH, and supplementary payments including upper payment limits, intergovernmental transfers, certified government expenditures, provider taxes, other government payments, and payments for local or state indigent care.

• One commenter suggested that CMS integrate payer mix into Worksheet S–10, as providers with a substantial commercial payer mix often have operating margins that help offset uncompensated care costs. The commenter recommended that CMS examine methods to adjust the uncompensated care amount for payer mix.

• One commenter noted that CCRs in Worksheet S–10 are reported with Reasonable Compensated Equivalency (RCE) limits applied. The commenter cited the discussion in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50161), which states that RCE limits have no effect on IPPS provider payments. Therefore, the commenter believed that if the CCR in Worksheet S–10 is used, IPPS hospital's payments would be affected by RCE limits, and RCE disallowances should therefore be removed from the CCR on Line 1 of Worksheet S–10.

• Commenters observed that CCRs for ''parts of hospitals'' such as facility-based skilled nursing facilities and inpatient rehabilitation facilities are very different from the CCRs for acute care hospitals paid under the IPPS. The commenters questioned the appropriateness of including parts of hospitals in the CCR in Worksheet S–10.

Response: Some of the commenters express concerns and raise questions that have not been raised before, while others have been raised in previous rulemaking. We intend to address many of these comments as part of our planned clarifications and revisions to Worksheet S–10. As mentioned above in response to previous comments, at this time, we are not finalizing the proposed regulations text changes at § 412.106(g)(C)(*4*) through (*7*) regarding the data that would be used to estimate the amount of hospital uncompensated care for FY 2018 and subsequent fiscal years. In these proposed regulation text changes, we had proposed to define uncompensated care costs for FY 2018 and subsequent years to mean charity care costs plus non-Medicare bad debt costs. Our intent is still to begin to incorporate Worksheet S–10 data into the computation of Factor 3 in the near future, and no later than FY 2021. When we undertake rulemaking to propose to incorporate Worksheet S–10 data, we also expect to propose the same definition of uncompensated care costs—charity care costs plus non Medicare bad debt costs, because we believe it is advisable to adopt a definition that is used by several government agencies and key stakeholders.

With regard to the comments asking whether Worksheet S–10 data should reflect inpatient or outpatient services, or both, we note that the cost report instructions at Section 4012 of the PRM–II, Pub. 15–2, state: ''Worksheet S–10—Hospital Uncompensated and Indigent Care Data—Section 112(b) of the Balanced Budget Refinement Act (BBRA) requires that short-term acute care hospitals (§ 1886(d) of the Act) submit cost reports containing data on the cost incurred by the hospital for providing *inpatient and outpatient hospital services* for which the hospital is not compensated'' (emphasis added). In a similar vein, the CCR used on Worksheet S–10, line 1 is from Worksheet C, Part I, line 202. This CCR reflects costs and charges of all hospital inpatient departments and outpatient department and clinics. Thus, Worksheet S–10 is designed to capture uncompensated care costs associated with the hospital under all of the hospital's Medicare provider agreements, including provider-based facilities. However, Worksheet S–10 is not intended to capture uncompensated care related to physician services. We note that at various points on Worksheet S–10, the instructions state, ''Include payments for all covered services *except physician or other professional services''* (emphasis added).

Finally, with regard to the comment that the CCRs on Worksheet S–10 are reported with the RCE limits applied, we believe the commenter is mistaken. Line 1 of Worksheet S–10 instructs hospitals to compute the CCR by dividing the costs from Worksheet C, Part I, line 202, *column 3,* by the charges on Worksheet C, Part I, line 202, column 8. The RCE limits are applied in column 4, not in column 3; thus, the RCE limits do not affect the CCR on line 1 of Worksheet S–10.

Comment: Many commenters expressed concerns relating to, and provided suggestions for, calculating charity care and bad debt as captured on Worksheet S–10:

• Commenters expressed confusion about what is identified as an indigent care program, and when charity care and Medicaid noncovered charges are components of charity care. These commenters stated that the instructions for line 20 in Worksheet S–10 provide

that ''Charges for non-covered services provided to patients eligible for Medicaid or other indigent care program . . . can be included, if such inclusion is specified in the hospital's charity care policy and the patient meets the hospital's charity care criteria.'' Commenters believed that government providers are misreporting data related to charity care by including all charges for their indigent care/general relief patient populations in the definition while not accounting for offsetting payments. The commenters expressed their view that these programs are not uncompensated, but are funded through State and local tax assessments. Therefore, the commenters requested that CMS require that patient charges cannot be included in the cost of charity care unless the related services are not covered by an indigent care program.

- Commenters raised a similar concern about line 20 regarding a possible discrepancy between considering noncovered charges for Medicaid patients as eligible for charity care, but not allowing noncovered charges for patients that have some commercial coverage to be considered charity care. Some commenters believed that this approach understates charity care costs for patients who participate in high deductible plans, which is becoming more common.
- One commenter stated that CMS' instructions for reporting charity care on Worksheet S–10 are inconsistent with the instructions given by other State and Federal programs which instruct hospitals to report charity care based upon the hospital's financial policy and consistent with its mission statement, financial ability, and other circumstances. Another commenter stated that because section 501(r) of the Internal Revenue Code requires hospitals to establish financial assistance policies and to reduce charges for services furnished to individuals who qualify for assistance under those policies as a requirement for tax-exemption as a charitable hospital organization, those policies, including the eligibility criteria established under those policies, necessarily must be regarded as the hospital's ''charity care criteria'' for purposes of Worksheet S–10, to ensure consistency in reporting.
- Commenters stated that hospitals report charity care amounts for patients that qualify for partial charity inconsistently, and requested that CMS clarify how amounts should be reported for patients that qualify for partial charity care, for both an uninsured individual as well as a patient with financial responsibility after his or her insurance pays.
- Many commenters believed that the definition of bad debt is unclear and that the methodology CMS uses to arrive at the cost of bad debt significantly understates the uncompensated care expense that hospitals incur as a result of uncollectable amounts. For example, commenters requested that CMS clarify whether recoveries received during the cost reporting period should be deducted from the non-Medicare bad debt claimed on line 26.
- In addition, commenters expressed their view that line 26 comingles bad debt for both uninsured patients and patients who have some form of insurance but are not able to meet their cost sharing responsibility. Commenters stated that applying a CCR to calculate cost is not accurate when the amounts have already been reduced from gross charges. These commenters believed that applying the hospital's CCR to the amount on line 26 understates the costs associated with deductibles and coinsurance for insured patients written off to bad debt. They noted that, given the increased cost sharing many insured individuals currently face, a growing portion of a hospital's bad debt is related to unpaid deductibles, coinsurance, and copayments. The commenters recommended that CMS revise Worksheet S–10 to require separate reporting for bad debt written off for the uninsured and for those who are insured but cannot afford their cost sharing, similar to the instructions for line 20.

Response: The commenters have raised various issues that directly relate to reporting of charity care and bad debt costs on Worksheet S–10. We intend to consider these issues as we review Worksheet S–10 and will make clarifications or revisions to the Worksheet S–10 instructions, as appropriate, to address these concerns.

Comment: Commenters noted that using data from Worksheet S–10 to calculate Factor 3, as opposed to using the current low-income insured days proxy, has serious implications for entire States. One commenter stated that the proposed policy to transition to Worksheet S–10 would result in a $3 billion shift in Medicare DSH funding across providers and States. This commenter believed that the reductions in payments resulting from this redistribution would have a significant deleterious impact on hospitals in parts of the country that have relied on DSH funding to support services for vulnerable populations. The commenter stated that, given unforeseeable factors that have affected Medicaid and insurance expansion across States, these massive funding redistributions are not aligned with the goals of the Affordable Care Act and could not have been predicted or intended by Congress. Another commenter provided specific examples from its own analysis of how the use of Worksheet S–10 data to estimate hospital uncompensated care costs would reward hospitals in States that have chosen not to expand their Medicaid programs and punish those that have done so. Many commenters noted that the States losing DSH dollars are States that have expanded their Medicaid programs, as the current proxy captures Medicaid days and Worksheet S–10 does not. Meanwhile, the commenters stated, States that would likely gain the most Medicare uncompensated care dollars are those States that have not expanded their Medicaid programs, and as a result their uncompensated care is relatively high. Many commenters generally believed it should not be public policy to harm States that have responded positively to new opportunities created through legislation and to reward those that have rejected them.

Response: We understand the commenters' concerns regarding the effects on hospitals' payments of moving from calculating Factor 3 using a proxy based on low-income days to the use of uncompensated care data from Worksheet S–10. We believe that postponing the decision regarding when to begin incorporating data from Worksheet S–10 data into the calculation of Factor 3 will allow us time to consider what revisions to the cost reporting instructions may be necessary to ensure that uncompensated care cost data are reported appropriately and consistently.

Comment: Many commenters expressed opinions regarding the definition of uncompensated care as captured by Worksheet S–10. Numerous commenters believed that shortfall from Medicaid underpayment should be included in the definition of uncompensated care. These commenters argued that from a policy perspective, it is vitally important to include Medicaid losses to ensure that hospitals in Medicaid-expansion states are not disadvantaged vis-à-vis hospitals in non-expansion States, as noted by commenters that described the differential impact of the use of Worksheet S–10 data in States that have expanded Medicaid compared to States that have not. The commenters stated that including Medicaid losses in the definition of uncompensated care would align with the Medicaid DSH program and the IRS method of calculating the

community benefit provided by nonprofit hospitals. Other commenters requested that, in addition to Medicaid shortfall, shortfall from SCHIP and State and local indigent care programs should be included in uncompensated care costs.

However, other commenters supported the exclusion of Medicaid shortfalls from the definition of uncompensated care. These commenters believed that section 3133 does not allow for the inclusion of Medicaid shortfalls in the Factor 3 calculation, based on the statutory language at section 1886(r)(2)(C)(i) of the Act, which refers to the costs of hospitals treating the ''uninsured.'' One commenter noted that, under section 3133, Congress required that the Factor 2 calculation include a reduction of the amount determined under Factor 1 (that is, the amount by which the aggregate amount of DSH payments that would have been made under section 1886(d)(5)(F) of the Act for the fiscal year exceeds the aggregate amount of empirically justified DSH payments under section 1886(r)(1) for that fiscal year) equal to the growth in the insured population from a base year, and it does so by reference to specific CBO estimates of the insured patient rate. The commenter stated that Congress was well aware that the CBO includes the growth in the Medicaid population within the insured rate, and therefore Congress did not intend that Medicaid patients would be considered uninsured for purposes of determining Factor 3. Another commenter believed that it is inappropriate for Medicare to include Medicaid shortfall when estimating uncompensated care costs because the ''shortfall'' will depend on a specific hospital's cost structure and the Medicaid payments they receive. In addition, the commenter stated that computing losses for Medicaid patients is operationally problematic for several reasons. The commenter indicated that one operational complexity stems from Medicaid paying hospitals a single DSH payment that in part covers costs of the uninsured and in part covers estimates of a hospital's Medicaid ''shortfall,'' and it is not clear how CMS would determine how much Medicaid ''shortfall'' is left after the Medicaid DSH payments are made. In addition, the commenter noted that hospitals in some states return a portion of their Medicaid revenue to the state through provider taxes. The commenter stated that it would be difficult for CMS to arrive at a net ''shortfall'' figure, given the lack of reported data on the net value of Medicaid DSH payments less provider taxes. Commenters also noted that compensating hospitals for Medicaid shortfalls as part of a Medicare payment could provide an incentive for Medicaid to underpay hospitals for services provided to Medicaid patients.

In addition to comments about Medicaid shortfalls, commenters stated that the Affordable Care Act directed that the uncompensated care payments should account for uncompensated care costs for the uninsured, and argued that the data reported on the Worksheet S–10 do not include all costs for treating the uninsured. One of these commenters stated that Worksheet S–10 needs to be amended to allow for reporting discounts provided to the uninsured as part of the total uncompensated care costs. The commenter noted that on Worksheet S–10, uncompensated care costs are specifically defined to ''not include courtesy allowances or discounts given to patients'' (the cost report instructions at CMS Pub. 15–2, Section 4012). The commenter stated that this definition has created confusion, and it is unclear if ''courtesy'' applies to both ''allowance'' and ''discounts,'' or whether the term ''discounts'' is unmodified by ''courtesy.'' Commenters observed that States differ in how they define uncompensated care costs, and that not all costs incurred by hospitals in treating the uninsured are categorized as charity care and bad debt, such as discounts to the uninsured who are unable to pay or unwilling to provide income information. The commenters requested that all costs related to treating the uninsured be included in the definition of uncompensated care costs, including discounts to the uninsured, regardless of whether they are officially called ''discounts.'' Commenters noted that Worksheet S–10 does not distinguish discounts to the uninsured from charity care and bad debt and expressed concern that hospitals that attempt to collect on a full debt with no discount receive the same or higher uncompensated care total as hospitals that provide discounts. One commenter provided examples that it asserted demonstrate that excluding the cost of discounts to uninsured patients ''favors'' hospitals unwilling to discount care over those that do. Specifically, in the examples, the cost of uncompensated care for a particular uninsured patient is the same at each hospital. However, the commenter asserted that as a result of the current Worksheet S–10 instructions to exclude discounts given to the uninsured, the cost of uncompensated care at one of the hospitals in the example is undercounted. The commenter believed that this policy ''favors hospitals unwilling to discount care over those that do,'' and could create a disincentive for hospitals to ''maintain generous uninsured discount programs.''

Commenters noted that section 3133 of the Affordable Care Act does not mention charity care or even gross non-Medicare bad debt; it simply focuses on the uncompensated care costs of the uninsured. These commenters noted that the instructions of Worksheet S–10 appear to exclude uninsured status explicitly: ''Do not include charges for . . . uninsured patients given discounts without meeting the hospital's charity care criteria.'' The commenters believed that because the instructions to Worksheet S–10 state that ''this worksheet does not produce the estimate of the cost of treating uninsured patients required for disproportionate share payments under the Medicaid program'' (the instructions at the beginning of Worksheet S–10, section 4012 of CMS Pub. 15–2), this indicates that Worksheet S–10 does not capture the information relevant to the purposes of section 3133 of the Affordable Care Act.

Response: In general, we will endeavor to address commenters' concerns in future cost report clarifications so as to ensure that Worksheet S–10 is an appropriate instrument to use to implement section 3133 of the Affordable Care Act. With regard to the comments regarding Medicaid shortfalls, as we stated in the proposed rule (81 FR 25092), we believe there are compelling arguments for excluding Medicaid shortfalls from the definition of uncompensated care, including the fact that several key stakeholders do not consider Medicaid shortfalls in their definition of uncompensated care, and that it is best to allow Medicare uncompensated care payments to target hospitals that have a disproportionate share of uncompensated care for patients with no insurance coverage. Accordingly, as discussed above in response to previous comments, we anticipate re-proposing through rulemaking a definition of uncompensated care costs that includes charity care and non-Medicare bad debt as part of our intent to begin to incorporate Worksheet S–10 data into the computation of Factor 3, no later than FY 2021. With regard to the comments that States differ in how they define uncompensated care costs, and that hospitals' costs of treating the uninsured are not always categorized as charity care and bad debt, such as discounts to the uninsured who are

unable to pay or unwilling to provide income information, we believe the commenters are referring to the Worksheet S–10 instructions for Line 20, which state, in part, ''Do not include charges for either uninsured patients given discounts without meeting the hospital's charity care criteria or patients given courtesy discounts.'' We believe that hospitals have the discretion to design their charity care policies as appropriate, and may include discounts offered to uninsured patients as ''charity care.'' However, we will also further consider the concern raised by the commenter as to whether inadvertent disincentives may be occurring under CMS' current instructions, and we may consider revisions to the instructions on line 20 of Worksheet S–10 to further clarify when patient discounts would be considered charity care versus bad debt.

(4) Other Methodological Considerations for FY 2018 and Subsequent Fiscal Years

In the past several years, we have received technical comments from stakeholders regarding the timing of reporting charity care and the CCRs used in determining uncompensated care costs. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25093), we discussed these issues and how we proposed to incorporate them into the calculation of uncompensated care costs for purposes of determining uncompensated care payments for FY 2018 and subsequent fiscal years as follows:

• *Timing of Reporting Charity Care.* The determination and write-off of charity care often happens outside of the hospital fiscal year in which the services are provided. Some commenters have requested that the charity care captured on Line 20 of Worksheet S–10 include only the charity care that was written off in the particular cost reporting year, regardless of when the services were provided, consistent with charity write-offs that hospitals report in accordance with GAAP. In addition, hospitals currently report non-Medicare bad debt without regard to when the services were provided. The current Worksheet S–10 does not follow this hospital practice, and specifies that charity care provided (not necessarily written off) during the period should to be recorded on Line 20. (Instructions for Line 20 of Worksheet S–10 of the Medicare cost report CMS-Form-2552–10, ''Enter the total initial payment obligation of patients who are given a full or partial discount based on the hospital's charity care criteria (measured at full charges), for care delivered *during this cost reporting period* for the entire facility . . .'' (emphasis added) are included in CMS Pub. 15–2, Chapter 40, Section 4012.) While these differences in reporting should average out over time for a hospital, consistency in reporting has been requested by some stakeholders. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25093), we acknowledged these concerns, and stated that we intend to revise the current Worksheet S–10 cost report instructions for Line 20 concerning the timing of reporting charity care, such that charity care will be reported based on date of write-off, and not based on date of service.

Comment: Many commenters supported the proposal to revise the current Worksheet S–10 cost report instructions for line 20 concerning the timing of reporting charity care, such that charity care will be reported based on date of write-off, and not based on date of service. Commenters requested clarification about how CMS intends to implement the change. One commenter asked whether the revision to Worksheet S–10 to report charity care based on the date of the write-off would be a prospective change, or whether it would change previously filed reports from 2014, 2015, or 2016. Another commenter requested that CMS clarify whether charity care should exclude accounts reported in previously filed cost reports to avoid a double reporting of charity care costs. Commenters noted that providers will need additional time to implement this change, as hospitals will need to revisit numbers reported in 2012 and 2013 to accurately report 2014 costs.

Response: We will revise line 20 of Worksheet S–10 to instruct hospital to report the payment obligation for care ''that was written off during this cost reporting period, regardless of when the services were provided.'' This change must be effective prospectively for cost reporting periods beginning on or after October 1, 2016, because line 20 as it currently exists is used to calculate EHR incentive payments (in accordance with the policy stated in the final rule for the Electronic Health Record Incentive Program (75 FR 44456), and instituting a change to the instructions on line 20 without a prospective effective date would constitute retroactive rulemaking. Additional clarifications regarding charity care exclusions reported in previously filed cost reports may be forthcoming.

• *Revisions to the CCR on Line 1 of Worksheet S–10.* Many commenters have requested that the CCR used to convert charges to costs should include the cost of training residents (direct GME costs). The CCR on line 1 of Worksheet S–10 currently does not include GME costs, while the charges of teaching hospitals do include charges for GME. Thus, the CCR excludes GME costs in the cost component (or numerator), but includes GME costs in the charge component (or denominator). In the FY 2017 IPPS/LTCH PPS proposed rule, we noted that commenters have requested that CMS consider using the GME costs reported in Worksheet B Part I (column 24, line 118) to capture these additional costs. Unless these GME costs are included, commenters have maintained that the CCRs of teaching hospitals are artificially low, not capturing true uncompensated care costs, thereby disadvantaging teaching hospitals in the calculation of their uncompensated care costs.

Using data from FY 2011 and 2012 cost reports, we analyzed the effect on all hospitals' uncompensated care costs when GME costs are included in the numerator. Specifically, instead of calculating the CCRs as specified currently on line 1 of Worksheet S–10 (which pulls the CCR from Worksheet C, Part I, column 3, line 202/Worksheet C, column 8, line 202), we calculated the CCRs using Worksheet B, Part I, column 24, line 118/Worksheet C, Part I, column 8, line 202. As can be seen on the file posted on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html* under the Downloads section, and as expected, including GME costs in the numerator of the CCR results in an increased share of uncompensated care payments being made to teaching hospitals. Of the more than 1,000 teaching hospitals included in the analysis, the CCRs of 830 hospitals increase by less than 5 percent, 178 hospitals' CCRs increase by more than 5 percent but less than 10 percent, and 71 hospitals' CCRs increase by 10 percent or more. Thirty-three hospitals experience a decrease in their CCRs, with 32 hospitals experiencing a decrease of less than 5 percent, and 1 hospital experiencing a decrease of more than 5 percent, but less than 10 percent. As we have stated previously in response to this issue, we believe that the purpose of uncompensated care payments is to provide additional payment to hospitals for treating the uninsured, not for the costs incurred in training residents. In addition, because the CCR on line 1 of Worksheet S–10 pulled from Worksheet C, Part I, is also used in other IPPS ratesetting contexts (such as high-cost outliers and the

calculation of the MS–DRG relative weights) from which it is appropriate to exclude GME because GME is paid separately from the IPPS, we are hesitant to adjust the CCRs in the narrower context of calculating uncompensated care costs. Therefore, in the proposed rule, we stated that we do not believe it is appropriate at this time to modify the calculation of the CCR on line 1 of Worksheet S–10 to include GME costs in the numerator.

Comment: Commenters noted that the CCR used on Worksheet S–10 to convert charges to costs implicitly includes direct GME charges in the denominator, and therefore requested that the CCR on Worksheet S–10 be revised to include direct GME payments in the cost numerator. One commenter noted that because GME costs are a significant component of inpatient and outpatient services at teaching hospitals, not including GME in the numerator of the CCR significantly understates the cost of care and thus the losses incurred by these hospitals as a result of uncompensated care. The commenter pointed out that Medicare and State Medicaid programs contribute their share of GME costs, and CMS permits teaching hospitals to revise their CCRs to include GME costs under the Medicaid DSH program because Medicaid payments cover GME. Finally, the commenter stated that Schedule H of IRS Form 990 specifically includes GME losses as a component of uncompensated care. Several commenters suggested using the costs from Worksheet B, Part I, column 24, Line 118 in the numerator of the CCR, while another commenter recommended that, for accuracy of the data, CMS should limit the use of the Worksheet B to determine CCRs to teaching hospitals that report GME FTEs.

Response: As described in the proposed rule (81 FR 25093), we have analyzed the effect on all hospitals' uncompensated care costs when GME costs are included in the numerator of the CCR using data from FY 2011 and 2012 cost reports. As can be seen on the file posted on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html* under the ''Downloads'' section, and as expected, we found that including GME costs in the numerator of the CCR results in an increased share of uncompensated care payments being made to teaching hospitals. As we have stated previously in response to this issue, we believe that the purpose of uncompensated care payments is to provide additional payment to hospitals for treating the uninsured, not for the costs incurred in training residents. In addition, because the CCR on line 1 of Worksheet S–10 pulled from Worksheet C, Part I, is also used in other IPPS rate-setting contexts (such as high-cost outliers and the calculation of the MS–DRG relative weights) from which it is appropriate to exclude GME because GME is paid separately from the IPPS, we hesitate to adjust the CCRs in the narrower context of calculating uncompensated care costs. Therefore, we continue to believe that it is not appropriate at this time to modify the calculation of the CCR on line 1 of Worksheet S–10 to include GME costs in the numerator. Accordingly, we do not anticipate proposing to include GME costs in the numerator of the CCR when we begin to incorporate Worksheet S–10 data into the calculation of Factor 3.

- *Trims to Apply to CCRs on Line 1 of Worksheet S–10.* In the FY 2017 IPPS/LTCH PPS proposed rule, we noted that commenters also have suggested that uncompensated care costs reported on Worksheet S–10 should be audited due to the extremely high values consistently reported by some hospitals. We believe that, just as we apply trims to hospitals' CCRs used to calculate high-cost outlier payments to eliminate anomalies in payment determinations (§ 412.84(h)(3)(ii)), it is appropriate to apply statistical trims to the CCRs that are considered anomalies on Worksheet S–10, Line 1. Specifically, § 412.84(h)(3)(ii) states that the Medicare contractor may use a statewide CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean (that is, the CCR ''ceiling''). This mean is recalculated annually by CMS and published in the proposed and final IPPS rules each year. To control for data anomalies, we stated in the proposed rule that we are considering proposals that would trim hospitals' CCRs to ensure reasonable CCRs are used to convert charges to costs for purposes of determining uncompensated care costs.

One approach we considered as a possible proposal for FY 2018 and subsequent years would be a ''double trim'' methodology as follows:

First Trim

Step 1: Prior to calculating the statewide average CCRs, all hospitals with a CCR reported on Worksheet S–10, line 1, of greater than the corresponding CCR ''ceiling'' (that is, the CCR ''ceiling'' published in the final rule for the fiscal year that is contemporaneous to the particular Worksheet S–10 data) would be removed from the calculation. We proposed to remove the hospitals with a CCR of greater than 3 standard deviations above the corresponding national geometric mean in order to calculate the statewide average CCRs so that these aberrant CCRs do not skew the statewide average CCR.

Step 2: Using the CCRs for the remaining hospitals in Step 1, determine the statewide average CCRs using line 1 of Worksheet S–10 for hospitals within each State (including non-DSH eligible hospitals).

Step 3: Calculate the simple average CCR (not weighted by hospital size) for each State.

Step 4: First CCR Trim—Assign the statewide average CCR calculated in Step 3 to all hospitals with a CCR greater than 3 standard deviations above the corresponding national geometric mean (that is, the CCR ''ceiling'').

Second Trim

Step 5: Calculate the natural logarithm of the CCR for all hospitals (including those with replaced CCRs and those not eligible for Medicare DSH payments).

Step 6: Calculate the geometric mean and standard deviation of the log values across all hospitals (including those not eligible for Medicare DSH payments).

Step 7: Second CCR Trim—Assign the statewide average CCR calculated in Step 3 to each Medicare DSH eligible hospital with a CCR greater than 3.0 standard deviations above the geometric mean. All hospitals not eligible for Medicare DSH payments should be excluded from further analyses.

The analysis that we performed under this ''double trim'' approach was based on CCRs from FY 2012 Worksheet S–10, Line 1. Under Step 1, we used the FY 2013 CCR ''ceiling'' of 1.146 published in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53697). (We used the FY 2013 CCR ''ceiling'' because it was computed from the March 2012 update of the Provider Specific File, which contained CCRs that are relatively contemporaneous to the CCRs in the FY 2012 cost reports.) Our analysis showed that 27 hospitals would receive their respective statewide average CCR. (We refer readers to our analysis posted on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html* under the Downloads section.)

Alternatively, we considered proposing for FY 2018 and subsequent years to use the same trim process that is used for high-cost outliers under § 412.84(i), under which we calculate separate urban and rural average CCRs for each state. Thus, the CCR of an

urban or rural hospital above the applicable CCR ''ceiling'' for a given fiscal year would be replaced by its respective urban or rural statewide average CCR. As a reference, the FY 2013 IPPS statewide average urban and rural CCRs are in Table 8A included on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download-Items/FY2013-FinalRule-CorrectionNotice-Files.html*.

After applying the applicable trims to a hospital's CCR as appropriate, we would calculate a hospital's uncompensated care costs as being equal to line 30, which is the sum of line 23 and line 29, as follows:

Hospital Uncompensated Care Costs = line 30 (=line 23 + line 29), which is equal to—

[(Line 1 CCR *adjusted by trim if applicable* x charity care line 20)—(Payments received for charity care line 22)]

+

[(Line 1 CCR *adjusted by trim if applicable* x Non-Medicare and non-reimbursable Bad Debt line 28)].

Comment: Several commenters supported CMS' proposal to trim hospitals' CCRs to ensure reasonable CCRs are used to convert charges to costs for purposes of determining uncompensated care costs. These commenters agreed with CMS that this trim will prevent some of the large variance outliers from artificially influencing the distribution percentages.

While some commenters agreed that identifying aberrant CCRs through an edit is appropriate, many commenters objected to the ''double trim'' methodology outlined in the FY 2017 IPPS/LTCH PPS proposed rule for FY 2018 and subsequent years. One commenter recommended that hospitals with extremely high CCRs be audited and an appropriate CCR determined, versus arbitrarily trimming these high CCRs to a statewide average. Several commenters expressed concern over the proposed CCR trim methodology because hospitals that are considered ''all-inclusive rate providers'' are not required to complete Worksheet C, Part I, which is used for reporting CCR on Line 1 of Worksheet S–10. Commenters expressed their view that the proposed CCR trim methodology inappropriately modifies the uncompensated care costs for these hospitals, and that a high CCR could be accurate if the hospital's charges are close to costs, as is usually the case for ''all-inclusive rate providers.'' Commenters believed that CMS should correct the methodology to ensure these hospitals are not inappropriately captured in this double trim methodology. Similarly, commenters recommended that CMS not apply a trim to hospital CCRs until it identifies the reasons for variations in CCRs and gives hospitals that have legitimate reasons for having higher CCRs adequate time to produce CCRs that are usable for converting costs to charges on the cost report. One commenter suggested that, instead of applying a trim, CMS evaluate CCRs on cost reports to identify misreported, erroneous values and not penalize hospitals that are accurately reporting information under a CMS-sanctioned methodology. The commenter recommended that if CMS intends to require that hospitals revise their charge structures and cost apportionment methodologies, CMS provide hospitals sufficient lead time to bring their systems in line with these requirements.

Several commenters provided alternative approaches to the CCR trim methodology. These commenters recommended using the ceiling derived from the 2014 CCRs, which was published in the FY 2015 IPPS/LTCH PPS final rule. Commenters also recommended that CMS use the sum of the operating and capital CCR ceilings because the CCRs derived in Worksheet C are based on both operating and capital costs. Under this methodology, the commenter-recommended ceiling for the first trim was 1.402 instead of 1.146 as proposed. Commenters also suggested that CMS truncate CCRs at the second trim ceiling unless a hospital's MAC validates the reported CCR.

Response: We appreciate the support and additional information provided by the commenters related to applying trims to the CCRs. We intend to further explore which trims are appropriate to apply to the CCRs on line 1 of Worksheet S–10, including whether it is appropriate to apply a unique trim to certain subsets of hospitals, such as All Inclusive Rate Providers. With regard to the comment recommending that CMS use the sum of the operating and capital CCR ceilings because the CCRs derived in Worksheet C are based on both operating and capital costs, after considering this matter, we agree that Worksheet C CCRs do reflect both the operating and capital costs of a hospital, and it may be appropriate to apply a CCR ceiling that is the sum of both the operating and capital CCRs. We intend to consider this recommendation further when preparing to use Worksheet S–10 data to compute Factor 3, and will undertake rulemaking in advance on this matter.

Other Related Comments

Comment: Several commenters expressed concern that the use of data from Worksheet S–10 to calculate uncompensated care costs does not take into account the Indian Health Service's (IHS') unique funding structure and therefore may jeopardize all of IHS's uncompensated care payments. The commenters stated that CMS has indicated that due to their unique funding structure, Indian Health Care Providers (IHCPs) do not have uncompensated care costs under Worksheet S–10. The commenters indicated that because funding for the costs of patient care is provided through congressional appropriations, all care is considered compensated, even though appropriations fund only approximately 59 percent of the health care needs for American Indians/Alaska Natives. The commenters also stated that many Tribes and Tribal organizations invest non-Federal resources in their health care programs to furnish care that could easily be classified as uncompensated care because IHCPs may not charge beneficiaries to receive care and thus, may not have the accounting methods to track these costs. As a result, the commenters stated that IHCP hospitals are currently unable to support charity care and non-Medicare bad debt consistent with the proposed definition of uncompensated care in the proposed rule. The commenters estimated that if the proposals in the proposed rule are finalized, they will decrease IHS's collections significantly, negatively impacting an already underfunded health system and leading to reduced quality of care and the loss of life.

Commenters acknowledged a previous conversation with CMS and IHS to attempt to resolve these issues, but requested that CMS engage in further analysis and meaningful Tribal consultation before issuing the final rule. The commenters stated that comments on the rulemaking process are not considered meaningful consultation per Executive Order 13175 or in CMS Tribal consultation policy approved December 5, 2015, and that additional Tribal consultation is necessary.

Response: We appreciate these comments and acknowledge that the use of data from Worksheet S–10 to calculate uncompensated care costs does not take into account the unique funding structure of IHS hospitals and therefore using these data to determine Factor 3 may have an unintended impact on the uncompensated care payments to these hospitals. We intend to continue working with IHS and

Tribal stakeholders to devise an appropriate solution for estimating uncompensated care for these facilities and will undertake further rulemaking as appropriate to address this issue.

Comment: One commenter requested that Puerto Rico hospitals be excluded from the use of Worksheet S–10 to calculate uncompensated care costs. The commenter noted that Puerto Rico's socioeconomic reality and the statutory treatment of its hospitals under Medicaid and Medicare Part A may result in an unintended penalty for its providers, and standard forms, data collections or categories may not be appropriate in Puerto Rico. As an alternative, the commenter supported delaying the use of Worksheet S–10 data to calculate Factor 3 for hospitals in Puerto Rico until disparities are corrected. The commenter requested that CMS work with Puerto Rico hospitals to conduct a specific study of uncompensated versus undercompensated care before moving away from the current uncompensated care formula.

Response: We understand the unique challenges faced by hospitals in Puerto Rico with regard to calculating uncompensated care costs. We note that we are finalizing our proposal to use a proxy for Medicare SSI days for hospitals in Puerto Rico for FY 2017. In the event that we continue to use Medicare SSI days as a proxy for uncompensated care in subsequent years, we anticipate that we would propose to continue to employ this proxy for Puerto Rico.

In summary, we are not finalizing our proposal to begin to incorporate Worksheet S–10 data into the computation of Factor 3 for FY 2018, and we are not finalizing the proposed regulations text changes at § 412.106(g)(C)(*4*) through (*7*) regarding FY 2018 and subsequent fiscal years. In light of the significant concerns expressed by commenters, we are postponing the decision regarding when to begin incorporating data from Worksheet S–10 and proceeding with revisions to the cost report instructions to address the commenters' concerns in an appropriate manner. We believe that revised Worksheet S–10 data will be available to use in the calculation of Factor 3 in the near future, and no later than FY 2021. With regard to how Factor 3 will be computed in FY 2018 and subsequent fiscal years, we intend to explore whether there is an appropriate proxy for uncompensated care that could be used to calculate Factor 3 until we determine that revised Worksheet S–10 data can be used for this purpose. We will undertake further notice-and-comment rulemaking to address the issue of the appropriate data to use to determine Factor 3 for FY 2018 and subsequent fiscal years. We also anticipate proposing to continue to use data from three cost reports to calculate Factor 3, as we are doing for the calculation of Factor 3 for FY 2017, which would have a transitioning effect as we described in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25091).

G. Hospital Readmissions Reduction Program: Updates and Changes (§§ 412.150 Through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act, added section 1886(q) to the Act, which establishes the ''Hospital Readmissions Reduction Program'' effective for discharges from ''applicable hospitals'' beginning on or after October 1, 2012. Under the Hospital Readmissions Reduction Program, payments to applicable hospitals may be reduced to account for certain excess readmissions. We refer readers to section IV.E.1. of the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) for a detailed discussion and additional information on of the statutory history of the Hospital Readmissions Reduction Program.

2. Regulatory Background

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676), we addressed the issues of the selection of readmission measures and the calculation of the excess readmissions ratio, which are used, in part, to calculate the readmissions adjustment factor. Specifically, in that final rule, we finalized policies that relate to the portions of section 1886(q) of the Act that address the selection of and measures for the applicable conditions, the definitions of ''readmission'' and ''applicable period,'' and the methodology for calculating the excess readmissions ratio. We also established policies with respect to measures for readmission for the applicable conditions and our methodology for calculating the excess readmissions ratio.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401), we finalized policies that relate to the portions of section 1886(q) of the Act that address the calculation of the hospital readmission payment adjustment factor and the process by which hospitals can review and correct their data. Specifically, in that final rule, we addressed the base operating DRG payment amount, aggregate payments for excess readmissions and aggregate payments for all discharges, the adjustment factor, applicable hospital, limitations on review, and reporting of hospital-specific information, including the process for hospitals to review readmission information and submit corrections. We also established a new Subpart I under 42 CFR part 412 (§§ 412.150 through 412.154) to codify rules for implementing the Hospital Readmissions Reduction Program.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676), we finalized our policies that relate to refinement of the readmissions measures and related methodology for the current applicable conditions, expansion of the ''applicable conditions'' for FY 2015 and subsequent fiscal years, and clarified the process for reporting hospital-specific information, including the opportunity to review and submit corrections. We also established policies related to the calculation of the adjustment factor for FY 2014.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048), we made refinements to the readmissions measures and related methodology for applicable conditions for FY 2015 and subsequent fiscal years, discussed the maintenance of technical specifications for quality measures, and described a waiver from the Hospital Readmissions Reduction Program for hospitals formerly paid under section 1814(b)(3) of the Act (§ 412.154(d)). We also specified the ''applicable period'' for FY 2015 and made changes to the calculation of the aggregate payments for excess readmissions to include two additional applicable conditions for the FY 2015 payment determination. Finally, we expanded the list of applicable conditions for the FY 2017 payment determination to include the Hospital-Level, 30-Day, All-Cause, Unplanned Readmission Following Coronary Artery Bypass Graft (CABG) Surgery measure.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543), we made a refinement to the pneumonia readmissions measure that expanded the measure cohort for the FY 2017 payment determination and subsequent years (80 FR 49532 through 49536); adopted an extraordinary circumstance exception policy to address hospitals that experience a disaster or other extraordinary circumstance beginning in FY 2016 and for subsequent years (80 FR 49542 through 49543); and specified the calculation of aggregate payments for excess readmissions for FY 2016 (80 FR 49537 through 49542).

3. Policies for the FY 2017 Hospital Readmissions Reduction Program

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25094 through 25098), we:

- Proposed that the public reporting of excess readmission ratios be posted on an annual basis to the *Hospital Compare* Web site as soon as is feasible following the preview period.
- Discussed the methodology to include the addition of the CABG applicable condition in the calculation of the readmissions payment adjustment for FY 2017.

We note that, during the comment period for the FY 2017 IPPS/LTCH PPS proposed rule, we received public comments that were not related to our specific proposals for the Hospital Readmissions Reduction Program and therefore considered out of the scope of the proposed rule. Some of the out of scope comments were related to a wide range of aspects of the Hospital Readmissions Reduction Program and its readmissions measures. For example, there were recommendations that we risk-adjust for socioeconomic and sociodemographic status; that statutory changes be made to the program payment structure and previously finalized program definitions; and that we consider adjusting for skilled nursing facilities' (SNF) quality in calculating scores under the Hospital Readmissions Reduction Program. While we appreciate the commenters' feedback, we consider these topics to be out of the scope of the proposed rule. Therefore, we are not addressing most of these comments in this final rule.

Comment: Several commenters appreciated that CMS did not propose new conditions or make substantial changes to the program in this year's rule and suggested that this may be an indication that further improvements in aggregate readmission rates may not be achievable.

Response: We appreciate the input and will take this feedback into consideration in future measure selection and rulemaking.

4. Maintenance of Technical Specifications for Quality Measures

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50039) for a discussion of the maintenance of technical specifications for quality measures for the Hospital Readmissions Reduction Program. Technical specifications of the readmission measures are provided on our Web site in the Measure Methodology Reports at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* Additional resources about the Hospital Readmissions Reduction Program and measure technical specifications are on the QualityNet Web site on the Resources page at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412995.*

We want to remind readers that, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49532), we discussed our policies regarding the use of sociodemographic factors in quality measures. We understand the important role that socioeconomic and sociodemographic status (SES/SDS) plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The National Quality Forum (NQF) is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

5. Applicable Period for FY 2017

Under section 1886(q)(5)(D) of the Act, the Secretary has the authority to specify the applicable period with respect to a fiscal year under the Hospital Readmissions Reduction Program. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671), we finalized our policy to use 3 years of claims data to calculate the readmission measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53675), we codified the definition of ''applicable period'' in the regulations at 42 CFR 412.152 as the 3-year period from which data are collected in order to calculate excess readmissions ratios and adjustments for the fiscal year, which includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49537), for FY 2016, consistent with the definition specified at § 412.152, we established an ''applicable period'' for the Hospital Readmissions Reduction Program of the 3-year period from July 1, 2011 through June 30, 2014. In other words, the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2016 were determined using data from the 3-year time period of July 1, 2011 through June 30, 2014.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25095), for FY 2017, consistent with the definition specified at § 412.152, we proposed that the ''applicable period'' for the Hospital Readmissions Reduction Program will be the 3-year period from July 1, 2012 through June 30, 2015. In other words, we proposed that the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2017 would be calculated using data from the 3-year time period of July 1, 2012 through June 30, 2015.

We did not receive public comments related to this proposal. Therefore, we are finalizing as proposed, without modification, the applicable period of the 3-year time period of July 1, 2012 to June 30, 2015 to calculate the excess readmission ratios and the readmission payment adjustment factors for FY 2017

under the Hospital Readmissions Reduction Program.

6. Calculation of Aggregate Payments for Excess Readmissions for FY 2017

Section 1886(q)(3)(B) of the Act specifies the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. It states that the ratio is equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions and (ii) the aggregate payments for all discharges. The definition of ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges,'' as well as a methodology for calculating the numerator of the ratio (aggregate payments for excess readmissions) and the denominator of the ratio (aggregate payments for all discharges) are codified at § 412.154(c)(2).

Section 1886(q)(4) of the Act sets forth the definitions of ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges'' for an applicable hospital for the applicable period. The term ''aggregate payments for excess readmissions'' is defined in section 1886(q)(4)(A) of the Act and § 412.152 of our regulations as, for a hospital for an applicable period, the sum, for applicable conditions of the product, for each applicable condition, of: (i) The base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the excess readmissions ratio for such hospital for such applicable period minus 1.

The excess readmissions ratio is a hospital-specific ratio calculated for each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmissions ratio as the ratio of ''risk-adjusted readmissions based on actual readmissions'' for an applicable hospital for each applicable condition, to the ''risk-adjusted expected readmissions'' for the applicable hospital for the applicable condition. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673) for additional information on the methodology for the calculation of the excess readmissions ratio. ''Aggregate payments for excess readmissions'' is the numerator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program.

The term ''aggregate payments for all discharges'' is defined at section 1886(q)(4)(B) of the Act as for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period. We codified this definition of ''aggregate payments for all discharges'' under the regulations at § 412.152. ''Aggregate payments for all discharges'' is the denominator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program.

The Hospital Readmissions Reduction Program currently includes the following five applicable conditions: Acute myocardial infarction (AMI), heart failure (HF), pneumonia (PN), total hip arthroplasty/total knee arthroplasty (THA/TKA), and chronic obstructive pulmonary disease (COPD). In the FY 2015 IPPS/LTCH PPS final rule effective for FY 2017 (79 FR 50033 through 50039), we finalized the inclusion of an additional applicable condition, Hospital-Level, 30-Day, All-Cause, Unplanned Readmission Following Coronary Artery Bypass Graft (CABG) Surgery.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25095 through 25098), we discussed the proposed methodology to include this additional measure in the calculation of the readmissions payment adjustment for FY 2017. Specifically, we proposed how the addition of CABG applicable conditions would be included in the calculation of the aggregate payments for excess readmissions (the numerator of the readmissions payment adjustment). We note that this proposal does not alter our established methodology for calculating aggregate payments for all discharges (that is, the denominator of the ratio).

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payments for the applicable period. ''Aggregate payments for excess readmissions'' (the numerator) is defined as the sum, for applicable conditions, of the product, for each applicable condition, of: (i) The base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the excess readmissions ratio for such hospital for such applicable period minus 1.

When determining the base operating DRG payment amount for an individual hospital for such applicable period for such condition, we use Medicare inpatient claims from the MedPAR file with discharge dates that are within the same applicable period to calculate the excess readmissions ratio. We use MedPAR claims data as our data source for determining aggregate payments for excess readmissions and aggregate payments for all discharges, as this data source is consistent with the claims data source used in IPPS rulemaking to determine IPPS rates.

For FY 2017, we proposed to use MedPAR claims with discharge dates that are on or after July 1, 2012, and no later than June 30, 2015, consistent with our historical use of a 3-year applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source (that is, the March updates of the respective Federal fiscal year MedPAR files) for the final rules.

The FY 2012 through FY 2015 MedPAR data files can be purchased from CMS. Use of these files allows the public to verify the readmissions adjustment factors. Interested individuals may order these files through the CMS Web site at: *http://www.cms.hhs.gov/LimitedDataSets/* by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the files and provides directions and detailed instructions for how to order the data sets.

In the proposed rule, for FY 2017, we proposed to determine aggregate payments for excess readmissions and aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2012, and no later than June 30, 2015. However, we noted that, for the purpose of modeling the proposed FY 2017 readmissions payment adjustment factors for the proposed rule, we used excess readmissions ratios for applicable hospitals from the FY 2016 Hospital Readmissions Reduction Program applicable period. For this FY 2017 IPPS/LTCH PPS final rule, applicable hospitals have had the opportunity to review and correct data from the proposed FY 2017 applicable period of July 1, 2012 to June 30, 2015, before they are made public under our policy regarding the preview and reporting of hospital-specific information, which we discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401).

For FY 2017, we proposed to use MedPAR data from July 1, 2012 through June 30, 2015. Specifically, for the proposed rule, we used the March 2013 update of the FY 2012 MedPAR file to identify claims within FY 2012 with discharges dates that are on or after July 1, 2012, the March 2014 update of the FY 2013 MedPAR file to identify claims within FY 2013, the March 2015 update of the FY 2014 MedPAR file to identify

claims within FY 2014, and the December 2015 update of the FY 2015 MedPAR file to identify claims within FY 2015 with discharge dates no later than June 30, 2015. For this final rule, as we proposed, we used the same MedPAR files as listed above for claims within FY 2012, FY 2013 and FY 2014, and for claims within FY 2015, we used the March 2016 update of the FY 2015 MedPAR file.

For a discussion of how we identified the applicable conditions to calculate the aggregate payments for excess readmissions for FY 2016, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49538 through 49541). For FY 2017, with the addition of the CABG measure to the applicable conditions under the Hospital Readmissions Reduction Program, we proposed to follow this same approach.

In the proposed rule, for FY 2017, we proposed to continue to apply the same exclusions to the claims in the MedPAR file as we applied for FY 2016 for the AMI, HF, PN, THA/TKA, and COPD applicable conditions. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49539) for a list of these exclusions. Updates to these exclusions will be posted on the QualityNet Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology.

In addition to the exclusions described above, for FY 2017, we proposed the following steps to identify admissions specifically for CABG for the purposes of calculating aggregate payments for excess readmissions. These exclusions were previously finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50037):

- Admissions for patients who are discharged against medical advice (excluded because providers do not have the opportunity to deliver full care and prepare the patient for discharge);
- Admissions for patients who die during the initial hospitalization (these patients are not eligible for readmission);
- Admissions for patients with subsequent qualifying CABG procedures during the measurement period (a repeat CABG procedure during the measurement period very likely represents a complication of the original CABG procedure and is a clinically more complex and higher risk surgery; therefore, we select the first CABG admission for inclusion in the measure and exclude subsequent CABG admissions from the cohort); and
- Admissions for patients without at least 30 days post-discharge enrollment in Medicare FFS (excluded because the 30-day readmission outcome cannot be assessed in this group).

As noted previously, these exclusions are consistent with our current methodology, and any updates to these exclusions will be posted on the QualityNet Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology.

Furthermore, under our proposal, we would only identify Medicare FFS claims that meet the criteria (that is, claims paid for under Medicare Part C, Medicare Advantage, would not be included in this calculation), consistent with the methodology to calculate excess readmissions ratios based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2017, we proposed to continue to exclude admissions for patients enrolled in Medicare Advantage as identified in the Medicare Enrollment Database. This policy is consistent with how admissions for Medicare Advantage patients are identified in the calculation of the excess readmissions ratios under our established methodology.

In order to identify the admissions for each applicable condition for FY 2017 to calculate the aggregate payments for excess readmissions for an individual hospital, we proposed to identify each applicable condition, including the CABG condition, using the appropriate ICD–9–CM codes. (Although the compliance date for the ICD–10–CM and ICD–10–PCS code sets was October 1, 2015, the proposed policies apply to data submitted prior to this compliance date.) Under our existing policy, we identify eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital having a principal diagnosis for the measured condition in an applicable period (76 FR 51669). The discharge diagnoses for each applicable condition are based on a list of specific ICD–9–CM codes for that condition. The ICD–9–CM codes for the AMI, HF, PN, THA/TKA, COPD, and CABG applicable conditions can be found on the QualityNet Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology. Consistent with our established policy (76 FR 51673 through 51676), we proposed to use the ICD–9–CM codes to identify the applicable conditions in calculation of the excess readmissions ratios, which are provided in the measure methodology reports on the QualityNet Web site, to identify each applicable condition to calculate the aggregate payments for the excess readmissions ratios for FY 2017. For a complete list of the ICD–9–CM codes we proposed to use to identify the applicable conditions, we refer readers to the following tables of those reports:

- 2015 Measure Updates: AMI, HF, Pneumonia, COPD, Stroke Readmission (*AMI—Version 8.0, HF—Version 8.0, Pneumonia—Version 8.0, COPD—Version 4.0, and Stroke—Version 4.0: 2015 Condition-Specific Readmission Measures Updates and Specifications Report*)—

++ Table D.1.1—ICD–9–CM Codes for AMI Cohort (page 74).
++ Table D.2.1—ICD–9–CM Codes for HF Cohort (page 78).
++ Table D.3.1—ICD–9–CM Codes for Pneumonia Cohort (page 82).
++ Table D.4.1—ICD–9–CM Codes for COPD Cohort (page 87).

- 2015 Measure Updates: THA/TKA and CABG Readmission (*THA and/or TKA—Version 4.0, CABG—Version 2.0: 2015 Procedure-Specific Readmission Measures Updates and Specifications Report*)—

++ Table D.1.1—ICD–9–CM Codes Used to Identify Eligible THA/TKA Procedures (page 45).
++ Table D.2.1—ICD–9–CM Codes Used to Identify Eligible CABG Procedures (page 53).

For FY 2017, we proposed to calculate aggregate payments for excess readmissions, using MedPAR claims from July 1, 2012 to June 30, 2015, to identify applicable conditions based on the same ICD–9–CM codes used to identify the conditions for the readmissions measures, and to apply the proposed exclusions for the types of admissions (as previously discussed). To calculate aggregate payments for excess readmissions for each hospital, we proposed to calculate the base operating DRG payment amounts for all claims in the 3-year applicable period for each applicable condition (AMI, HF, PN, COPD, THA/TKA, and CABG) based on the claims we have identified as described above. Once we have calculated the base operating DRG amounts for all the claims for the six applicable conditions, we proposed to sum the base operating DRG payments amounts by each condition, resulting in six summed amounts, one amount for each of the six applicable conditions. We proposed to then multiply the amount for each condition by the respective excess readmissions ratio minus 1 when that excess readmissions ratio is greater than 1, which indicates that a hospital has performed, with respect to readmissions for that

applicable condition, worse than the average hospital with similar patients. Each product in this computation represents the payments for excess readmissions for that condition. We proposed to then sum the resulting products which represent a hospital's proposed ''aggregate payments for excess readmissions'' (the numerator of the ratio). Because this calculation is performed separately for each of the six conditions, a hospital's excess readmissions ratio must be less than or equal to 1 on each measure to avoid CMS' determination that there were payments made by CMS for excess readmissions (resulting in a payment reduction under the Hospital Readmissions Reduction Program). In other words, in order to avoid a payment reduction a hospital's excess readmissions ratio must be less than or equal to 1 on each measure. We note that we did not propose any changes to our existing methodology to calculate ''aggregate payments for all discharges'' (the denominator of the ratio).

Section 1886(q)(3)(A) of the Act defines the ''adjustment factor'' for an applicable hospital for a fiscal year as equal to the greater of: (i) The ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C). Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions and (ii) the aggregate payments for all discharges. The calculation of this ratio is codified at § 412.154(c)(1) of the regulations and the floor adjustment factor is codified at § 412.154(c)(2) of the regulations. Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, codified at § 412.154(c)(2), for FY 2017, the adjustment factor is either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2017, a hospital subject to the Hospital Readmissions Reduction Program will have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

We proposed the following methodology for FY 2017 as displayed in the chart below.

FORMULAS TO CALCULATE THE READMISSIONS ADJUSTMENT FACTOR FOR FY 2017

AGGREGATE PAYMENTS FOR EXCESS READMISSIONS = [sum of base operating DRG payments for AMI × (Excess Readmissions Ratio for AMI − 1)] + [sum of base operating DRG payments for HF × (Excess Readmissions Ratio for HF − 1)] + [sum of base operating DRG payments for PN × (Excess Readmissions Ratio for PN − 1)] + [sum of base operating DRG payments for COPD) × (Excess Readmissions Ratio for COPD − 1)] + [sum of base operating DRG payments for THA/TKA × (Excess Readmissions Ratio for THA/TKA − 1)] + [sum of base operating DRG payments for CABG × (Excess Readmissions Ratio for CABG − 1)].

* We note that if a hospital's excess readmissions ratio for a condition is less than/equal to 1, there are no aggregate payments for excess readmissions for that condition included in this calculation.

AGGREGATE PAYMENTS FOR ALL DISCHARGES = sum of base operating DRG payments for all discharges.

RATIO = 1 − (Aggregate payments for excess readmissions/Aggregate payments for all discharges).

Proposed Readmissions Adjustment Factor for FY 2017 is the higher of the ratio or 0.9700.

* Based on claims data from July 1, 2012 to June 30, 2015 for FY 2017.

We invited public comment on these proposals.

Comment: Commenters supported the proposed calculation for the new CABG readmission measure, and program efforts to maintain focus on cardiology and cardiovascular care. Another commenter noted that the proposed calculation will include the CABG readmission measure in the payment formula in alignment with other program measures. One commenter expressed concern that the addition of the CABG measure may result in double counting of cases under both CABG and AMI, and recommended that cases should only count under either AMI or CABG to prevent double counting.

Response: We appreciate the commenters' support and will continue to monitor and analyze the impact of our measure selection for further adjustments to the Hospital Readmissions Reduction Program. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53376) for further discussion on preventing double counting.

We are finalizing, as proposed and without modification, the methodology to include the addition of the CABG applicable condition in the calculation of the readmissions payment adjustment for FY 2017.

7. Extraordinary Circumstance Exception Policy

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543) for a detailed discussion of our Extraordinary Circumstance Exception policy for the Hospital Readmissions Reduction Program.

During the review of a hospital's request for an extraordinary circumstance exception, we maintain the general principle that providing high quality of care and ensuring patient safety is of paramount importance. We intend to provide relief only for hospitals whose ability to accurately or timely submit all of their claims (from which readmission measures data are derived) has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of the hospital. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543) we finalized that the request process for an extraordinary circumstance exception begins with the submission of an extraordinary circumstance exception request form by a hospital within 90 calendar days of the natural disaster or other extraordinary circumstance. Under this policy, a hospital is able to request a Hospital Readmissions Reduction Program extraordinary circumstance exception at the same time it may request a similar exception under the Hospital IQR Program, the Hospital VBP Program, and the HAC Reduction Program. The extraordinary circumstance exception request form is available on the QualityNet Web site.

The following information is required to submit the request:

- Hospital CCN;
- Hospital name;
- Hospital Chief Executive Officer (CEO) and any other designated personnel contact information, including name, email address, telephone number, and mailing address (must include a physical address; a post office box address is not acceptable);
- Hospital's reason for requesting an exception, including:

++ CMS program name (for example, the Hospital Readmissions Reduction

Program, the Hospital VBP Program, or the Hospital IQR Program);

++ The measure(s) and submission quarters affected by the extraordinary circumstance that the hospital is seeking an exception for should be accompanied with the specific reasons why the exception is being sought; and

++ How the extraordinary circumstance negatively impacted performance on the measure(s) for which an exception is being sought;

• Evidence of the impact of the extraordinary circumstances, including but not limited to, photographs, newspaper, and other media articles; and

• The request form must be signed by the hospital's CEO or designated non-CEO contact and submitted to CMS.

The same set of information is currently required under the Hospital IQR Program and the Hospital VBP Program on the request form from a hospital seeking an extraordinary circumstance exception with respect to these programs. The specific list of required information is subject to change from time to time at the discretion of CMS.

Following receipt of the request form, CMS will: (1) Provide a written acknowledgement of receipt of the request using the contact information provided in the request form to the CEO and any additional designated hospital personnel; and (2) provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of our decision. We review each request for an extraordinary circumstance exception on a case-by-case basis at our discretion. To the extent feasible, we also review requests in conjunction with any similar requests made under other IPPS quality reporting and payment programs, such as the Hospital IQR Program and the Hospital VBP Program.

This policy does not preclude CMS from granting extraordinary circumstance exceptions to hospitals that do not request them if we determine at our discretion that a disaster or other extraordinary circumstance has affected an entire region or locale. If CMS makes such a determination to grant an extraordinary circumstance exception to hospitals in an affected region or locale, we would convey this decision through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet Web site. This provision aligns with the Hospital IQR Program's extraordinary circumstances extensions or exemptions policy.

8. Timeline for Public Reporting of Excess Readmission Ratios on *Hospital Compare* for the FY 2017 Payment Determination

Section 1886(q)(6) of the Act requires the Secretary to make information available to the public regarding readmission rates of each subsection (d) hospital under the program, and states that such information shall be posted on the *Hospital Compare* Internet Web site in an easily understandable format. Accordingly, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53401), we indicated that public reporting for excess readmission ratios could be available on the *Hospital Compare* Web site as early as mid-October. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25098), we clarified that public reporting of excess readmission ratios will be posted on an annual basis to the *Hospital Compare* Web site as soon as is feasible following the review period. This may occur as early as October, but it could occur later for a particular year in order to streamline reporting and align with other hospital quality reporting and performance programs.

Comment: Numerous commenters urged CMS to continue to ensure there is an adequate period of at least 30 days for hospitals to review their rate calculations and make necessary corrections before the rates are publicly displayed. One commenter supported the opportunities to allow hospitals to review their readmission data in a timelier fashion as part of the formal review period. Several commenters requested that CMS calculate and more frequently report to hospitals their performance on the readmission measures.

Response: We appreciate the commenters' input and support. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51672 through 51673), we adopted the same preview and correction process and timeframe used for subsection (d) hospitals for the rates calculated for the Hospital Readmissions Reduction Program. That is, we provide hospitals with an opportunity to preview their readmission rates for 30 days prior to posting them on the *Hospital Compare* Web site. We note that hospitals have the opportunity to correct the rate calculations and not the underlying data. This process meets the statutory requirement in section 1886(q)(6)(B) of the Act which requires the Secretary to ensure that a subsection (d) hospital has the opportunity to review and submit corrections before the information is made public. In addition to the statutory requirements, we also considered hospitals' experience with the measure and the data production timeline when proposing the 30-day preview period. While the Hospital Readmissions Reduction Program is fairly new, subsection (d) hospitals are already familiar with the three 30-day risk-standardized readmission measures that the program uses to determine payment adjustment. Because hospitals are working with measures in which they have prior experience from the Hospital IQR Program, we believe that a 30-day preview period is sufficient for hospitals to review and correct their excess readmission ratios.

Due to the complexity of these measures and the need for bootstrapping in measure calculations, significant programming resources are required. It takes several months to complete the production and extensive quality assurance procedures needed to calculate results for more than 3,500 hospitals. As a result, we will not be able to begin the preview period earlier than late June. Also, we will not be able to extend the preview period to more than 30 days. This is because if hospitals find data problems that we determine to be attributable to our calculation or programming errors, we will need adequate time between mid-July and the end of September to: (1) Recalculate the excess readmission ratios; (2) regenerate and redisseminate corrected results to hospitals in time for payment adjustment in early October (the beginning of the subsequent fiscal year); and (3) publicly report the excess readmission ratios on the *Hospital Compare* Web site to meet the statutory reporting requirements under section 1886(q)(6) of the Act.

Comment: A few commenters asked that CMS establish a regular deadline for the release of annual data on hospital excess readmission ratios and also make clear when the data will be made available to the public on the *Hospital Compare* Web site. One commenter specifically requested that excess readmission ratios be posted to the *Hospital Compare* Web site more often than annually and prior to October.

Response: We appreciate the commenters' feedback. The public reporting of excess readmission ratios will be posted on an annual basis to the *Hospital Compare* Web site as soon as is feasible following the review period. This may occur as early as October, but it could occur later for a particular year in order to streamline reporting and align with other hospital quality reporting and performance programs.

After consideration of the public comments we received, we are finalizing the clarification that the public reporting of excess readmission ratios will be posted on an annual basis to the *Hospital Compare* Web site as soon as is feasible following the preview period.

H. Hospital Value-Based Purchasing (VBP) Program: Policy Changes for the FY 2018 Program Year and Subsequent Years

1. Background

a. Statutory Background and Overview of Past Program Years

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660); the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50676 through 50707); the CY 2014 OPPS/ASC final rule (78 FR 75120 through 75121); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087); and the FY 2016 IPPS/LTCH PPS final rule with comment period (80 FR 49544 through 49570).

We also have codified certain requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

b. FY 2017 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573) and refer readers to that rule for further details.

Under section 1886(o)(7)(C)(iv) of the Act, the applicable percent for the FY 2017 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2017 is approximately $1.8 billion, based on the March 2016 update of the FY 2015 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule, we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS) (77 FR 53573 through 53576). We will then calculate a value-based incentive payment adjustment factor that will be applied to the base operating DRG payment amount for each discharge occurring in FY 2017, on a per-claim basis. We are publishing proxy value-based incentive payment adjustment factors in Table 16A associated with this final rule (which is available via the Internet on the CMS Web site). The proxy factors are based on the TPSs from the FY 2016 program year. These FY 2016 performance scores are the most recently available performance scores that hospitals have been given the opportunity to review and correct. The updated slope of the linear exchange function used to calculate those proxy value-based incentive payment adjustment factors is 2.7717318150. This slope, along with the estimated amount available for value-based incentive payments, is also published in Table 16A.

After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2017, we will add Table 16B (which will be available via the Internet on the CMS Web site) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2017 program year. We expect that Table 16B will be posted on the CMS Web site in October 2016.

2. PSI 90 Measure in the FY 2018 Program and Future Program Years

a. PSI 90 Measure Performance Period Change for the FY 2018 Program Year

We previously finalized the performance period for the PSI 90: Patient Safety for Selected Indicators (Composite Measure) (then referred to as both the ''PSI 90 measure'' and the ''AHRQ PSI Composite Measure'') for the FY 2018 program year (78 FR 50694). We have calculated and finalized performance standards for the FY 2018 program year based on a baseline period that uses ICD–9–CM claims data. The previously finalized performance period for the FY 2018 program year runs from July 1, 2014 through June 30, 2016. Because hospitals began ICD–10–CM/PCS implementation on October 1, 2015, the performance period as currently finalized for the FY 2018 program year would necessitate using both ICD–9 and ICD–10 claims data to calculate performance standards for the PSI 90 measure.

Since the ICD–10 transition was implemented on October 1, 2015, we have been monitoring our systems, and claims are processing normally. Currently, the measure steward, AHRQ, is reviewing any potential issues related to ICD–10 conversion of coded operating room procedures (*https://www.cms.gov/icd10manual/fullcode_cms/P1616.html*), which directly impact the AHRQ PSI 90 component indicators. Nevertheless, given the complexity of converting the PSI 90 component indicators from ICD–9 to ICD–10 and considering that there are approximately 70,000 [24] ICD–10 codes, the measure steward has recommended against combining measure performance data that use both ICD–9 and ICD–10 data at this time. In addition, to meet program requirements and implementation schedules, our system requires an ICD–10 risk-adjusted version of the AHRQ QI PSI software [25] by December 2016 for use in the FY 2018 payment year. However, AHRQ needs a full year of nationally representative ICD–10 coded data before it can complete development of risk-adjusted models based on a national reference population. At this time, a risk adjusted ICD–10 version of the modified PSI 90 software is not expected to be available until late CY 2017. We refer readers to section VIII.A.6.b. of the preamble of this final rule relating to the Hospital IQR Program for a discussion of the modified PSI 90 measure update.

To address the above issues, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25099 through 25100), we proposed to shorten the performance period for the FY 2018 program year. We proposed

[24] International Classification of Diseases (ICD–10–CM/PCS) Transition—Background. Available at: *http://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm*.

[25] The AHRQ QI Software is the software used to calculate PSIs and the composite measure. More information is available at: *http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf*.

to use a 15-month performance period from July 1, 2014 through September 30, 2015 for the FY 2018 program year. The 15-month performance period would only apply to the FY 2018 program year and would only use ICD–9 data. For the FY 2018 program year, the performance standards that were previously established and announced in past rules would not change because they were calculated based on the baseline period of July 1, 2010 through June 30, 2012, which would remain the same. In order to align the use of this measure with other hospital quality programs, we proposed (and are finalizing) similar modifications to the FY 2018 reporting period for the PSI 90 measure for the HAC Reduction Program, as discussed in section IV.I.3.b. of the preamble of this final rule, and for the Hospital IQR Program, as discussed in section VIII.A.6.b.(4) of the preamble of this final rule.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25100), we discussed that we are aware that the FY 2019 program year also has a performance period that contains ICD–9 and ICD–10 data and that we would continue to review our options for calculating the performance period for the FY 2019 program year and further address this in next year's rulemaking. Because an ICD–10 version of the current PSI 90 is not being developed, we intend to propose to remove the PSI 90 measure from the Hospital VBP Program beginning with the FY 2019 program year in next year's rulemaking.

We noted that in proposing a shortened performance period for the PSI 90 measure, a prior reliability analysis of the PSI 90 measure showed that the majority of hospitals attain a moderate or high level of reliability for the PSI 90 measure after a 12-month period.[26] Further, this reliability analysis is based on older data that does not include improvements in present on admission (POA) coding, which is likely to improve reliability. We believe that the data we will collect is likely to be reliable during a 15-month performance period. We do not anticipate any delay for hospitals to review their TPSs for the FY 2018 program year during the review and correction period.

Prior to deciding to propose an abbreviated performance period for the FY 2018 program year, we took several factors into consideration, including the recommendations of the measure steward, the feasibility of using a combination of ICD–9 and ICD–10 data without the availability of the appropriate measure software, minimizing provider burden, program implementation timelines, and the reliability of using shortened performance periods, as well as the importance of continuing to publicly report this measure. We stated our belief that using a 15-month performance period for FY 2018 best serves the need to provide important information on hospital patient safety and adverse events by allowing sufficient time to process the claims data and calculate the measures, while minimizing the reporting burden and program disruption.

Furthermore, we stated that we plan to propose to adopt the modified PSI 90 measure, which includes several substantive measure updates, for the Hospital VBP Program in subsequent rulemaking, as soon as it is feasible. We discussed this future proposed adoption in section IV.H.2.b. of the preamble of the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25100) and reaffirm this intention in section IV.H.2.b. of the preamble of this final rule.

We invited public comments on this proposed plan to shorten the performance period for the PSI 90 measure for the FY 2018 program year.

Comment: A few commenters supported the proposal to adopt a 15-month performance period for FY 2018 to account for the transition from ICD–9–CM to ICD–10–CM/PCS.

Response: We thank the commenters for their support.

Comment: Many commenters did not support the proposal to shorten the performance period for PSI 90 in the FY 2018 program year to 15 months of data because commenters are concerned that shortening the performance period will degrade the measure's reliability. In addition, several commenters were concerned that only 81 percent of hospitals achieve median reliability with 12 months of data and 86 percent achieve median reliability with 18 months of data. Many commenters recommended suspending or removing the use of PSI 90 in the Hospital VBP Program beginning with the FY 2018 program year. Some commenters also recommended suspending or removing the measure for at least the FY 2018 and FY 2019 program years because of the inability to calculate the measure using ICD–10 data. One commenter recommended that CMS change the PSI 90 performance period to a 24-month performance period (October 1, 2013 through September 30, 2015) because this commenter believed that 24 months would ensure the measure results are more reliable and enable the use of only ICD–9–CM data.

Response: We note that the measure reliability analysis the commenters have cited does not apply a case minimum threshold like the one the Hospital VBP Program applies. Thus, we believe that a 15-month performance period is sufficiently reliable, particularly in light of the case minimum of three cases for any of the underlying PSI 90 indicators as finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53609). Because we believe the measure is sufficiently reliable with 15 months of data, we do not believe we need to suspend or remove the measure or extend the measure's performance period for the FY 2018 program year. We appreciate the commenter's suggestion that we use October 1, 2013 to September 30, 2015 as a 24-month performance period for the PSI 90 measure in the FY 2018 program year, but it overlaps substantially with the performance period for the PSI 90 measure in the FY 2017 program year (which runs from October 1, 2013 to June 30, 2015 (78 FR 50692)).

Comment: Many commenters did not support shortening the performance period for the FY 2018 program year because commenters believe there are numerous flaws in the measure, including gaming, selective reporting, and surveillance/ascertainment bias. Several commenters recommended that CMS remove the PSI 90 measure from the program and replace it with more reliable measures of patient safety. One commenter recommended that if CMS retains the PSI 90 measure in the FY 2018 program year, CMS change the measure so that the PSI 07 Central Venous Catheter-related Bloodstream Infection Rate excludes cases with a length of stay of less than 2 days. This commenter further recommended extending the length of stay exclusion criterion for PSI 07 Central Venous Catheter-related Bloodstream Infection Rate to 4 days to remain consistent with the length of stay outlined in other PSI components.

Response: We thank the commenters for their suggestions, but we do not believe the PSI 90 measure is flawed. The PSI 90 measure was developed using a scientifically rigorous process that involved the input of technical experts and stakeholders. Further, AHRQ has supported a series of validation studies, based on detailed abstraction of medical records, that have informed AHRQ's PSI development process, including making further refinements to indicators and working

[26] Mathematica Policy Research (November 2011). Reporting period and reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf.*

with others to improve coding practices. We refer commenters to the AHRQ PSI Development zip file and AHRQ Composite Measures Workgroup document available at: *http://www.qualityindicators.ahrq.gov/modules/psi_resources.aspx.* We believe that the PSI 90 measure in its current form is reliable, valid, and appropriate to retain in the Hospital VBP Program for the FY 2018 program year because it appropriately encourages robust hospital attention to patient safety. We also believe that the length of stay exclusion criterion of 2 days in the PSI 07 Central Venous Catheter-related Bloodstream Infection Rate is adequate because positive blood cultures within the first 2 days of admission are likely to reflect a bloodstream infection that was present on admission, rather than a bloodstream infection associated with care provided by the hospital. We note that the modified PSI 90 no longer includes PSI 07 Central Venous Catheter-related Bloodstream Infection Rate. However, AHRQ plans to maintain PSI 07 Central Venous Catheter-related Bloodstream Infection Rate as a separate PSI and it is included in an 11-indicator version of PSI 90 that is not NQF-endorsed. Suggestions regarding potential PSI measure revisions can be made directly to: *QISupport@ahrq.hhs.gov.*

Comment: A few commenters did not support the continued use of the PSI 90 measure in the Hospital VBP Program for the FY 2018 and FY 2019 program years because the Hospital VBP Program will be misaligned with the Hospital IQR Program and the HAC Reduction Program, which have both proposed to adopt the modified PSI 90 measure in the FY 2017 IPPS/LTCH PPS proposed rule. A few commenters recommended that CMS adopt the modified PSI 90 measure in the Hospital VBP Program beginning with the FY 2018 program year.

Response: We thank the commenters for their suggestions, but we note that we are unable to adopt the modified PSI 90 measure beginning with the FY 2018 program year due to certain statutory requirements in the Hospital VBP Program that are not required in the Hospital IQR Program or the HAC Reduction Program. As we noted in the proposed rule, section 1886(o)(2)(A) of the Act requires the Hospital VBP Program to select measures that have been specified for the Hospital IQR Program. The Hospital IQR Program is finalizing the modified PSI 90 measure in this FY 2017 IPPS/LTCH PPS final rule (see section VIII.A.6.b. of the preamble of this final rule). In addition, section 1886(o)(2)(C)(i) of the Act requires the Hospital VBP Program to refrain from beginning the performance period for a new measure until data on the measure have been posted on *Hospital Compare* for at least one year. The Hospital IQR Program is finalizing the modified PSI 90 measure in this final rule but measure data have not yet been posted on *Hospital Compare,* and we are required to wait one full year after data has been posted before that measure's performance period may begin in the Hospital VBP Program. Finally, section 1886(o)(3)(C) of the Act requires that the Hospital VBP Program establish performance standards for each measure not later than 60 days prior to the beginning of the performance period. We anticipate adopting the modified PSI 90 measure in future rulemaking as soon as we have met the statutory requirements laid out in the Act.

Comment: One commenter expressed concern with the currently adopted PSI 90 measure because it may penalize hospitals that have a robust surveillance program or that have strict policies on what physicians include in their notes.

Response: We acknowledge commenter's concerns regarding the currently adopted PSI 90, but note that there is little evidence that hospitals that may have a less robust surveillance program underreport diagnoses for the PSI 90 indicators. Further, there is high degree of sensitivity (true positives) with respect to indicator diagnoses among hospitals.

Comment: Numerous commenters requested that we remove the currently adopted version of the PSI 90 measure. Specifically, many commenters noted that using the currently adopted version of the measure in the Hospital VBP Program would not align with the Hospital IQR Program and the HAC Reduction Program, both of which are using the modified PSI 90 measure in their programs.

Response: While we understand commenters' concerns, we have decided to retain the currently adopted version of the PSI 90 measure for the FY 2018 program year because we have the option to shorten the performance period so that performance standards can be calculated using the ICD–9 AHRQ QI software. We believe that this measure meets the program goal of providing important information on hospital performance on patient safety and adverse events. We recognize that the performance period for the current PSI 90 measure cannot be shortened in the FY 2019 program year because ICD–10 AHRQ QI software for the currently adopted measure will not be available. In light of this, we intend to propose to remove the PSI 90 measure from the Hospital VBP Program beginning with the FY 2019 program year in next year's rulemaking. We also intend to propose to adopt the modified PSI 90 measure for the Hospital VBP Program in future rulemaking as soon as it is feasible, which we discuss further in section IV.H.2.b. of the preamble of this final rule.

After consideration of the public comments we received, we are finalizing the proposal to shorten the performance period for the PSI 90 measure for the FY 2018 program so that it runs from July 1, 2014 through September 30, 2015 as proposed.

b. Intent To Propose in Future Rulemaking To Adopt the Modified PSI 90 Measure

The PSI 90 measure underwent NQF maintenance review in 2014. The 2014 NQF maintenance review process led to several measure changes.[27] Due to statutory requirements [28] in the Hospital VBP Program, we would not be able to adopt the NQF-endorsed modified PSI 90 measure, now known as Patient Safety and Adverse Events Composite, until a future program year. We refer readers to section VIII.A.6.b. of the preamble of this final rule relating to the Hospital IQR Program for a discussion of the modified PSI 90 measure update.

Comment: Several commenters supported CMS' intent to propose to adopt the modified PSI 90 measure. One commenter specifically supported the modified specification of component indicators PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate and PSI 15 Unrecognized Abdominopelvic Accidental Puncture/Laceration Rate as well as the removal of PSI 07 Central Venous Catheter-related Bloodstream Infection Rate. One commenter encouraged CMS to adopt the modified PSI 90 measure as soon as possible because this measure has been reendorsed by the NQF following modification. One commenter noted

[27] National Quality Forum QPS Measure Description for ''Patient Safety for Selected Indicators (modified version of PSI90) (Composite Measure)'' found at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3.*

[28] First, section 1886(o)(2)(A) of the Act requires the Program to select measures that have been specified for the Hospital IQR Program. Second, section 1886(o)(2)(C)(i) of the Act requires the Hospital VBP Program to refrain from beginning the performance period for a new measure until data on the measure have been posted on *Hospital Compare* for at least one year. Finally, section 1886(o)(3)(C) of the Act requires that the Hospital VBP Program establish performance standards for each measure not later than 60 days prior to the beginning of the performance period.

that the modifications to the measure identify harmful healthcare events that are potentially preventable. One commenter believed that the modified measure addresses prior concerns including the weighting of components, issues with public reporting, and biases in the distribution of incentive payments.

Response: We thank commenters for their support of our intent to propose the modified PSI 90 in future rulemaking.

Comment: Several commenters expressed concern that the software hospitals use to monitor and assess their performance has not yet been updated to reflect ICD–10 coding, which hinders hospitals' ability to monitor performance and continually improve their quality of care. The commenter urged CMS to work with AHRQ to update the software as soon as possible.

Response: We acknowledge the comments received and are working with AHRQ to have the ICD–10 measure software available as soon as possible.

Comment: Several commenters recommended that CMS reevaluate the PSI 90 measure for appropriateness in the program because it is susceptible to surveillance bias, measures components that may not be preventable through evidence-based practices, lacks appropriate and necessary exclusions associated primarily with large academic centers, and is based on administrative claims data that do not capture the full scope of patient-level risk factors. The commenters also believe that it may disproportionately impact teaching hospitals because they tend to have a larger volume of surgical cases.

Response: While we acknowledge commenters' preference for chart-abstracted measures, administrative claims data are valid for quality measurement and significantly less burdensome on hospitals for quality reporting. Many teaching hospitals do as well or better on the measure than non-teaching hospitals, and many of the PSI components are preventable through evidenced-based practices. We have previously addressed commenters' concerns regarding the use of administrative claims, coding issues, and the impact on academic hospitals. We refer commenters to this discussion in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50684) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50064).

Comment: One commenter did not support CMS' intent to propose to adopt the modified PSI 90 measure because this commenter believed the measure, despite modifications, continues to lack the level of accuracy, reliability, and validity necessary to ascertain high-performing facilities.

Response: We acknowledge commenter's concerns and will consider them when we consider a future proposal to adopt the modified PSI 90 measure for the Hospital VBP Program. We refer the commenter to section VIII.A.6.b. of the preamble of this final rule where we discuss the modified PSI 90 and similar concerns in the context of the Hospital IQR Program, including why we believe the modified PSI 90 is sufficiently accurate, reliable, and valid, and section IV.I.3.a. of the preamble of this final rule in the context of the HAC Reduction Program.

Comment: One commenter did not support CMS' intent to propose to adopt the modified PSI 90 measure because the commenter believed that the modified measure does not take into account clinical considerations involved in transplant surgery. The commenter noted that the risk adjustment methodology is not specific to transplantation and lacks adjustments for severity of illness and donor characteristics. Specifically, the commenter stated that the PSI 09 Postoperative Hemorrhage or Hematoma Rate component indicator of the measure does not properly exclude transplant patients, which is inappropriate because perioperative hemorrhage or hematoma is common after liver, kidney, and many other transplants despite high quality care. Further, the commenter stated that the PSI 10 Postoperative Acute Kidney Injury Rate component indicator inappropriately includes liver transplant patients, many of whom develop acute renal failure after a transplant despite high quality care.

The commenter stated that the PSI 11 Postoperative Respiratory Failure Rate component indicator inappropriately includes liver and kidney transplant patients, many of whom have high incidences of acute respiratory failure, mechanical ventilation, and reintubation after a transplant despite high quality care. Finally, the commenter stated that the PSI 12 Perioperative PE or DVT Rate component indicator inappropriately includes liver and kidney transplant patients, many of whom develop deep vein thrombosis despite high quality care.

Response: We acknowledge commenter's concerns and will share the feedback with the measure steward, AHRQ, as well as take the concerns into consideration when we consider a future proposal to adopt the modified PSI 90 measure for the Hospital VBP Program. We refer the commenter to section VIII.A.6.b. of the preamble of this final rule where we discuss the modified PSI 90 and similar concerns in the context of the Hospital IQR Program and section IV.I.3.a. of the preamble of this final rule in the context of the HAC Reduction Program.

Comment: One commenter did not support CMS' intent to propose to adopt the modified PSI 90 measure in the Hospital VBP Program because the underlying PSIs rely on administrative claims data and are inaccurate in assessing postoperative complications. The commenter believed the component indicators of the modified PSI 90 are flawed by gaming, selective reporting, and surveillance/ascertainment bias.

Specifically, the commenter did not support PSI 12 Perioperative PE or DVT Rate because the commenter believed it is susceptible to surveillance bias and not a valid measure of quality. The commenter suggested using a comprehensive prophylaxis measure because it is a better measure of quality in VTE prevention and more widely used. While the commenter supported the decreased weighting of PSI 12 Perioperative PE or DVT Rate and PSI 15 Unrecognized Abdominopelvic Accidental Puncture/Laceration, commenter expressed concern that they were still weighted too high and that high-quality hospitals may be unfairly deemed poor performers due to methodological flaws in the weighting. The commenter did not support the continued inclusion of PSI 15 Unrecognized Abdominopelvic Accidental Puncture/Laceration because no large-scale assessment has been done to assess the validity of the component indicator and it is difficult to determine if a reoperation was directly related to the accidental puncture/laceration.

The commenter recommended that the exclusion criteria in PSI 04 Stratum 4A be broadened to include diagnoses that reflect a hypercoagulable state. The commenter recommended broadening the exclusion criteria in Stratum 4B to include cases that started in Major Diagnostic Category (MDC) 4 but advanced to Pre-MDC. The commenter recommended broadening the exclusion criteria in Stratum 4C to include sepsis diagnosis codes that are present on admission. The commenter recommended broadening the exclusion criteria of Stratum 4D to include cases that started in MDC 4 or 5 but advanced to Pre-MDC and cases that are present on admission. The commenter recommended removing the inclusion criterion of K92.1 melena in Stratum 4E. The commenter also recommended broadening the exclusion criteria for

Stratum 4E to focus on the Present on Admission Indicator rather than the principal diagnosis position and also exclude Pre-MDC.

The commenter recommended broadening the exclusion criteria of PSI 03 Pressure Ulcer Rate to include those from Appendix I-Immunocompromised State Diagnosis and Procedure Code in the PSI Technical Specifications Update manual. The commenter recommended broadening PSI 06 Iatrogenic Pneumothorax Rate to include pneumothorax related to CPR. The commenter recommended broadening the exclusion criteria of PSI 07 Central Venous Catheter-related Blood Stream Infection Rate to include cases with a length of stay of less than 2 days. The commenter recommended broadening the exclusion criteria of PSI 08 In-Hospital Fall with Hip Fracture Rate to include anything falling within Appendix H: Cancer Diagnosis Codes regardless of metastasis and regardless of Present on Admission status. The commenter recommended broadening the exclusion criteria of PSI 09 Postoperative Hemorrhage and Hematoma Rate to include Abnormal Coagulation Profile R79.1 as an exclusion criterion with present on admission, and creating a new seroma ICD–10 code. The commenter recommended changing the exclusion criteria of PSI 10 Postoperative Acute Kidney Injury Rate to a time based element in hours as opposed to the number of postoperative days and including sinus bradycardia and sinus tachycardia cardiac arrhythmias in the exclusion criteria.

The commenter recommended changing the numerator inclusion criteria of the PSI 11 Postoperative Respiratory Failure Rate to vent time, reintubation criteria, and broadening the exclusion criteria to include cases that started in MDC 4 or 5 but advanced to the Pre-MDC. The commenter recommended broadening the exclusion criteria of PSI 12 Perioperative PE or DVT Rate to include inheritable hypercoagulable conditions, acquired hypercoagulable conditions, and present on admission status. The commenter also recommended that PSI 12 Perioperative PE or DVT Rate be excluded from public reporting and pay-for-performance programs. The commenter recommended modifying PSI 13 Postoperative Sepsis Rate to delete the inclusion criteria for post-procedural shock. The commenter recommended extending the exclusion criteria of PSI 14 Postoperative Wound Dehiscence Rate to a length of stay of 4 days. The commenter recommended excluding from PSI 12 Perioperative PE or DVT Rate inheritable hypercoagulable conditions: Factor V Leiden, Factor VIII, Factor IX, Factor XI, and the acquired hypercoagulable conditions: Cancer, recent trauma or surgery, central venous catheter placement, obesity, supplemental estrogen use including oral contraceptives, hormone replacement therapy, prolonged bed rest or immobility, heparin induced thrombocytopenia, previous history of DVT/PE, myeloproliferative disorders such as polycythemia vera or essential thrombocytosis, inflammatory bowel syndrome, HIV/AIDS, and nephrotic syndrome. For PSI 13 Postoperative Sepsis Rate, the commenter recommended deleting the inclusion criteria of post-procedural shock, unspecified T811OXA as it may not be related to sepsis and does not reflect the true spirit of the measure. For PSI 14 Postoperative Wound Dehiscence, the commenter recommended extending the exclusion criteria to a length of stay of 4 days to remain consistent with criteria in other PSI components.

Response: We thank the commenter for the suggestions, especially with regard to measure specifications, such as weighting of components and inclusion and exclusion criteria, and we will share them with the measure steward, AHRQ. We acknowledge commenter's concerns and will consider them when we consider a future proposal to adopt the modified PSI 90 for the Hospital VBP Program. We refer the commenter to section VIII.A.6.b. of the preamble of this final rule where we discuss the modified PSI 90 and similar concerns in the context of the Hospital IQR Program and section IV.I.3.a. of the preamble of this final rule in the context of the HAC Reduction Program.

Comment: A few commenters did not support CMS' intent to propose to adopt the modified PSI 90 measure because the commenters stated that all measures should be publicly reported for at least one year before being proposed for a performance program.

Response: We agree that all measures should be publicly reported for at least one year before being used in the Hospital VBP Program, and we are required to do so by statute. We intend to propose to adopt the modified PSI 90 measure in a manner that complies with all the statutory requirements, including the public reporting requirement.

Comment: A few commenters supported CMS' intent to propose to adopt the modified PSI 90 measure to replace the current PSI 90 measure, but would prefer that neither version of the measure be used in the program because of major concerns with the components of the measure. One commenter believed the PSI 90 measure is reliable for internal quality improvement efforts, but not as a basis for comparing hospital quality. Another commenter requested that CMS improve the NHSN measures' methodology so that it can be relied upon as the best source of safety measurement.

Response: We acknowledge commenter's concerns and will consider them when we consider a future proposal to adopt the modified PSI 90 for the Hospital VBP Program; however, as we noted above, the PSI 90 measure was developed using a scientifically rigorous process that involved the input of technical experts and stakeholders. We refer the commenter to section VIII.A.6.b. of the preamble of this final rule where we discuss the modified PSI 90 and similar concerns in the context of the Hospital IQR Program and section IV.I.3.a. of the preamble of this final rule in the context of the HAC Reduction Program.

Comment: One commenter did not support the use of the modified PSI 90 measure in the program as a composite measure because the commenter believed each of the component indicators should be reported separately, which will increase transparency for consumers and providers.

Response: We appreciate commenter's suggestion. However, since we have adopted the composite measure for the Hospital VBP Program, we believe it is appropriate to publish hospitals' performance on that measure as a composite score, rather than its individual components, as a reflection of performance measured and scored under the Hospital VBP Program. The composite measure is the basis for awarding achievement and improvement points, not its underlying indicators, and we believe it is appropriate to focus the public reporting of Hospital VBP Program scores on the measures that receive points. We note that hospital performance on the individual component indicators of PSI 90 as calculated in the Hospital IQR Program are publicly available in downloadable datasets located at: *https://data.medicare.gov/data/hospital-compare* because we agree with the commenter about the importance of this information to consumers and providers.

3. Retention Policy, Domain Name Change, and Updating of Quality Measures for the FY 2019 Program Year

a. Retention of Previously Adopted Hospital VBP Program Measures

Since the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we have retained measures from prior program years for each successive program year, unless otherwise proposed and finalized. We are not proposing any changes to this policy.

b. Domain Name Change

We strive to align quality measurement and value-based purchasing programs with the NQS priority and the CMS Quality Strategy. Value-based purchasing programs in particular allow us to link the CMS Quality Strategy with Medicare payments to providers and suppliers on a national scale. Given this objective, as well as our objective to focus quality measurement on the patient-centered outcome of interest to the extent possible, we reclassified the Hospital VBP Program measures into domains based on the 6 priorities of the CMS Quality Strategy. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50702), we combined the priorities of Care Coordination and Patient- and Caregiver-Centered Experience of Care into one domain for purposes of aligning the Hospital VBP Program domains with the CMS Quality Strategy. The domain name is often shortened to say PCCEC/CC. The HCAHPS measure, which includes the care transitions measure (CTM–3), currently comprises the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain.

This domain name has proven to be long and unwieldy. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25100 through 25101), we proposed to change the domain name from Patient- and Caregiver-Centered Experience of Care/Care Coordination to, more simply, Person and Community Engagement beginning with the FY 2019 program year. We stated our belief that this domain name captures 2 goals of the CMS Quality Strategy, as shown in the table below:

Hospital VBP program domain	CMS quality strategy goal
Safety	Make Care Safer by Reducing Harm Caused in the Delivery of Care.
Efficiency and Cost Reduction.	Make Care Affordable.
Clinical Care	Promote Effective Prevention and Treatment of Chronic Disease.
	Promote Effective Communication and Coordination of Care.
Person and Community Engagement.	Strengthen Persons and Their Families as Partners in Their Care.
	Work with Communities to Promote Best Practices of Healthy Living.
N/A.	

We invited public comments on this proposal.

Comment: Several commenters supported renaming the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to the Person and Community Engagement domain because it simplifies the domain reference and aligns with the CMS Quality Strategy. One commenter noted that the name change accurately represents the purpose of the measures included in the domain.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing the proposed domain name change from the Patient- and Caregiver-Centered Experience of Care/Care Coordination to the Person and Community Engagement domain. We will begin referring to the domain by its new name beginning with the FY 2019 program year.

c. Inclusion of Selected Ward Non-Intensive Care Unit (ICU) Locations in Certain NHSN Measures Beginning With the FY 2019 Program Year

The Hospital VBP Program has used the CLABSI measure since the FY 2015 program year and has used the CAUTI measure since the FY 2016 program year. Both measures use adult, pediatric, and neonatal intensive care unit (ICU) data to calculate performance standards and measure scores (79 FR 50061). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50787), we expanded the CAUTI and CLABSI measures to selected ward (non-ICU) settings for the Hospital IQR Program, effective January 1, 2015 (78 FR 50787). Data were first posted on *Hospital Compare* in December 2015. Selected ward (non-ICU) locations are defined as adult or pediatric medical, surgical, and medical/surgical wards (78 FR 50787; 79 FR 50061). More information on the CLABSI and CAUTI measures can be found at: *http://www.cdc.gov/nhsn/pdfs/pscmanual/4psc_clabscurrent.pdf* and *http://www.cdc.gov/nhsn/pdfs/pscmanual/7psccauticurrent.pdf,* respectively.

In the FY 2015 and FY 2016 IPPS/LTCH PPS final rules, we discussed our intent to consider using data from selected ward (non-ICU) locations for the Hospital VBP Program beginning in the FY 2019 program year for purposes of calculating performance standards for the CAUTI and CLABSI measures (79 FR 50061; 80 FR 49556). Several public commenters supported our proposal to include performance data from non-ICU locations in the CLABSI and CAUTI measures beginning in the FY 2019 program year, noting that CLABSI and CAUTI measures are important targets for dedicated surveillance and prevention efforts outside the ICU setting (80 FR 49566).

Based on the public comments we have received in prior rulemaking, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25101), we proposed to include the selected ward (non-ICU) locations in the CAUTI and CLABSI measures for the Hospital VBP Program beginning with the FY 2019 program year, with a baseline period of January 1, 2015 through December 31, 2015 and a performance period of January 1, 2017 through December 31, 2017. This expansion of the CAUTI and CLABSI measures aligns with the Hospital IQR Program. It also aligns with the HAC Reduction Program, which adopted the expansion of the CAUTI and CLABSI measures beginning with its FY 2018 program year (80 FR 49576 through 49578). This expansion is also consistent with the NQF reendorsement update to these measures, which allows application of the measures beyond ICU locations (78 FR 50787). The MAP conditionally supported the expansion of the CAUTI (MUC–S0138) and CLABSI (MUC–S0139) measures for the Hospital VBP Program on the condition of gaining experience publicly reporting these measure data, as detailed in the ''Spreadsheet of MAP 2015 Final Recommendations.'' [29] We continue to believe this expansion of the measures would allow all hospitals, including hospitals that do not have ICU locations, to use the tools and resources of the

[29] ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711* and ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' available at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx.*

NHSN for quality improvement and public reporting efforts.

We invited public comments on this proposal.

Comment: Many commenters supported the inclusion of selected ward non-ICU locations for the CAUTI and CLABSI measures beginning with the FY 2019 program year. Several commenters noted that the expansion will reduce confusion by aligning these measures with the Hospital IQR Program. Several commenters believed the expansion will encourage system-wide adoption of infection prevention protocols and allow hospitals that do not have ICU locations to use NHSN tools and resources in their quality improvement efforts. One commenter noted that a significant proportion of community hospitals have smaller ICUs, meaning lower total number of device days, which can lead to the inability to calculate standardized infection ratios because the expected number of infection events is < 1. The commenter believed that the inclusion of ward (non-ICU) locations will lessen this limit in calculation of this measure.

Response: We thank the commenters for their support.

Comment: One commenter recommended that, before implementing these measures in selected ward (non-ICU) locations, CMS provide these locations with the mechanisms to begin voluntarily collecting data in order to use that data in calculating performance standards for subsequent years of the program.

Response: The refined NHSN CAUTI and CLABSI measures that include select ward locations were finalized in the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule and data collection began on January 1, 2015 (78 FR 50787). Because the Hospital VBP Program uses Hospital IQR Program data, and hospitals have been publicly reporting on this measure for greater than one year, we do not believe additional voluntary reporting is necessary.

After consideration of the public comments we received, we are finalizing the proposal to expand the NHSN CAUTI and CLABSI measures to include the selected ward (non-ICU) locations beginning with the FY 2019 program year.

d. Summary of Previously Adopted Measures and Newly Finalized Measure Refinements for the FY 2019 Program Year

In summary, for the FY 2019 program year, we are adopting the following measure set:

PREVIOUSLY ADOPTED MEASURES AND NEWLY FINALIZED MEASURE REFINEMENTS FOR THE FY 2019 PROGRAM YEAR ±

Short name	Domain/measure name	NQF #
	Person and Community Engagement Domain*	
HCAHPS	HCAHPS + 3-Item Care Transition Measure	0166 0228
	Clinical Care Domain	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468
THA/TKA	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
	Safety Domain	
CAUTI**	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI**	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
PSI 90	Patient Safety for Selected Indicators (Composite Measure)	0531
PC–01	Elective Delivery	0469
	Efficiency and Cost Reduction Domain	
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158

± We are changing some of the short names for measures from previous years' rulemakings to align these names with the usage in the Hospital IQR Program, and we are changing some measure names from previous years' rulemakings to use complete NQF-endorsed measure names.

* In section IV.H.3.b. of the preamble of this final rule, we finalized changing the name of this domain from Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to Person and Community Engagement domain beginning with the FY 2019 program year.

** As discussed in section IV.H.3.c. of the preamble of this final rule, we are finalizing inclusion of selected ward (non-ICU) locations in the measure.

4. Finalized Measures and Measure Refinements for the FY 2021 Program Year and Subsequent Years

We consider measures for adoption based on the statutory requirements, including specification under the Hospital IQR Program, posting dates on the *Hospital Compare* Web site, and our priorities for quality improvement as outlined in the current CMS Quality Strategy, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html*.

Due to the time necessary to adopt measures, we often adopt policies for the Hospital VBP Program well in advance of the program year for which they will be applicable (for example, 76 FR 26490 through 26547; 76 FR 51653 through 51660; 76 FR 74527 through 74547; 77 FR 53567 through 53614; 78 FR 50676 through 50707; 78 FR 75120 through 75121; 79 FR 50048 through 50087; 80 FR 49556 through 49559).

a. Condition-Specific Hospital Level, Risk-Standardized Payment Measures

Providing high-value care is an essential part of our mission to provide better health care for individuals, better health for populations, and lower healthcare costs. Our aim is to encourage higher value care where there is the most opportunity for improvement, the greatest number of patients to benefit from improvements, and the largest sample size to ensure reliability. In order to incentivize innovation that promotes high-quality care at high value, we believe it is critical to examine measures of resource use, efficiency, and cost reduction.

In prior rules we have discussed our interest in expanding the Hospital VBP Program's Efficiency and Cost Reduction domain to include condition-specific or treatment-specific Medicare payment measures, and we have sought public comments (78 FR 50688; 79 FR 50066). In response to comments, we have stated that risk-adjusted standardized Medicare payments, viewed in light of other quality measures in a program, are an appropriate indicator of efficiency because they allow us to compare hospitals without regard to factors such as geography and teaching status. This comparison is particularly important with clinically coherent episodes because it distinguishes the degree to which practice pattern variation influences the cost of care. In addition, we have stated that the granularity of condition-specific or treatment-specific payment measures may provide specific actionable feedback to hospitals to implement targeted improvements. The observed differences in episode payments revealed by these measures may also encourage hospitals to assess local, postacute health care services (for example, SNF and home health services) to ensure that efficient services are available to all patients. Given these factors, we believe that the addition of condition-specific or treatment-specific payment measures to the Hospital VBP Program is necessary not only to facilitate a better understanding of service utilization and costs associated with conditions or treatments, but also as an important next step in the evolution of value-based purchasing to transform how Medicare pays for care and services.

We recognize that high or low payments to hospitals are difficult to interpret in isolation. Some high payment hospitals may produce better clinical outcomes when compared with low payment hospitals, while other high payment hospitals may not produce better outcomes. For this reason, payment measure results viewed in isolation are not necessarily an indication of quality. However, by viewing such information along with quality measure results, we believe that consumers, payers, and providers would be able to better assess the value of care. We believe that adopting condition-specific or treatment-specific payment measures for the Hospital VBP Program that can be more directly paired with clinical outcome measures, aligned by comparable populations, performance periods, or risk-adjustment methodologies, help move toward achievement of this goal. We also believe that adopting condition-specific or treatment-specific payment measures would create stronger incentives for appropriately reducing practice pattern variation to achieve the aim of lowering the cost of care and creating better coordinated care for Medicare beneficiaries.

In the Hospital VBP Program, we adopted the MSPB measure beginning with the FY 2015 program year to incentivize hospitals to redesign care systems in order to provide coordinated, high-quality, and cost-efficient care (77 FR 53590). Currently, the Hospital VBP Program measures efficiency by weighting and combining the MSPB measure with other quality measures in order to calculate each hospital's TPS. However, we have previously expressed our interest in expanding the Efficiency and Cost Reduction domain and continue to believe that additional supplemental measures would create incentives for greater coordination between hospitals and physicians to optimize the care they provide to Medicare beneficiaries (78 FR 50688; 79 FR 50066).

We believe that when examining variation in payments, an episode-of-care triggered by admission is meaningful for several reasons. First, hospitalizations represent brief periods of illness that require ongoing management postdischarge, and decisions made at the admitting hospital affect payments for care in the immediate postdischarge period. Second, attributing payments for a continuous episode-of-care to admitting hospitals may reveal variations in care decision-making and resource utilization. Third, an episode-of-care with a specified time period (30 days in the case of the measures discussed below) provides a standard observation period by which to compare all hospitals. For all of the reasons described above, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25102 through 25105), we proposed to add 2 condition-specific payment measures in the Hospital VBP Program that can be directly paired with existing clinical outcome measures in the program.

We invited public comments on the proposed measures as detailed below. We further invited public comment on the addition of other condition-specific or treatment-specific payment measures that are directly paired with quality measures, as well as episode-based payment measures not directly paired with quality measures, for future program years.

Comment: Several commenters supported the continued use of the MSPB measure in the Hospital VBP Program and the development of additional measures to add to the Efficiency and Cost Reduction domain to create incentives for greater coordination between hospitals and physicians. One commenter recommended that CMS seek to broaden the scope of its efficiency measures for the FY 2018 rulemaking cycle. One commenter recommended that CMS adopt additional cost and efficiency measures and that any new cost and efficiency measures be paired with corresponding quality measures because they provide a link to balance cost and quality. Another commenter recommended that CMS consider adopting other macro-level measures of efficiency and cost reduction, such as: (1) Total Medicare cost per capita; (2) Medicare spending per beneficiary in the last 2 years of life; and (3) Medicare spending per beneficiary in the last 6 months of life.

Commenters noted that the proposed payment measures, when paired with the mortality measures, can help to incentivize incorporation of evidence-based processes of care to reduce cost-per-episode while improving quality of care, potentially through improved patient monitoring and management. One commenter believed the proposed measures are appropriate indicators of efficiency since they allow for clinical comparisons without external factors like age and comorbidities. One commenter believed these measures may encourage the use of innovative technologies that assist in providing high quality care while reducing overall costs. One commenter believed these measures allow for specific actionable feedback to hospitals to implement improvements. One commenter believed these measures increase incentives for hospitals to better manage patients' chronic conditions after discharge and avoid subsequent visits to the emergency department and readmissions.

Response: We appreciate the commenters' support. We note that we are unable to adopt any additional efficiency measures for the FY 2018 program year due to statutory restrictions. We thank the commenters for the suggestions of future measures to adopt for the domain, and we will take that into account for future measure development and rulemaking. We encourage commenters to submit any fully developed measures for consideration for the Measures Under Consideration List as part of the pre-rulemaking process (details available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html*).

Comment: One commenter recommended that CMS take advantage of the agency's development of episode groupers, which are intended to assign specific services to a particular episode, when implementing any measure of episode costs.

Response: The episode groupers define episodes by DRGs and not ICD–10–CM codes. The goal of the AMI Payment and HF Payment measures is to provide information on the value of care by comparing payments for an episode of care with performance on quality measures, like CMS' 30-day mortality measures. Thus, it is important that the patient cohorts are as closely aligned as possible between payment and quality measures. This would not be possible if we used the AMI or HF episode grouper.

Comment: One commenter supported expansion of the domain to include condition-specific payment measures but recommended that CMS standardize the process for validating elements on claims submitted for the purpose of quality reporting because, without a standardized validation process, observed differences in performance rates cannot be assumed to reflect differences in care alone.

Response: We appreciate commenter's support of the payment measures. We interpret the commenter's recommendation regarding validating elements on claims to refer to the claims review process. All claims data submitted by hospitals for the Hospital VBP Program are reviewed by Medicare Claims Review Programs, which are a collection of initiatives responsible for reviewing claims according to Medicare rules and regulations.

(1) New Measure for the FY 2021 Program Year: Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) (NQF #2431)

Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for AMI (NQF #2431) (AMI Payment) is an NQF-endorsed measure assessing hospital risk-standardized payment associated with a 30-day episode-of-care for AMI. We adopted this measure in the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50802 through 50805). The measure includes Medicare FFS patients aged 65 or older admitted for an AMI and calculates payments for these patients over a 30-day episode-of-care, beginning with the index admission, using administrative claims data. In general, the measure uses the same approach to risk-adjustment as our 30-day outcome measures previously adopted for the Hospital VBP Program, including the AMI mortality measure. Initial measure data were posted on *Hospital Compare* in December 2014 and the full measure specifications are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

AMI remains a high-volume condition that is one of the top 20 conditions contributing to Medicare costs.[30] There is evidence of variation in payment for AMI patients among hospitals; median 30-day risk-standardized payment (in 2013 dollars) for AMI was $21,620 and ranged from $12,862 to $29,802 for the July 2011 through June 2014 reporting period in the Hospital IQR Program.[31] This variation in payment suggests there is opportunity for improvement.

We believe it is important to adopt the AMI Payment measure because variation in payment may reflect differences in care decision-making and resource utilization (for example, treatment, supplies, or services) for patients with AMI both during hospitalization and immediately postdischarge. The AMI Payment measure also addresses the NQS priority and CMS Quality Strategy goal to make quality care more affordable. Lastly, the AMI Payment measure is intended to be paired with our 30-day AMI mortality measure, MORT–30–AMI (NQF #0230), thereby directly linking payment to quality by the alignment of comparable populations and risk-adjustment methodologies to facilitate the assessment of efficiency and value of care.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25103), we proposed to adopt the AMI Payment measure beginning with the FY 2021 program year. The AMI Payment measure would be added to the Efficiency and Cost Reduction domain. The proposed measure fulfills all statutory requirements for the Hospital VBP Program based on our adoption of the measure in the Hospital IQR Program, and our posting of measure data on *Hospital Compare* for at least one year before the beginning of the performance period. The AMI Payment measure (MUC15–369) was reviewed by the MAP in December 2015 and did not receive support for adoption into the Hospital VBP Program.[32] The result of the MAP vote was 27 percent support, 15 percent conditional support, and 58 percent do not support. MAP members expressed concern that treatment-specific or condition-specific payment measures may overlap and double count services that are already captured in the MSPB measure. In addition, stakeholders expressed a desire to have

[30] Torio, C.M. and Andrews, R.M., 2013. National inpatient hospital costs: the most expensive conditions by payer, 2011. In Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project Statistical Brief# 160. Available at: *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.pdf.*

[31] 2015 Condition-Specific Measure Updates and Specifications Report Hospital-Level 30-Day Risk Standardized Payment Measures. AMI, HF, PN Payment Updates (zip file). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[32] ''Spreadsheet of MAP 2015–2016 Final Recommendations'' available at: *http://www.qualityforum.org/map/* and ''Process and Approach for MAP Pre-Rulemaking Deliberations 2016'' found at: *http://www.qualityforum.org/Publications/2016/02/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations.aspx.*

more experience with the measure in the Hospital IQR Program to understand whether there may be unintended consequences or a need to adjust for sociodemographic status (SDS) factors.

With respect to MAP stakeholder concerns that treatment-specific or condition-specific payment measures may overlap and double count services, we noted that these measures cover topics of critical importance to quality improvement in the inpatient hospital setting. As discussed above, we selected these measures because we believe that it is appropriate to provide stronger incentives for hospitals to provide high-value and efficient care. We believe that even if some services were double counted, hospitals that offer quality service and maintain better results on the MSPB and condition-specific payment measures relative to other hospitals in the Hospital VBP Program could receive an increased benefit by performing well on both quality measures and payment measures. Furthermore, because hospitals would have bigger financial incentives, they would strive to perform better, which would lead to better quality. At the same time, however, we proposed that the Efficiency and Cost Reduction domain remain weighted at 25 percent of the TPS even as additional payment measures may be adopted for this domain in the FY 2021 program year; therefore, the impact of poor performance on the MSPB measure or on any other particular payment measure would be reduced.

In regard to MAP stakeholder concerns regarding the need to adjust for SDS, we noted that the AMI Payment measure already incorporates a risk-adjustment methodology that accounts for age and comorbidities. We understand the important role that SDS plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse SDS because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of SDS on hospitals' results on our measures; however, we remain committed to monitoring for unintended consequences.

We invited public comments on this proposal.

Comment: A few commenters supported the addition of the AMI Payment measure. Two commenters noted it will be linked to the MORT–30–AMI measure, which will allow CMS to begin comparing quality and efficiency in treating this condition. One commenter supported the measure because it is NQF-endorsed and addresses a condition that is a significant driver of cost for the Medicare program.

Response: We thank the commenters for their support.

Comment: One commenter did not support the addition of the AMI Payment measure because patients can have different types of AMI which would be treated differently with varying costs. The commenter noted that the measure specifications do not delineate between the 2 types of AMI admissions, and therefore will not provide hospitals with information on whether the hospital successfully managed resource utilization with respect to the treatment received.

Response: While we recognize there are subtypes of myocardial infarction, the goal of the AMI Payment measure is to provide information on the value of care for a specific-condition rather than subtypes of a condition. This measure is meant to be paired with the MORT–30–AMI measure in order to gain a better understanding of the value of care for a hospital's patients.

Comment: One commenter did not support adding the AMI Payment measure to the Hospital VBP Program because AMI is a high-volume condition that commenter believed, particularly with the overlap in the MSPB measure, would disproportionately impact hospital performance in the Efficiency and Cost Reduction domain and mask performance around other conditions.

Response: While performance on the MSPB measure may correlate with performance on the condition-specific payment measures for some hospitals, we continue to believe that the AMI Payment measure will provide condition-specific information to hospitals that can be interpreted in the context of overall payment and incentivize targeted improvements in care. Though the adoption of the AMI Payment and HF Payment measures will dilute the weight of the MSPB measure in the Efficiency and Cost Reduction domain (from 25 percent of the TPS to 8.33 percent of the TPS), we continue to believe they are important new measures for the Hospital VBP Program.

Comment: One commenter did not support adding the AMI Payment measure to the Hospital VBP Program because this commenter believed the predictive models used in developing the measure do not apply equally well to hospitals providing complex services, such as advanced heart failure care.

Response: We appreciate the commenter's concern about complex patient factors, such as advanced heart failure, that may contribute to the cost of care. The payment measures are risk-adjusted in order to account for differences in case-mix, or patient complexity, between hospitals. For each patient, the claims for the 12 months prior to the measured hospitalization are examined to identify additional clinical conditions that patients may have which could contribute to costs of care. These conditions are included in the risk-model for the measure to ensure that all hospitals are assessed fairly and avoid putting hospitals at risk of appearing to have patient costs that are higher than other hospitals due to the clinical complexity of their patients.

We also received several comments that applied to both the AMI Payment and HF Payment measures:

Comment: Many commenters did not support the addition of the payment measures because they are not risk-adjusted for SDS factors. One commenter believed that the current risk adjustment for patient age, prior procedures, and comorbidities is insufficient to fully capture what influences resource use. Another commenter requested that CMS clearly articulate the risk adjustment methodology for the AMI Payment and HF Payment measures because risk adjustment will help ensure hospitals are not inadvertently penalized for treating sick and more complex patients. One commenter recommended that CMS exclude hospitals operating in health professional shortage areas from the payment measures in order to mitigate the impact of operating in a health professional shortage area. One commenter believed the condition-specific payment measures should include risk adjustment or stratification for SDS factors because otherwise hospitals caring for at-risk patients may be unfairly penalized.

Response: As we noted in the FY 2017 IPPS/LTCH PPS proposed rule, the NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures

developed by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

For more details regarding risk adjustment of the AMI Payment and HF Payment measures, we refer the commenters to the measure methodology reports and measure risk adjustment statistical model available in the AMI, HF, and PN Payment Updates zip file at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: Many commenters did not support the addition of the condition-specific payment measures because they will overlap with the MSPB measure in the Efficiency and Cost Reduction domain. Several commenters recommended that we remove episodes of AMI Payment and HF Payment from the MSPB calculation, such as excluding costs associated with episode-based payment measures from broader payment measures. Several other commenters recommended removing the MSPB measure if CMS adopts the condition-specific payment measures. One commenter believed the overlap between these condition-specific measures and the MSPB measure may lead to unnecessary confusion among hospitals, sending mixed signals to hospitals about their resource use performance, rather than facilitating a meaningful assessment of resource use. One commenter also noted that it will be possible for hospitals to score well on the MSPB measure, but poorly on the AMI Payment or HF Payment measures, even though the measures will capture many of the same services.

Response: While we acknowledge that there may be some overlap between the MSPB and these condition-specific payment measures, we believe that the condition-specific measures are of critical importance to improving efficiency of care. Including condition-specific measures alongside the MSPB measure provides hospitals with actionable feedback that will better equip them to implement targeted improvements, in comparison to an overall payment measure alone. Moreover, these condition-specific measures will allow consumers, providers, and payers to make a more fully informed assessment of value of care.

Comment: Many commenters did not support the addition of condition-specific payment measures because the commenters believed the measures inappropriately assign costs to the hospitals. A few commenters believed it is physicians that control the majority of decisions that impact spending across an episode of care and it will be difficult to isolate and ascribe responsibility for a beneficiary's overall spending to a given hospital. Another commenter noted that the measures capture all costs associated with the patient, including postdischarge care, which may be outside the scope of the admitting hospital. One commenter noted that hospitals have little control over spending during the defined episode with the exception of preventable readmissions. A few commenters recommended CMS work with the hospital community to develop and implement efficiency metrics of spending that hospitals directly influence. Other commenters recommended limiting inclusion of payments used in the calculation of the measures to only payment directly related to the condition-specific index admission, because commenters believed this would be a more accurate proxy for factors within a hospital's control than all spending over a 30-day period.

Response: We continue to believe that hospitals that provide quality inpatient care and conduct appropriate discharge planning can work with providers and suppliers in coordinating efficient follow-up care. When examining variation in payments, consideration of the episode-of-care triggered by admissions is meaningful for several reasons. First, hospitalizations represent a brief period of illness that require ongoing management postdischarge, and decisions made at the admitting hospital affect payments for care in the immediate postdischarge period. Second, attributing payments for a continuous episode-of-care to admitting hospitals may reveal practice variations in the full care of the illness that can result in increased payments. Third, a 30-day preset window provides a standard observation period by which to compare all hospitals. Lastly, the AMI Payment and HF Payment measures are meant to be paired with the MORT–30–AMI measure and the MORT–30–HF measure, respectively, to capture payments for Medicare patients across all care settings, services, and supplies, except for Medicare Part D (that is, inpatient, outpatient, skilled nursing facility, home health, hospice, physician/clinical laboratory/ambulance services, durable medical equipment, prosthetics/orthotics, and supplies).

We thank commenters for the recommendations and note that we have developed, and will continue to develop, efficiency measures in consultation with clinical and measurement experts, key stakeholders (including the hospital community), and the public. We disagree with commenters that all payment measures should be limited to only payments directly related to the index admission because, as noted above, we continue to believe that inclusion of payments on a broad range of services does incentivize quality care and care coordination. Transitions to outside facilities and readmissions to the hospitals may be the result of quality failures that have led to poor clinical outcomes.

Comment: A few commenters expressed concern about adding the condition-specific payment measures into the Hospital VBP Program because the commenters believe these measures do not capture quality of care, despite directly pairing with the mortality measures, and will not provide hospitals with actionable data for quality improvement efforts. One commenter did not believe the payment measures are appropriately aligned by comparable populations/performance periods/risk-adjusted methodologies.

Response: We disagree with the commenters that the condition-specific payment measures will not provide hospitals with actionable data for quality improvement efforts. By adopting condition-specific payment measures and viewing results alongside quality measure results, we believe that consumers, payers, and providers will be able to better assess the overall value of care. We believe that adopting condition-specific payment measures for the Hospital VBP Program that are directly paired with clinical outcome measures, aligned by comparable populations, performance periods, or risk-adjustment methodologies, helps move toward achievement of this goal. We also believe that adopting condition-specific payment measures will create stronger incentives for appropriately reducing practice pattern variation to

achieve the aim of lowering the cost of care and creating better coordinated care for Medicare beneficiaries.

In regard to the commenter who did not believe the payment measures are appropriately aligned, we note that the AMI Payment and HF Payment measures do have populations, outcome timeframes, and approaches to risk adjustment that are comparable with the MORT–30–AMI and MORT–30–HF outcome measures. We refer the commenter to the measure methodology reports in the AMI, HF, PN, COPD, and Stroke Mortality Update zip file and the AMI, HF, and PN Payment Updates zip file at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: A few commenters recommended that CMS adjust the Efficiency and Cost Reduction domain to mitigate the impact of quality of care in SNFs and other postacute settings on the hospitals' performance in the Efficiency and Cost Reduction domain because hospitals are not able to proactively steer beneficiaries to high-quality SNFs. The commenters also noted that receiving patients from low-quality postacute care settings may impact hospitals' performance on the Efficiency and Cost Reduction domain.

Response: We disagree with commenters' recommendation to adjust the Efficiency and Cost Reduction domain to mitigate the potential impact of low quality SNFs or other postacute care settings. Payment measures are not risk-adjusted for patients' admission source (for example, SNFs) because admission source factors are associated with the structure of the healthcare system, rather than solely patients' clinical comorbidities. The payment measures are, however, appropriately risk-adjusted for patient comorbidities that are clinically relevant and have a strong relationship with the outcome. Further, we have established several postacute care quality programs, including SNF, IRF, and Home Health Quality Reporting Programs, as well as a SNF VBP Program, to assist hospitals and the public in identifying high-value postacute care providers. We continue to believe that hospitals that are committed to providing quality inpatient care can work with SNFs and other postacute care providers and suppliers to ensure efficient postdischarge care for the patients they serve.

Comment: A few commenters did not support the use of condition-specific payment measures in the program because commenters believe that hospitals should only be rewarded or penalized based on a broad all-condition, 30-day payment measure, like the MSPB measure, which evaluates both quality of care and cost of care.

Response: We disagree with the commenter that the condition-specific payment measures would not evaluate both quality and cost of care because we believe the payment measures, in light of other quality measures in the program, are an appropriate indicator of efficiency. We further note that the condition-specific payment measures align with the condition-specific mortality measures to provide specific feedback to hospitals to implement targeted improvements. We continue to believe that an episode-of-care triggered by admission is meaningful to the program.

Comment: A few commenters did not support the condition-specific measures because they took issue with the NQF endorsement of the measures. One commenter believed the condition-specific payment measures are not endorsed by NQF. Another commenter did not support the addition of the condition-specific measures because the commenter and others have appealed the measures' NQF endorsement on the grounds that the NQF measure review committee did not consider appropriate risk adjustment for SDS factors. These commenters recommended that CMS not adopt condition-specific measures in the Hospital VBP Program, but instead provide condition-specific cost of care data to hospitals to help them understand what is driving MSPB performance.

Response: The AMI Payment (NQF #2431) and HF Payment (NQF #2436) measures are NQF-endorsed as reliable and valid as of 2014. We continue to believe it is important to publicly report this data in order to allow consumers, providers, and payers to make a more fully informed assessment of value of care.

Comment: One commenter recommended that CMS reach out to stakeholders for feedback during the development of payment measures.

Response: We routinely solicit public comment on our payment measures and other measures under development. For current and future opportunities, we encourage the commenter to visit the CMS Quality Measures Public Comment page at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html*. In addition, there are also opportunities for stakeholders to serve on Technical Expert Panels and provide technical input to CMS and the measure contractors on the development, selection, and maintenance of measures. We refer the commenter to the following Web site for more information: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html*.

Comment: One commenter expressed concern that condition-specific measures do not capture all outcomes relevant to understanding the care that patients received, such as readmissions and subsequent cardiac events.

Response: We disagree that the condition-specific measures do not capture all outcomes like readmissions and subsequent cardiac events. The condition-specific payment measures do capture payments for all care, including readmissions and subsequent cardiac events, across multiple care settings, services, and supplies during the 30-day episode of care.

Comment: One commenter recommended that instead of adding condition-specific payment measures to the Hospital VBP Program now, CMS should first examine methods of pairing cost and payment measures so that they signal value to beneficiaries.

Response: We believe that adding the AMI Payment and HF Payment measures now will provide actionable feedback to hospitals on the overall value of their services to beneficiaries.

After consideration of the public comments we received, we are finalizing the proposal to add the AMI Payment measure to the Hospital VBP Program beginning with the FY 2021 program year.

(2) New Measure for the FY 2021 Program Year: Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure (HF) (NQF #2436)

Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for HF (NQF #2436) (HF Payment) is an NQF-endorsed measure assessing hospital risk-standardized Medicare payment associated with a 30-day episode-of-care for heart failure. The measure includes Medicare FFS patients aged 65 or older admitted for heart failure and calculates payments for these patients over a 30-day episode-of-care, beginning with the index admission, using administrative claims data. In general, the measure uses the same approach to risk-adjustment as our 30-day outcome measures previously adopted for the Hospital VBP Program, including the HF mortality measure. We adopted this measure in the Hospital IQR Program in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50231 through 50235). Initial measure data were posted

on *Hospital Compare* in July 2015 and the full measure specifications are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Heart failure is one of the leading causes of hospitalization for Americans 65 and over and costs roughly $34 billion annually.[33] [34] There is evidence of variation in Medicare payments at hospitals for heart failure patients; median 30-day risk-standardized payment (in 2013 dollars) among Medicare FFS patients aged 65 or older was $15,139, and ranged from $11,086 to $21,867 for the July 2011 through June 2014 reporting period in the Hospital IQR Program.[35] This variation in payment suggests there is opportunity for improvement.

We believe it is important to adopt the HF Payment measure because variation in payment may reflect differences in care decision-making and resource utilization (for example, treatment, supplies, or services) for patients with heart failure both during hospitalization and immediately postdischarge. The HF Payment measure also addresses the NQS priority and CMS Quality Strategy goal to make quality care more affordable. Lastly, the HF Payment measure is intended to be paired with our 30-day HF mortality measure, MORT–30–HF, thereby directly linking payment to quality by the alignment of comparable populations and risk-adjustment methodologies to facilitate the assessment of efficiency and value of care.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25104), we proposed to adopt the HF Payment measure beginning with the FY 2021 program year. The HF Payment measure would be added to the Efficiency and Cost Reduction domain. The measure fulfills all statutory requirements for the Hospital VBP Program based on our adoption of the measure in the Hospital IQR Program and our posting of measure data on *Hospital Compare* for at least one year before the beginning of the performance period for this measure. The HF Payment measure (MUC15–322) was reviewed by the MAP in December 2015 and did not receive support for adoption into the Hospital VBP Program, due to the same concerns that we noted in our discussion of the AMI Payment measure.[36] The result of the MAP vote was 27 percent support, 8 percent conditional support, and 65 percent do not support. Although the final MAP decision was ''do not support,'' we continue to believe that the NQF-endorsed HF Payment measure provides beneficiaries and hospitals with valuable information about relative value for an episode-of-care. We support the HF Payment measure for the same reasons that we noted in our general discussion of condition-specific payment measures in section IV.H.4.a. of the preamble of this final rule and in our discussion of the AMI Payment measure in section IV.H.4.a.(2) of the preamble of this final rule.

We noted that some MAP members did express support for the HF Payment measure and other condition-specific payment measures. Members agreed that the increased granularity provided by condition-specific payment measures will provide valuable feedback to hospitals for targeted improvement. In addition, we believe that the condition-specific payment measures we are proposing, which directly pair with clinical outcome measures already in the Hospital VBP Program, follow the recommended approach outlined in the NQF white paper on how best to measure efficiency.[37] Based on our analysis of the issues surrounding condition-specific payment measures, we believe that the benefits of adopting this measure into the Hospital VBP program outweigh any potential risks. However, we remain committed to monitoring for unintended consequences.

We invited public comments on this proposal.

Comment: Several commenters supported the addition of the HF Payment measure. One commenter supported the addition of the HF Payment measure because it links the HF Payment measure to the MORT–30–HF (NQF #0229) measure and will allow CMS to begin comparing quality and efficiency in treating this condition. One commenter supported the measure because it is NQF-endorsed and addresses conditions that are significant drivers of cost for the Medicare program.

Response: We thank the commenters for their support.

Comment: One commenter supported the use of a 3-year baseline period for the HF Payment measure because a longer baseline period can account for the longer-term predictive value of health events such as HF better than a 1-year baseline period.

Response: We thank the commenter for its support. We note that the HF Payment measure will only have a 24-month performance period for its first year in the program, but we are adopting a 36-month performance period for future program years in section IV.H.6.c.(2) of this final rule.

Comment: One commenter expressed general concern about the HF Payment measure's risk adjustment methodology and requested additional information regarding the discrimination and calibration for the measure's predictive models.

Response: We note that the HF Payment measure was submitted before NQF, which endorsed the measure with the current risk adjustment methodology. For more information regarding the risk adjustment methodology, we refer readers to the AMI, HF, PN, and Hip and Knee Arthroplasty Payment Updates zip file available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: One commenter asked CMS to clarify whether patients in advanced states discharged into palliative or hospice care are excluded from the HF Payment measure's denominator.

Response: The HF Payment measure does not exclude heart failure patients discharged into palliative care or hospice care or who transition to hospice or palliative care during the index admission. Instead, the measure excludes index admissions for patients enrolled in the Medicare hospice program any time in the 12 months prior to the index admission, including the first day of the index admission. We adopted this policy because the transition of patients to hospice or palliative care during the admission may be the result of quality failures that have led to poor clinical outcomes.

After consideration of the public comments we received, we are finalizing the proposal to add the HF

[33] Russo CA, Elixhauser, A. Hospitalizations in the Elderly Population, 2003. Agency for Healthcare Research and Quality. 2006.

[34] Heidenriech PA, Trogdon JG, Khavjou OA, Butler J, Dracup K, Ezekowitz MD, et al. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. Circulation. 2011;123(8):933–44.

[35] 2015 Condition-Specific Measure Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Payment Measures. AMI, HF, PN Payment Updates (zip file). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

[36] ''Spreadsheet of MAP 2015–2016 Final Recommendations'' available at: *http://www.qualityforum.org/map/* and ''Process and Approach for MAP Pre-Rulemaking Deliberations 2016'' found at: *http://www.qualityforum.org/Publications/2016/02/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations.aspx*.

[37] Ryan AM, Tompkins CP. Efficiency and Value in Healthcare: Linking Cost and Quality Measures. Washington, DC: NQF; 2014.

Payment measure to the Hospital VBP Program beginning with the FY 2021 program year.

(3) Finalized Scoring Methodology for the AMI Payment and HF Payment Measures

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25105 through 25106), we proposed to score the proposed AMI Payment and HF Payment measures using the same methodology we use to score the MSPB measure, so that all measures in the Efficiency and Cost Reduction domain are scored in the same manner and have the same case minimum threshold.

For achievement points, we proposed to calculate a spending ratio of AMI spending and HF spending for each hospital to the median AMI spending and median HF spending, respectively, across all hospitals during the performance period. We would then use each hospital's AMI spending ratio and HF spending ratio to calculate between 0 and 10 achievement points. We proposed to set the achievement thresholds at the median AMI spending ratio and HF spending ratio across all hospitals during the performance period. We proposed to set the benchmarks at the mean of the lowest decile of the AMI spending ratios and the HF spending ratios during the performance period. Therefore, a hospital whose individual AMI spending or HF spending ratios fall above the achievement threshold would score 0 achievement points on the measure. A hospital whose individual AMI spending or HF spending ratios fall at or below the benchmark would score the maximum 10 achievement points on the measure. A hospital whose individual AMI spending or HF spending ratios fall at or below the achievement threshold but above the benchmark would score between 1 and 9 points according to the following formula:

[9 * ((achievement threshold − Hospital's performance period ratio)/(achievement threshold − benchmark))] + 0.5

For improvement points, we proposed to calculate a spending ratio of AMI spending and HF spending for each hospital to the median AMI spending and median HF spending, respectively, across all hospitals during the performance period. We would then use each hospital's AMI spending ratio and the HF spending ratio to calculate between 0 and 9 improvement points by comparing each hospital's ratio to its own performance during the baseline period. We proposed to set the improvement benchmark as the mean of the lowest decile of AMI spending and HF spending ratios across all hospitals. Therefore, a hospital whose AMI spending or HF spending ratios are equal to or higher than its baseline period ratios would score 0 improvement points on the measure. If a hospital's score on the measure during the performance period is less than its baseline period score but above the benchmark, the hospital would receive a score of 0 to 9 according to the following formula:

[10 * ((Hospital baseline period ratio − Hospital performance period ratio)/(Hospital baseline period ratio − benchmark))] − 0.5

For more information about the proposed scoring methodology for the AMI Payment and HF Payment measures, we referred readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656) and to 42 CFR 412.160 where we discussed the MSPB measure's identical scoring methodology in detail.

In order to codify this scoring methodology for the proposed payment measures, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25105 through 25106), we proposed to amend our regulations at 42 CFR 412.160 to revise the definitions of ''Achievement threshold'' and ''Benchmark'' to reflect this methodology, not just for the MSPB measure, but more generally for all measures in the Efficiency and Cost Reduction domain.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25106), we also considered and sought public feedback on scoring the AMI Payment and HF Payment measures using the same methodology that we use to score most other measures, including the MORT–30–AMI and MORT–30–HF measures. Under that scoring methodology, hospitals receive achievement points along an achievement range, which is a scale between the achievement threshold (the minimum level of hospital performance required to receive achievement points) and the benchmark (the mean of the top decile of hospital performance during the baseline period). A hospital receives improvement points for a measure if the hospital improves upon its measure score from its own baseline period measure score (76 FR 26514). We stated that we decided to propose the scoring methodology that more closely aligns with the MSPB measure because we believe it would be helpful for hospitals to be compared against performance standards constructed from more current performance period data, given potential changes in Medicare payment policy, changes in market forces, and changes in utilization practices.

We invited public comment on the proposed scoring methodology in the calculation of achievement and improvement points for the AMI Payment and HF Payment measures beginning with the FY 2021 program year.

Comment: Several commenters did not support the addition of the AMI Payment and HF Payment measures because few conditions have large enough volume to support a reliable metric. The commenters recommended that CMS use condition-specific cost measures broadly and that CMS not base financial incentives on them. One commenter asserted that because not all hospitals will have sufficient volume to be scored on each condition-specific measure, the statistical reliability of the condition-specific measures is likely to be weaker than the MSPB measure.

Response: We disagree with the commenter that hospitals will not be able to report statistically reliable information on the condition-specific payment measures because, as we proposed in the FY 2017 IPPS/LTCH PPS proposed rule, hospitals must report a minimum number of 25 cases to receive a payment measure score (81 FR 25117). We believe the case minimum will ensure that each hospital's payment measure rate is sufficiently reliable to generate a score that meaningfully distinguishes hospital performance on the measures. We also disagree with the commenter's assertion that the statistical reliability of the condition-specific payment measures is likely to be weaker than the MSPB measure. The statistical model that CMS uses to calculate the payment measures allows for the inclusion of hospitals with relatively few cases by taking into account the uncertainty associated with sample size.

Comment: A few commenters did not support the proposed scoring methodology for the payment measures because half of hospitals will receive no achievement points on these measures. The commenters recommended that CMS score the payment measures the same way that other quality measures are scored, with the achievement threshold set based on the median during the baseline period.

Response: While we acknowledge the commenter's concerns regarding the potential to achieve maximum achievement points, we believe scoring the payment measures in the same way as the MSPB measure is appropriate. We continue to believe it is more helpful for hospitals to be compared against

performance standards constructed from more current performance period data, rather than baseline period data, given potential changes in Medicare payment policy, changes in market forces, and changes in utilization practices.

Comment: One commenter expressed concern that the current structure does not provide hospitals with meaningful information to improve efficiency because it does not allow for interpretation of cost and quality measures in tandem.

Response: We are aware that the quality measures and payment measures are not scored in tandem at this moment, but we believe the information provided by the payment measures provides more granular information to hospitals that can be interpreted in the context of overall payment and in conjunction with their performance on the mortality measures.

After consideration of the public comments we received, we are finalizing the proposal to score the AMI Payment and HF Payment measures using the same scoring methodology as the MSPB measure and to amend our regulations at 42 CFR 412.160 to reflect this policy.

In addition, we are considering adopting a scoring methodology for a future program year that would assess quality measures and efficiency measures in tandem to produce a composite score reflective of value. To support the goals of value-based purchasing and to provide consumers and purchasers with information about value of care provided by hospitals, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 21505), we solicited public comments on ways we can incorporate scoring value into the Hospital VBP Program. The concept of value reflects highest quality achieved with most efficiency or least costs. Currently, the Hospital VBP Program assesses quality and efficiency separately through distinct performance measures and domains. Because each domain is weighted and combined to determine each hospital's TPS, a hospital could earn a higher payment adjustment relative to other hospitals by performing well on the quality-related domains but without performing well in the Efficiency and Cost Reduction domain, or vice versa. Without a measure or score for value that reflects both quality and costs, our ability to assess value is limited.

There are various different ways value could be incorporated into the Hospital VBP Program. We sought public comments on 2 general approaches. First, specific measures of value could be developed by measure developers and incorporated into the Hospital IQR Program and then the Hospital VBP Program through the measure development process. This may be a lengthy process and will depend upon interest from measure developers. However, specific measures of value could be more interpretable by consumers, and would have rates that could be trended, benchmarked, and scored using the current Hospital VBP Program scoring methodology for assessing achievement and improvement.

A second potential approach is for the Hospital VBP Program to use the Program's scoring methodology to incorporate value based on the performance of hospitals by either: (a) Comparing scores on specific quality and cost measures; or (b) comparing quality and efficiency domain scores. First, the measure-specific approach could target high-cost, high clinical-impact conditions by pairing condition-specific quality and cost measures, such as by assessing a ratio of a hospital's reported quality over costs. A value score based on the paired clinical outcome and cost measures could be incorporated into the existing Efficiency and Cost Reduction domain (or Clinical Care or Safety domains) or included in a separate new 'Value' domain. Alternatively, a domain-based value scoring approach could be similar to the current quality/cost tiering approach in the Physician Value-Based Modifier Program, which tiers providers into 9 high, average, or low cost and quality (or ''value'') categories to determine payments. The domain-based value score could be weighted and incorporated into the calculation of a hospital's overall Hospital VBP Program TPS along with the other existing domains, or potentially as a multiplier or adjuster to additionally reward higher value hospitals.

We welcomed the public's feedback and suggestions on how to appropriately incorporate the concept of value in the Hospital VBP Program, and we invited specific suggestions on how to measure or score value that will be meaningful to consumers, purchasers, and providers.

Comment: Several commenters supported CMS' intent to explicitly assess value of care. A few commenters further supported CMS' proposal to develop and implement specific measures of value because commenters believe it will result in a program that is simple, uncomplicated, and easily understood by consumers and providers. One commenter recommended that CMS resolve issues regarding SDS factors before implementing value scoring into the program.

Response: We thank the commenters for their suggestions, and we will take them into consideration in the future if we choose to propose to adopt value scoring.

Comment: One commenter recommended that CMS develop a value scoring methodology that would not reward hospitals with high mortality rates and low spending per patient. The commenter recommended that CMS use performance and baseline periods to score the value measures.

Response: We thank the commenter for its suggestions and will take them into consideration for future rulemaking.

Comment: A few commenters did not support CMS' proposed approach to measuring value by creating a ratio using paired condition-specific quality and cost measures. One commenter noted that this would further complicate the Hospital VBP Program's structure and could result in hospitals diverting more resources toward analyzing performance rather than focusing on improvement. A few commenters believe that such an approach could incentivize the provision of care that unintentionally leads to longer-term negative outcomes: Use of lower-cost/lower-quality implants; decreased length of stay; and insufficient use of physical therapy or home health care. A few commenters noted that the existing measures are limited in scope and were not designed to measure value; for example, THA/TKA is too narrow to capture the value of the underlying procedure, which should include factors like quality of life, duration of implant, and other issues beyond the 90-day timeframe of the THA/TKA measure. One commenter recommended CMS develop a measure that draws from patient-reported outcome measures, the American Joint Replacement Registry, and other sources to capture the value to the patient of the full life of a joint implant. These commenters generally suggested that if CMS implements value scoring, that CMS develop new value measures.

Response: We thank the commenters for their suggestions, and we will take them into consideration for future rulemaking.

Comment: A few commenters expressed general support for adopting a scoring methodology using composite ''value'' scores and recommended that CMS submit any newly developed composite measures to NQF for endorsement, as well as use them in the Hospital IQR Program before adding them to the Hospital VBP Program.

Response: We thank the commenters for their suggestions, and we note that any new measures the Hospital VBP Program considers for adoption, including any composite measures of ''value,'' will be submitted to the MAP and adopted into the Hospital IQR Program before we adopt it in the Hospital VBP Program, as required by statute.

Comment: A few commenters recommended that CMS explore using a scoring methodology that provides tandem scores for quality and cost measures, but they noted that implementing such a methodology would require additional work to identify and adopt quality and cost measures that can be aggregated into value scores. A few commenters would not support using a scoring methodology resembling the Physician Value-Based Payment Modifier in the Hospital VBP Program because the Physician Value-Based Payment Modifier uses broad categories to assess performance, which commenters believed would not capture hospital performance as precisely as the current linear-based methodology. One commenter expressed concern with value scoring in the program because CMS will have difficulty identifying controllable expenses for the denominator and defining meaningful quality metrics for the numerator.

Response: We thank all of the commenters for their suggestions, and we will take them into consideration in the future if we choose to propose to adopt a new value scoring methodology or otherwise modify the existing scoring methodology of the Hospital VBP Program.

b. Finalized Update to an Existing Measure for the FY 2021 Program Year: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) (Updated Cohort)

The Hospital 30-Day, All-Cause, RSMR Following Pneumonia Hospitalization (NQF #0468) (MORT–30–PN (updated cohort)) measure is a risk-adjusted, NQF-endorsed mortality measure monitoring mortality rates following pneumonia hospitalizations. As part of the CMS measure reevaluation process, the MORT–30–PN measure underwent a substantive revision, which expanded the measure cohort to include: (1) Patients with a principal discharge diagnosis of pneumonia (the current reported cohort); (2) patients with a principal discharge diagnosis of aspiration pneumonia; and (3) patients with a principal discharge diagnosis of sepsis (excluding severe sepsis) with a secondary diagnosis of pneumonia coded as present on admission. For the purposes of describing the refinement of this measure, we note that ''cohort'' is defined as the hospitalizations, or ''index admissions,'' that are included in the measure and evaluated to ascertain whether the patient subsequently died within 30 days of the index admission. This cohort is the set of hospitalizations that meet all of the inclusion and exclusion criteria.

The Hospital IQR Program adopted this measure refinement of MORT–30–PN (updated cohort) in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49653 through 49660), with initial MORT–30–PN (updated cohort) data to be posted on *Hospital Compare* on or around July 21, 2016 (now on or about July 27, 2016). The MORT–30–PN (updated cohort) measure (MUC–E0468) was included on the ''List of Measures Under Consideration for December 1, 2014'' and received conditional support from the MAP, pending NQF endorsement of the updated cohort as detailed in the ''Spreadsheet of MAP 2015 Final Recommendations.'' [38] The full measure specifications are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

This refinement to the MORT–30–PN measure was adopted to more accurately reflect quality and outcomes for patients with pneumonia. Recent evidence has shown an increase in the use of sepsis as a principal diagnosis code among patients hospitalized with pneumonia.[39] In response to this emerging evidence, we examined coding patterns across hospitals caring for Medicare patients and sought to forecast the impact of enhancing or broadening the measure cohort to include the complete patient population, at each hospital, who are receiving clinical management and treatment for pneumonia. Our findings were consistent with a published study.[40] That is, our results suggested that there is: (1) An increasing use of sepsis as a principal discharge diagnoses for pneumonia patients; and (2) wide variation across hospitals in the use of these codes. These published studies and CMS analyses also show that hospitals that use sepsis codes for the principal diagnosis frequently have better performance on the currently adopted MORT–30–PN measure. This coding practice improves performance on the measure because patients with greatest severity of illness (for example, those with sepsis) are systematically excluded from the measure under current measure specifications, leaving only patients with less severity of illness in the cohort.

In addition to assessing the use of the principal diagnosis codes of sepsis, we also analyzed coding patterns and the impact of expanding the pneumonia measure to include patients with the principal diagnosis of aspiration pneumonia. We noted after our analyses that aspiration pneumonia: (1) Is a common reason for pneumonia hospitalization, particularly among the elderly; (2) is currently not included in the CMS hospital outcome measure specifications for pneumonia patients; and (3) appears to be similarly subject to variation in diagnosis, documentation, and coding. The findings of published studies and CMS analyses suggested that a MORT–30–PN measure with an enhanced or broader cohort would ensure that the population of patients with pneumonia is more complete and comparable across hospitals.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25106 through 25107), we proposed this measure refinement for the Hospital VBP Program based on our adoption of the measure refinement in the Hospital IQR Program, and our posting of measure data on *Hospital Compare* for at least one year prior to the start of the measure performance period. In addition, the MORT–30–PN (updated cohort) measure addresses a high volume, high cost condition. The measure aligns with the NQS priority and CMS Quality Strategy Goal of ''Effective Prevention and Treatment of Chronic Disease.'' Based on the continued high risk of mortality after pneumonia hospitalizations, we proposed to add it to the Clinical Care domain beginning with the FY 2021 program year.

We invited public comments on this proposal.

Comment: Several commenters supported CMS' proposal to expand the

[38] ''Spreadsheet of MAP 2015 Final Recommendations'' available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711* and ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' available at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx*.

[39] Lindenauer PK, Lagu T, Shieh MS, Pekow PS, Rothberg MB. Association of diagnostic coding with trends in hospitalizations and mortality of patients with pneumonia, 2003–2009. Journal of the American Medical Association. Apr 4 2012; 307(13):1405–1413.

[40] Rothberg MB, Pekow PS, Priya A, Lindenauer PK. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. Annals of Internal Medicine. Mar 18 2014; 160(6):380–388.

MORT–30–PN measure because this update will align the Hospital VBP Program and Hospital IQR Program measures. One commenter noted that the expansion addresses coding variations and will ensure better collection of complete and comparable data across hospitals.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS have the American Hospital Association ICD–10 clinic review pneumonia coding for ICD–10 to see if changes are needed in these codes to capture coding variation for causes of aspiration pneumonia.

Response: We thank commenter for the recommendation and note that CMS is currently updating all measures from ICD–9 to ICD–10 through a systematic process of assessing the changes in all codes used in measure cohorts to ensure that the cohorts remain valid and capture the intended conditions. For those individuals who are interested in participating in future ICD–10 Coordination and Maintenance Committee meetings, information on the Committee can be found on the CMS Web site at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*. We encourage public participation at these meetings either in person, by conference lines, or by the livestream provided by CMS.

Comment: Many commenters did not support the addition of the MORT–30–PN updated measure because it is not NQF-endorsed. These commenters believe the endorsement process will allow the field to better understand the potential causes of coding differences. Specifically, many commenters are concerned that the inclusion of: (1) Patients with a principal discharge diagnosis of aspiration pneumonia; and (2) patients with a principal discharge diagnosis of sepsis (excluding severe sepsis) with a secondary diagnosis of pneumonia coded as present on admission may inadvertently conflate pneumonia as a discrete medical event with other underlying disease conditions.

Response: The MORT–30–PN measure with the expanded cohort was submitted to the NQF Pulmonary and Critical Care Project 2015–2016, with information on the project available at: *http://www.qualityforum.org/Projects/n-r/Pulmonary_and_Critical_Care_Measures/Pulmonary_and_Critical_Care_Project.aspx*. The MAP conditionally supported the measure, pending NQF endorsement. Because the original measure was previously endorsed and the intent of the measure has not changed, we anticipate the measure will be reendorsed with the expanded cohort.

We agree with commenters that aspiration pneumonia may be the result of a range of potential causes. We expanded the cohort to include the aspiration pneumonia population to more fully capture the complete population of hospital patients receiving management and treatment for pneumonia, and thereby capture the morbidity and mortality of this important cohort. We appreciate the commenters' concerns that community acquired pneumonia and aspiration pneumonia have different causes and associated risks (for example, recurrent aspiration due to other comorbidities).

While the pathological causes of aspiration pneumonia are slightly different from the causes of community acquired pneumonia, in routine clinical practice, evidence shows it can be very challenging for physicians to differentiate aspiration syndromes, including pneumonitis and pneumonia, from other types of pneumonia included in the measure. This is reflected in the tremendous variation across hospitals in the use of aspiration pneumonia diagnosis codes. This variation suggests that hospitals are not consistently distinguishing between these conditions as distinct subtypes regardless of patients' comorbid conditions. Thus, we continue to believe the modified expanded cohort for the measure balances the need to be more clinically comprehensive while also accurately capturing pneumonia mortality.

Comment: Several commenters did not support the inclusion of the MORT–30–PN update in the Hospital VBP Program because it does not adjust for differences in patient population.

Response: We disagree with commenters that the updated MORT–30–PN measure does not adjust for differences in patient population. The risk adjustment model adequately accounts for the varying severity and comorbidities of patients across the modified cohort; therefore, we believe that hospitals will not be unfairly penalized for treating sicker patients. We refer the commenter to the measure methodology report and measure risk adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Mortality Update zip file at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: One commenter did not support the MORT–30–PN expansion because commenter believed that it moves beyond the measure's original scope of community-acquired pneumonia and because hospitals that are successful in preventing the progression from pneumonia to sepsis will appear worse than hospitals with more septic patients.

Response: The purpose of expanding the MORT–30–PN measure cohort was to more fully capture patients that were previously excluded due to the variation in the use of sepsis codes, which systematically excluded these patients from the measure population. We believe that the MORT–30–PN (updated cohort) achieves this purpose by capturing patients with pneumonia who may progress to sepsis by expanding the measure cohort to include patients with a principal discharge diagnosis of sepsis (excluding severe sepsis) with a secondary diagnosis of pneumonia coded as present on admission. This ensures that patients with a principal discharge diagnosis code of sepsis, who also presented with pneumonia, will be included at all hospitals allowing for a more consistent cohort across hospitals. This expansion should not therefore hurt the performance of hospitals successful in preventing sepsis.

Comment: A few commenters did not support the MORT–30–PN update because the impact of the update has not yet been publicly reported. The commenters noted that the measure developer indicated that an increase in mortality rates may be attributed to the expanded cohort, but no information is available about how specific hospitals perform. The commenters suggested waiting to adopt the new measure until hospitals have had sufficient time to review and analyze their performance on the expanded measure. One commenter recommended that CMS implement a phased-in approach to the expanded measure that would first allow for public reporting before implementing the expanded measure in the Hospital VBP Program.

Response: We acknowledge that hospitals will not have an opportunity to review publicly reported data before the measure is finalized in the Hospital VBP Program; however, the measure has been refined to more fully capture the mortality of patients with pneumonia, which we believe is important to capture in the Hospital VBP Program as soon as possible.

We also note that hospitals will have time to review and analyze their performance on the expanded measure prior to the FY 2021 program year because the update to the MORT–30–PN measure was implemented by the Hospital IQR Program before we are finalizing it in the Hospital VBP

Program. The updated MORT–30–PN measure data will be first posted on *Hospital Compare* on or around July 27, 2016. Because the performance period for the updated MORT–30–PN measure will not begin until September 1, 2017 (instead of August 1, 2017, discussed in more detail below), hospitals will have one full year to review and assess their performance on the expanded measure prior to the beginning of the performance period.

Comment: A few commenters did not support the MORT–30–PN measure's expansion to include aspiration pneumonia because commenters believe the majority of patients with aspiration pneumonia are medically frail patients with comorbidities that predispose them to recurrent aspiration events and therefore represent a higher risk for complications, readmissions, and death despite evidence-based treatment and prevention strategies. The commenters also noted that the measure will capture different cohorts of patients with different baseline factors that influence morbidity and mortality, such as patients with psychiatric and substance abuse comorbidities, and commenter believed penalizing hospitals treating these patients may impact availability of services for these patients.

Response: We appreciate the commenters' concerns about the extent of the refinement of this measure and the inclusion of patients with greater illness severity. In particular, we understand commenters' concerns that aspiration pneumonia can have different causes and associated risks (for example, recurrent aspiration due to other comorbidities). However, while the pathological causes of aspiration pneumonia are slightly different from the causes of community acquired pneumonia, in routine clinical practice, evidence shows it can be very challenging for physicians to differentiate aspiration syndromes including pneumonitis and pneumonia, from other types of pneumonia included in the measure. This is reflected in the tremendous variation across hospitals in the use of aspiration pneumonia diagnosis codes. This variation suggests that hospitals are not consistently distinguishing between these conditions as distinct subtypes regardless of patients' comorbid conditions. Expanding the measure cohort would ensure that the measure is clinically comprehensive.

Moreover, the treatment of patients hospitalized for pneumonia, aspiration pneumonia, or sepsis due to pneumonia is very similar and involves treatment with antibiotics, IV fluids, and symptom management. In addition, although some patients with aspiration pneumonia, such as medically frail patients, have a higher predicted mortality risk, many of the associated comorbidities are captured in the MORT–30–PN (updated cohort) measure's risk-adjustment methodology. Of note, due to the increased number of patients that are included in the expanded cohort, we reselected risk-adjustment variables to ensure that the measure does not bias hospital performance as well as accounts for the differences in risk among the subgroup of patients. For example, the risk model includes clinical history of stroke, as well as conditions associated with frailty, such as neuromuscular disease, and dementia. We refer readers to the measure methodology report and measure risk adjustment statistical model, Condition-Specific Measures Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Mortality Measures—Pneumonia Mortality Version 10, in the AMI, HF, PN, COPD, and Stroke Mortality Update zip file available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

After consideration of the public comments we received, we are finalizing the proposal to add the MORT–30–PN (updated cohort) to the Hospital VBP Program beginning with the FY 2021 program year.

5. New Measure for the FY 2022 Program Year: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558)

The Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following CABG Surgery (NQF #2558) (MORT–30–CABG) measure is a risk-adjusted, NQF-endorsed mortality measure monitoring mortality rates following CABG hospitalizations. This measure includes Medicare FFS patients aged 65 or older who receive a qualifying CABG procedure and assesses hospitals' 30-day, all-cause risk-standardized rate of mortality, beginning with the date of the index procedure. The measure is calculated using administrative claims data. In general, the measure uses the same approach to risk adjustment as our 30-day outcome measures previously adopted for the Hospital VBP Program. We adopted this measure in the Hospital IQR Program in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50224 through 50227). Initial measure data were posted on *Hospital Compare* in July 2015 and the full measure specifications are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

CABG is a priority area because it is a common procedure associated with considerable morbidity, mortality, and healthcare spending. In the United States, over 200,000 CABG procedures are performed annually, and the majority of procedures are performed on Medicare beneficiaries.[41] In 2012, Medicare beneficiaries had 121,744 CABG surgery admissions, with or without percutaneous coronary intervention or valve surgery.[42] CABG surgeries are costly procedures that account for a large percentage of cardiac surgeries performed nationally. For example, isolated CABG surgeries accounted for almost half (40.02 percent) of all cardiac surgery hospital admissions in Massachusetts in FY 2012.[43] This provides an example of the frequency in which a CABG is performed for a patient admitted for cardiac surgery. The average Medicare payment was $32,564 for CABG without valve and $48,461 for CABG plus valve surgeries in 2011.[44]

Mortality rates following CABG surgery are not insignificant and vary across hospitals. For the July 2011 through June 2014 Hospital IQR Program reporting period, the median hospital-level risk-standardized mortality rate after CABG was 3.1 percent and ranged from 1.6 percent to 9.2 percent.[45] Variation in mortality rates following CABG surgery can be seen not only nationally, but also within a single State. Within the State of New York, the risk-adjusted mortality rate

[41] Fingar, K.R., Stocks, C., Weiss, A.J. and Steiner, C.A., 2014. Most frequent operating room procedures performed in US hospitals, 2003–2012. In Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project Statistical Brief #186. Available at: *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb186-Operating-Room-Procedures-United-States-2012.pdf*.

[42] Culler SD, Kugelmass AD, Brown PP, Reynolds MR, Simon AW. Trends in coronary revascularization procedures among Medicare beneficiaries between 2008 and 2012. Circulation. 2014 Dec 22:CIRCULATIONAHA–114.

[43] Massachusetts Data Analysis Center. Adult Coronary Artery Bypass Graft Surgery in the Commonwealth of Massachusetts: Hospital and Surgeons Risk-Standardized 30-Day Mortality Rates. Fiscal Year 2012 Report. Available at: *http://www.massdac.org/wp-content/uploads/CABG-FY2012-Update.pdf*.

[44] Pennsylvania Health Care Cost Containment Council. Cardiac Surgery in Pennsylvania 2011–2013. Harrisburg; 2013:60.

[45] September 2015 Medicare Hospital Performance Report on Outcome Measures: Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/OutcomeMeasures.html*.

among patients who were discharged after CABG surgery (without any other major heart surgery earlier in the hospital stay) ranged from 0.0 percent to 4.58 percent in 2011.[46] Variation in risk-standardized mortality rates among U.S. hospitals suggests that there is room for improvement.

An all-cause, risk-adjusted mortality measure for patients who undergo CABG surgery would provide hospitals with an incentive to reduce mortality through improved coordination of perioperative care and discharge planning. This is further supported by the success of registry-based mortality measures in reducing CABG mortality rates. For example, CABG mortality in California declined from 2.9 percent in 2003, the first year that the State implemented a mandatory CABG mortality reporting measure, to 2.1 percent in 2012.[47]

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25107), we proposed the MORT–30–CABG measure for the Hospital VBP Program beginning with the FY 2022 program year because it addresses a high-volume, high-cost procedure with variation in performance. The measure also aligns with the CMS Quality Strategy Goal of Effective Prevention and Treatment of Chronic Disease. The measure fulfills all statutory requirements for the Hospital VBP Program based on our adoption of the measure in the Hospital IQR Program and our posting of measure data on *Hospital Compare* for at least one year before the beginning of the measure performance period. The MAP supported the inclusion of the MORT–30–CABG measure (MUC15–395) in the Hospital VBP Program as detailed in the ''Spreadsheet of MAP 2016 Final Recommendations.'' [48] Based on the continued high risk of mortality after CABG hospitalizations, we proposed to add this measure to the Clinical Care domain beginning with the FY 2022 program year.

We invited public comments on this proposal.

Comment: Many commenters supported the MORT–30–CABG measure because it is NQF-endorsed and MAP-supported, noting that the measure addresses a high-volume, high-cost procedure with performance variation and including the measure will reduce mortality through improved coordination and planning. One commenter noted that an all-cause, risk-adjusted mortality measure for patients who undergo CABG surgery will provide hospitals with an incentive to reduce mortality through improved coordination of perioperative care and discharge planning. One commenter supported adding the MORT–30–CABG measure because the commenter believed the measure increases incentives for hospitals to better manage patients' chronic conditions after discharge.

Response: We thank the commenters for their support.

Comment: One commenter did not support the addition of the MORT–30–CABG measure because it captures mortality that could be unrelated to the procedure and beyond the hospital's control. The commenter suggested adding language excluding cases where patients die from causes unrelated to the CABG procedure.

Response: The measure assesses all-cause mortality rather than CABG-specific mortality for several reasons. First, limiting the measure to CABG-related mortalities may limit the focus of efforts to improve care to a narrow set of approaches as opposed to encouraging broader initiatives and innovative approaches aimed at improving the overall in-hospital care. Second, cause of death may be unreliably recorded and it is often not possible to exclude quality issues and accountability based on the documented cause of mortality.

Comment: Several commenters did not support the addition of the MORT–30–CABG for the FY 2022 program year. Commenters expressed concern that the MORT–30–CABG measure's reliability is inadequate and depends heavily upon whether a hospital has a sufficient volume of eligible patients. One commenter stated the measure is not NQF-endorsed. One commenter believed the data the MORT–30–CABG measure captures will overlap with the MORT–30–AMI measure.

Response: We disagree with commenters that the MORT–30–CABG measure is not reliable. We note that the NQF has endorsed the measure as reliable and valid (NQF #2558). For more information regarding measure reliability, we refer the commenter to the version 1.0 measure methodology report in CABG Mortality zip file at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

Further, while we acknowledge commenter's concern regarding the overlap between the MORT–30–AMI and MORT–30–CABG measures, we believe it is important that both measures represent the full spectrum of admissions eligible for the cohort for each individual measure to ensure the validity of the individual measures as endorsed by the NQF. We also find that the overlap is minimal between the measures, with prior analysis showing less than 7 percent of the AMI cohort included in the CABG measure cohort.

Comment: Some commenters recommended that CMS include adequate risk-adjustment modifications to the measure that addresses both SDS and clinical factors.

Response: The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how

[46] New York State Department of Health. Adult Cardiac Surgery in New York State 2009–2011. Available at: *https://www.health.ny.gov/statistics/diseases/cardiovascular/heart_disease/docs/2009-2011_adult_cardiac_surgery.pdf.*

[47] California Office of Statewide Health Planning and Development. CABG Outcomes Reporting Program. The California Report on Coronary Artery Bypass Graft Surgery: 2003–2012 Trendlines. Available at: *http://www.oshpd.ca.gov/hid/Products/Clinical_Data/CABG/03-12_Trends.html* or *http://www.oshpd.ca.gov/HID/Products/Clinical_Data/CABG/2012/ExecutiveSummary.pdf.*

[48] ''Spreadsheet of MAP 2015–2016 Final Recommendations'' available at: *http://www.qualityforum.org/map/* and ''Process and Approach for MAP Pre-Rulemaking Deliberations 2016'' found at: *http://www.qualityforum.org/Publications/2016/02/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations.aspx.*

they apply to our quality programs at such time as they are available.

Comment: A few commenters expressed concern that the MORT–30–CABG measure, as well as other previously finalized measures, does not exclude patients that desire comfort care, such as hospice services, because these patients have been found to impact mortality measure data and hospital performance for patients with pneumonia. One commenter recommended that CMS modify the measure to exclude patients that desire comfort care rather than treatment. Likewise, another commenter recommended that CMS exclude hospice patients from all mortality measures.

Response: The MORT–30–CABG measure does not exclude patients who transition to hospice care following the index admission because such transitions may be the result of quality failures that have led to poor clinical outcomes. However, all mortality measures proposed and finalized for the Hospital VBP Program, except for the MORT–30–CABG measure, do exclude index admissions for patients enrolled in the Medicare hospice program any time in the 12 months prior to the index admission, including the first day of the index admission, because these patients are likely continuing to seek comfort care only; thus, mortality is not necessarily an adverse outcome or signal of poor quality care for these patients. We note, however, that the MORT–30–CABG measure does not exclude hospice patients because any patient undergoing CABG surgery likely has survival as the primary goal.

After consideration of the public comments we received, we are finalizing the proposal to add the MORT–30–CABG measure beginning with the FY 2022 program year.

6. Previously Adopted and Newly Finalized Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49561 through 49562) for the baseline and performance periods for the Clinical Care, Person and Community Engagement, Safety, and Efficiency and Cost Reduction domains that we have adopted for the FY 2018 program year. In past final rules, we have proposed and adopted a new baseline and performance period for each program year for each domain in each final rule. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25107 through 25108), we proposed to adopt the following baseline and performance periods for all future program years, unless otherwise noted in future rulemaking.

b. Patient- and Caregiver-Centered Experience of Care/Care Coordination Domain (Person and Community Engagement Domain Beginning With the FY 2019 Program Year)

Since the FY 2015 program year, we have adopted a 12-month baseline period and a 12-month performance period for measures in the re-named Person and Community Engagement domain (previously referred to as the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain) (77 FR 53598; 78 FR 50692; 79 FR 50072; 80 FR 49561). We continue to believe that a 12-month period provides us sufficient data on which to score hospital performance.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25108), we proposed to adopt this baseline and performance period length for the FY 2019 program year and all future program years, unless otherwise noted in future rulemaking. Therefore, for the FY 2019 program year and future program years, we proposed to adopt a performance period that runs on the calendar year 2 years prior to the applicable program year. We proposed to adopt a baseline period that runs on the calendar year 4 years prior to the applicable program year. Applying these new policies, for the FY 2019 program year, the baseline period for the re-named Person and Community Engagement domain would run from January 1, 2015 through December 31, 2015. The performance period would run from January 1, 2017 through December 31, 2017.

We received no public comments on this proposal. Therefore, we are finalizing the proposal to adopt a performance period for the Person and Community Engagement domain that runs on the calendar year 2 years prior to the applicable program year and to adopt a baseline period that runs on the calendar year 4 years prior to the applicable program year, for the FY 2019 program year and all future program years.

c. Efficiency and Cost Reduction Domain

(1) MSPB Measure

Since the FY 2016 program year, we have adopted a 12-month baseline period and a 12-month performance period for the MSPB measure in the Efficiency and Cost Reduction domain (78 FR 50692; 79 FR 50072; 80 FR 49562). We continue to believe that a 12-month period for this measure provides sufficient data on which to score hospital performance. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25108), we proposed to adopt this baseline and performance period length for the FY 2019 program year and all future program years, unless otherwise noted in future rulemaking.

Therefore, for the FY 2019 program year and future program years, we proposed to adopt a performance period that runs on the calendar year 2 years prior to the applicable program year. We proposed to adopt a baseline period that runs on the calendar year 4 years prior to the applicable program year. Applying these new policies, for the FY 2019 program year, the baseline period for the MSPB measure would run from January 1, 2015 through December 31, 2015. The performance period would run from January 1, 2017 through December 31, 2017.

We received no public comments on this proposal. Therefore, we are finalizing the proposal to adopt a performance period for the MSPB measure that runs on the calendar year 2 years prior to the applicable program year and to adopt a baseline period that runs on the calendar year 4 years prior to the applicable program year, for the FY 2019 program year and all future program years.

(2) AMI Payment and HF Payment Measures in the FY 2021 Program Year

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25103 through 25105), we also proposed to adopt the AMI Payment and HF Payment measures as 2 new measures for the Efficiency and Cost Reduction domain beginning in the FY 2021 program year. In order to adopt the measures as early as feasible into the Hospital VBP Program, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25108 through 25109), we proposed to adopt a 36-month baseline period and a 24-month performance period. Therefore, for the FY 2021 program year, we proposed to adopt a 24-month performance period that runs from July 1, 2017 to June 30, 2019. We proposed to adopt a 36-month baseline period that runs from July 1, 2012 to June 30, 2015.

We believe that using a 24-month performance period for the AMI Payment and HF Payment measures, rather than a 36-month performance period, in the FY 2021 program year would accurately assess the quality of

care provided by hospitals and would not substantially change hospitals' performance on the measure. To determine the viability of using a 24-month performance period to calculate the AMI Payment and HF Payment measures' scores, we compared the measure score reliability for a 24-month and 36-month performance period. We calculated the Intraclass Correlation Coefficient (ICC) to determine the extent to which assessments of a hospital using different but randomly selected subsets of patients produces similar measures of hospital performance.[49] We calculated the risk-standardized payment (RSP) using a random split-sample of a 36-month performance period (we used July 1, 2012 through June 30, 2015).

For both the 36-month and the 24-month performance periods, we obtained 2 RSPs for each hospital, using an entirely distinct set of patients from the same time period. If the RSPs for both the 36-month and the 24-month performance periods agree, we can demonstrate that the measure assesses the quality of the hospital rather than the types of patients treated. To calculate agreement between these measure subsets, we calculated the ICC (2,1)[50] for both the 36-month and 24-month performance periods.

For the AMI Payment measure, there were 459,874 index admissions and 2,342 hospitals that met the minimum threshold for reporting a measure result (at least 25 cases) in the 36-month performance period. We also calculated the RSP using a random split-sample of the combined 24-month performance period (we used July 1, 2012 through June 30, 2014). There were 309,067 index admissions and 2,141 hospitals that met the minimum threshold for reporting a measure result in the 24-month performance period.

For the 36-month performance period, the ICC for the 2 independent assessments of each hospital was 0.775. For the 24-month performance period, the ICC for the 2 independent assessments of each hospital was 0.742. Therefore, the data subsets showcase ''substantial'' agreement of hospital performance, and we can demonstrate that, even with a 24-month performance period, the measure assesses the quality of care provided at the hospital rather than the types of patients that these hospitals treat.[51]

To assess whether using 24 months of data instead of 36 months of data changes the performance in the same hospital, we compared the percent change in a hospital's predicted/expected (P/E) ratio. For hospitals that met the minimum case threshold in the 24-month performance period, the median percent change was −0.06 percent (with an interquartile range of −1.7 percent to 1.5 percent). These results suggest minimal difference in same-hospital performance when using a 24-month measurement period.

To determine the viability of using a 24-month performance period to calculate the HF Payment measure's score, we assessed reliability and change in hospital performance for a 24-month and 36-month performance period using the same process as the AMI Payment measure. For the HF Payment measure, there were 877,856 index admissions and 2,981 hospitals that met the minimum threshold for reporting a measure result (at least 25 cases) in the 36-month performance period. We also calculated the RSP using a random split-sample of a 24-month performance period (we used July 1, 2012 through June 30, 2014). There were 580,741 index admissions and 2,883 hospitals that met the minimum threshold for reporting a measure result in the 24-month performance period.

For the 36-month performance period, the ICC for the 2 independent assessments of each hospital was 0.83. For the 24-month performance period, the ICC for the 2 independent assessments of each hospital was 0.81. Therefore, the data subsets showcase ''almost perfect'' agreement of hospital performance, and we can demonstrate that, even with a 24-month performance period, the measure assesses the quality of care provided at the hospital rather than the types of patients that these hospitals treat.[52]

To assess whether using a 24-month performance period instead of a 36-month performance period changes the performance in the same hospital, we compared the percent change in a hospital's P/E ratio. For hospitals that met the minimum case threshold in the 24-month performance period, the median percent change for hospitals' P/E ratio using 24-month performance periods compared with 36-month performance periods was −0.02 percent (with an interquartile range of −1.9 percent to 1.8 percent). These results suggest minimal difference in same-hospital performance when using a 24-month measurement period.

Therefore, we believe that using a 24-month performance period rather than a 36-month performance period would not substantially change hospitals' performance on the AMI Payment and HF Payment measures. In sum, based on the analyses described earlier, we believe that using 24-month performance periods, rather than 36-month performance periods, for the initial performance period for this measure would accurately assess the quality of care provided by that hospital and would not substantially change that hospital's performance on the measure.

Comment: A few commenters did not support the proposal to adopt the AMI Payment and HF Payment measures with a 24-month performance period in the FY 2021 program year because commenters believe the measures should have consistent baseline and performance periods across program years in order to fairly and accurately compare performance from program year to program year. Several commenters recommended that CMS delay adoption of the AMI Payment and HF Payment measures until the FY 2022 program year when CMS can adopt 36-month performance periods. One commenter supported the use of a three-year baseline period because a longer baseline period can account for the longer-term predictive value of health events such as AMI or HF better than a one-year baseline period.

Response: We note that the AMI Payment and HF Payment measures will only have a 24-month performance period for the FY 2021 program year, the first year these measures are in the program, but we are adopting a 36-month performance period for the FY 2022 program year, as detailed in the next section below. We continue to believe that the 24-month performance period for FY 2021 is sufficiently reliable to accurately assess the resource use by hospitals and would not substantially change hospitals' performance on the measure.

After consideration of the public comments we received, we are finalizing the proposal to adopt a 24-month performance period and 36-month baseline period for both the AMI Payment and HF Payment measures for the FY 2021 program year.

(3) AMI Payment and HF Payment Measures in the FY 2022 Program Year

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25109), for the FY 2022 program year, we proposed to adopt a 36-month performance period and a 36-month baseline period for the

[49] Shrout P, Fleiss J. Intraclass Correlations: Uses in Assessing Rater Reliability. Pyschol Bull. Mar 1979;86(2):420–428.

[50] Ibid.

[51] Landis J, Koch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. Mar 1997 1977;33(1):159–174.

[52] Landis J, Koch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. Mar 1997 1977;33(1):159–174.

AMI Payment and HF Payment measures. We have stated in past rules that we would strive to adopt 36-month performance periods and baseline periods when possible to accommodate the time needed to process measure data and to ensure that we collect enough measure data for reliable performance scoring for all mortality measures (80 FR 49588; 79 FR 50057; 78 FR 50074). Therefore, for the FY 2022 program year, we proposed to adopt a 36-month performance period that runs from July 1, 2017 to June 30, 2020. We proposed to adopt a 36-month baseline period that runs from July 1, 2012 to June 30, 2015.

After consideration of the public comments we received, we are finalizing the proposal to adopt a 36-month performance period and 36-month baseline period for the AMI Payment and HF Payment for the FY 2022 program year.

d. Safety Domain

Since the FY 2016 program year, we have adopted a 12-month baseline period and 12-month performance period for all measures in the Safety domain, with the exception of the PSI 90 measure (78 FR 50692; 79 FR 50071; 80 FR 49562). We continue to believe that a 12-month period for these measures provides us sufficient data on which to score hospital performance.

Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25109), we proposed to adopt a 12-month baseline period and a 12-month performance period for all measures in the Safety domain for the FY 2019 program year and all future program years, unless otherwise noted in future rulemaking. Under this proposed policy, for the FY 2019 program year and future program years, we proposed to adopt a performance period that runs on the calendar year 2 years prior to the applicable program year. We proposed to adopt a baseline period that runs on the calendar year 4 years prior to the applicable program year. Applying these new policies, for the FY 2019 program year, the baseline period for all measures in the Safety domain would run from January 1, 2015 through December 31, 2015. The performance period would run from January 1, 2017 through December 31, 2017.

We received no public comments on this proposal. Therefore, we are finalizing the proposal to adopt a performance period for all remaining measures in the Safety domain (we refer readers to the discussion below regarding the PSI 90 measure) that runs on the calendar year 2 years prior to the applicable program year and to adopt a baseline period that runs on the calendar year 4 years prior to the applicable program year, for the FY 2019 program year and all future program years.

As discussed in section IV.H.2.a. of the preamble of this final rule, we are finalizing our proposal to adopt a shortened performance period for the PSI 90 measure in the FY 2018 program year, which will be July 1, 2014 through September 30, 2015. As stated earlier, the baseline period for the PSI 90 measure for FY 2018 that we previously established would not change.

e. Clinical Care Domain

(1) Currently Adopted Measures in the Clinical Care Domain

For the FY 2019, FY 2020, and FY 2021 program years, we have adopted a 36-month baseline period and a 36-month performance period for currently adopted measures in the Clinical Care domain (78 FR 50692 through 50694; 79 FR 50073; 80 FR 49563).[53] In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25109), for the FY 2022 program year, we proposed to adopt a 36-month performance period and a 36-month baseline period for each of the other measures in the Clinical Care domain, the MORT–30–AMI, MORT–30–HF, and MORT–30–COPD measures, as well as the new MORT–30–CABG measure. The performance periods for these measures would run for 36-months from July 1, 2017 through June 30, 2020. The baseline period would run from July 1, 2012 through June 30, 2015. We proposed that the THA/TKA measure performance period would run from April 1, 2017 through March 31, 2020. The baseline period would run from April 1, 2012 through March 31, 2015.

We received no public comments on this proposal. Therefore, we are finalizing the proposal to adopt a 36-month performance period and 36-month baseline period for the FY 2022 program year for the measures currently adopted in the Clinical Care domain.

(2) MORT–30–PN (Updated Cohort) Measure in the FY 2021 Program Year

In order to adopt the new MORT–30–PN (updated cohort) measure into the Hospital VBP Program as early as feasible, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25110), we proposed to adopt a 36-month baseline period and a 23-month performance period for the FY 2021 program year. We proposed to adopt a 23-month performance period because the measure will not have been posted on *Hospital Compare* for one year until July 21, 2017 (now on or about July 27, 2017). We proposed to begin the performance period on August 1, 2017 to accommodate this statutory requirement.

We believe that using a 23-month performance period for the MORT–30–PN (updated cohort) measure, rather than a 36-month performance period, in the FY 2021 program year would accurately assess the quality of care provided by hospitals and would not substantially change hospitals' performance on the measure. To determine the viability of using a 23-month performance period to calculate the MORT–30–PN (updated cohort) measure's score, we compared the measure score reliability for a 23-month and a 36-month performance period. We calculated the ICC to determine the extent to which assessments of a hospital using different but randomly selected subsets of patients produces similar measures of hospital performance. We calculated the RSMR using a random split-sample of the combined 36-month performance period (we used July 1, 2012 through June 30, 2015). There were 1,292,701 index admissions and 3,103 hospitals that met the minimum threshold for reporting a measure result (at least 25 cases) in the 36-month performance period. We also calculated the RSMR using a random split-sample of the combined 23-month performance period (we used July 1, 2012 through May 31, 2014). There were 798,746 index admissions and 3,043 hospitals that met the minimum threshold for reporting a measure result in the 23-month performance period.

For both the 36-month data and the 23-month performance periods, we obtained 2 RSMRs for each hospital, using an entirely distinct set of patients from the same time period. If the RSMRs for both the 36-month subset and the 23-month performance periods agree, we can demonstrate that the measure assesses the quality of the hospital rather than the types of patients treated. To calculate agreement between these measure subsets, we calculated the ICC for both the 36-month and 23-month performance periods.

For the 36-month data performance period, the agreement between the 2 independent assessments of each hospital was 0.69. For the 23-month data performance period, the agreement

[53] The currently adopted measures in the Clinical Care domain include: MORT–30–AMI, MORT–30–HF, MORT–30–PN, and THA/TKA. The THA/TKA measure was added for the FY 2019 program year with a 36-month baseline period and a 24-month performance period (79 FR 50072), but we have since adopted 36-month baseline and performance periods for the FY 2021 program year (80 FR 49563). We intend to continue having 36-month baseline periods and 36-month performance periods in the future for all measures in the Clinical Care domain.

between the 2 independent assessments of each hospital was 0.58. Therefore, the data subsets showcase ''moderate'' agreement of hospital performance, and we can demonstrate that, even with a 23-month performance period, the measure moderately assesses the quality of care provided at the hospital rather than the types of patients that these hospitals treat.[54]

To assess whether using a 23-month performance period instead of a 36-month performance period changes the performance in the same hospital, we compared the percent change in a hospital's RSMR. In some cases, changing the performance period from 36 months to 23 months resulted in hospitals failing to meet the case threshold to report a measure score; therefore, these hospitals were removed from the measure. For the remaining hospitals, the median percent change was 1.52 percent (with an interquartile range of 2.32 percent to 5.32 percent). These results suggest minimal difference in hospital performance when using a 23-month measurement period.

Therefore, we believe that using 23 months of data rather than 36 months of data would not substantially change hospitals' performance on this measure. In summary, based on the analyses described earlier, we believe that using 23 months of data, rather than 36 months of data, for the initial performance period for this measure would, with moderate accuracy, assess the quality of care provided by that hospital. In addition, it would not substantially change that hospital's performance on the measure.

Further, adopting this performance period will enable us to include the updated measure cohort in the FY 2021 Hospital VBP Program, which would ensure that MORT–30–PN more accurately reflects quality and outcomes for patients with pneumonia. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25110), for the MORT–30–PN (updated cohort) measure, we proposed a performance period that would run from August 1, 2017 through June 30, 2019 for the FY 2021 program year. The baseline period would run from July 1, 2012 through June 30, 2015.

Comment: One commenter supported our inclusion of the MORT–30–PN measure for the FY 2021 program year with a 23-month performance period.

Response: We thank the commenter for its support.

Comment: A few commenters did not support the 23-month performance period for the MORT–30–PN measure in the FY 2021 program year because commenters believed the measure is only moderately reliable, which is insufficient for a payment program. One commenter did not believe CMS has proven that the measure is reliable with a shorter performance period, and the commenter recommended that CMS refrain from pushing to adopt measures for the Hospital VBP Program when doing so would require using shortened performance periods.

Response: As we note in the proposed rule (81 FR 25108), we calculated the Intraclass Correlation Coefficient (ICC) to determine the extent to which assessments of a hospital using different but randomly selected subsets of patients produces similar measures of hospital performance.[55] For the 23-month performance period the ICC was 0.58, which is consistent with other NQF-endorsed claims-based measures in the Hospital VBP Program. Therefore, we believe the measure is sufficiently reliable to include in the program.

Since publication of the FY 2017 IPPS/LTCH PPS proposed rule, we have become aware of operational issues that may delay publication of MORT–30–PN measure data on *Hospital Compare* by 1–2 weeks but past August 1, 2016. Under section 1886(o)(2)(C)(i) of the Act, the Hospital VBP Program must refrain from beginning the performance period for a new measure until data on the measure have been posted on *Hospital Compare* for at least one year. As a result, we believe it is necessary to delay the beginning of the performance period for the MORT–30–PN measure one additional month, from August 1, 2017 to September 1, 2017. We continue to believe the MORT–30–PN measure will be sufficiently reliable using 22 months of data because this is not a significant reduction in the amount of data used to calculate performance scores under the measure, and finalizing MORT–30–PN with the updated cohort will substantially increase the denominator of this measure. For these reasons, we are finalizing that instead of beginning the performance period for the MORT–30–PN measure for FY 2021 on August 1, 2017, the performance period will begin on September 1, 2017.

After consideration of the public comments we received, we are finalizing our proposal to adopt the MORT–30–PN (updated cohort) measure with a 22-month performance period and 36-month baseline period for the FY 2021 program year.

(3) MORT–30–PN (Updated Cohort) Measure in the FY 2022 Program Year

For the FY 2022 program year and subsequent years, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25110), we proposed to lengthen the MORT–30–PN (updated cohort) performance period to nearly a 36-month performance period (35 months) and continue to adopt a 36-month baseline period. For the FY 2022 program year, we proposed a performance period that would run from August 1, 2017 through June 30, 2020. The baseline period would run from July 1, 2012 through June 30, 2015.

Comment: A few commenters did not support the 35-month performance period for the MORT–30–PN measure in the FY 2022 program year because the commenters believe that CMS has not demonstrated that the measure is highly accurate.

Response: Since the MORT–30–PN measure was found to be statistically reliable at 23 months, we believe that the measure will be even more reliable at 35 months. As noted above, due to operational concerns associated with timely publication of MORT–30–PN data on *Hospital Compare,* we are delaying the start of the FY 2021 performance period by one month, to September 1, 2017. For these same reasons, we are finalizing that instead of beginning the performance period for the MORT–30–PN measure for FY 2022 on August 1, 2017, the performance period will begin on September 1, 2017. We do not believe shortening the FY 2022 MORT–30–PN performance period by one month will affect the reliability of the measure because it will not significantly impact the amount of data used to calculate performance scores under the measure.

After consideration of the public comments we received, we are finalizing our proposal to adopt the MORT–30–PN (updated cohort) measure with a 34-month performance period and 36-month baseline period for the FY 2022 program year. In the FY 2023 program year and subsequent years, we intend to lengthen the MORT–30–PN (updated cohort) performance period to a full 36-month performance period beginning in July, instead of September.

f. Summary of Previously Adopted and Newly Finalized Baseline and Performance Periods for the FY 2018, FY 2019, FY 2020, FY 2021, and FY 2022 Program Years

The tables below summarize the baseline and performance periods that

[54] Landis J, Koch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. Mar 1997 1977;33(1):159–174.

[55] Shrout P, Fleiss J. Intraclass Correlations: Uses in Assessing Rater Reliability. Pyschol Bull. Mar 1979;86(2):420–428.

we are adopting in this final rule (and include previously adopted baseline and performance periods for the Clinical Care domain).

NEWLY FINALIZED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2018 PROGRAM YEAR

Domain	Baseline period	Performance period
Safety		
• PSI 90 *	July 1, 2010–June 30, 2012	July 1, 2014–September 30, 2015.

* We are adopting a shortened performance period for the PSI 90 measure for the FY 2018 program year, as discussed in section IV.H.2.a. of the preamble of this final rule.

PREVIOUSLY ADOPTED AND NEWLY FINALIZED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2019 PROGRAM YEAR

Domain	Baseline period	Performance period
Person and Community Engagement		
• HCAHPS + 3-Item Care Transition	January 1, 2015–December 31, 2015	January 1, 2017–December 31, 2017.
Clinical Care		
• Mortality (MORT-30–AMI, MORT–30–HF, MORT-30–PN) *.	• July 1, 2009–June 30, 2012	• July 1, 2014–June 30, 2017.
• THA/TKA *	• July 1, 2010–June 30, 2013	• January 1, 2015–June 30, 2017.
Safety		
• PC–01 and NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2015–December 31, 2015	• January 1, 2017–December 31, 2017.
• PSI 90	• July 1, 2011–June 30, 2013	• July 1, 2015–June 30, 2017.
Efficiency and Cost Reduction		
• MSPB	January 1, 2015–December 31, 2015	January 1, 2017–December 31, 2017.

* Previously adopted baseline and performance periods that remain unchanged (80 FR 49562 through 49563).

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2020 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care		
• Mortality (MORT-30–AMI, MORT–30–HF, MORT-30–PN) *.	• July 1, 2010–June 30, 2013	• July 1, 2015–June 30, 2018.
• THA/TKA *	• July 1, 2010–June 30, 2013	• July 1, 2015–June 30, 2018.

* Previously adopted baseline and performance periods that remain unchanged (80 FR 49562 through 49563).

PREVIOUSLY ADOPTED AND NEWLY FINALIZED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2021 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care		
• Mortality (MORT-30–AMI, MORT–30–HF, MORT–30–COPD) *.	• July 1, 2011–June 30, 2014	• July 1, 2012–June 30, 2019.
• THA/TKA *	• April 1, 2011–March 31, 2014	• April 1, 2011–March 31, 2019.
• MORT–30–PN (updated cohort)	• July 1, 2012–June 30, 2015	• September 1, 2017–June 30, 2019.
Efficiency and Cost Reduction		
• MSPB	• January 1, 2017–December 31, 2017	• January 1, 2019–December 31, 2019.
• Payment (AMI Payment and HF Payment)	• July 1, 2012–June 30, 2015	• July 1, 2017–June 30, 2019.
Clinical Care		
• Mortality (MORT-30–AMI, MORT–30–HF, MORT–30–COPD) *.	• July 1, 2011–June 30, 2014	• July 1, 2016–June 30, 2019.
• THA/TKA *	• April 1, 2011–March 31, 2014	• April 1, 2016–March 31, 2019.
• MORT–30–PN (updated cohort)	• July 1, 2012–June 30, 2015	• September 1, 2017–June 30, 2019.
Efficiency and Cost Reduction		
• MSPB	• January 1, 2017–December 31, 2017	• January 1, 2019–December 31, 2019.
• Payment (AMI Payment and HF Payment)	• July 1, 2012–June 30, 2015	• July 1, 2017–June 30, 2019.
Clinical Care		
• Mortality (MORT-30–AMI, MORT–30–HF, MORT–30–COPD) *.	• July 1, 2011–June 30, 2014	• July 1, 2016–June 30, 2019.
• THA/TKA *	• April 1, 2011–March 31, 2014	• April 1, 2016–March 31, 2019.
• MORT–30–PN (updated cohort)	• July 1, 2012–June 30, 2015	• September 1, 2017–June 30, 2019.
Efficiency and Cost Reduction		
• MSPB	• January 1, 2017–December 31, 2017	• January 1, 2019–December 31, 2019.
• Payment (AMI Payment and HF Payment)	• July 1, 2012–June 30, 2015	• July 1, 2017–June 30, 2019.

* Previously adopted baseline and performance periods that remain unchanged (80 FR 49562 through 49563).

NEWLY FINALIZED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2022 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care		
• Mortality (MORT-30–AMI, MORT–30–HF, MORT–30–COPD, MORT-30–CABG).	• July 1, 2012–June 30, 2015	• July 1, 2017–June 30, 2020.
• THA/TKA	• April 1, 2012–March 31, 2015	• April 1, 2017–March 31, 2020.
• MORT-30–PN (updated cohort)	• July 1, 2012–June 30, 2015	• September 1, 2017–June 30, 2020.
Efficiency and Cost Reduction		
• MSPB	• January 1, 2018–December 31, 2018	• January 1, 2020–December 31, 2020.
• Payment (AMI Payment, HF Payment)	• July 1, 2012–June 30, 2015	• July 1, 2017–June 30, 2020.

7. Immediate Jeopardy Policy Changes

a. Background

Section 1886(o)(1)(C) of the Act states that the Hospital VBP Program applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act), but excludes from the definition of the term ''hospital'' with respect to a fiscal year a hospital ''for which, during the performance period for such fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients.''

In 42 CFR 412.160 of our Hospital VBP Program regulations, we defined the term ''Cited for deficiencies that pose immediate jeopardy'' to mean that ''during the applicable performance period, the Secretary cited the hospital for immediate jeopardy on at least 2 surveys using the Form CMS–2567, Statement of Deficiencies and Plan of Correction'' (OMB Control Number 0938–0391). In 42 CFR 412.160, we also adopted the definition of ''immediate jeopardy'' found in 42 CFR 489.3 of our regulations.

Our current interpretation of the Hospital VBP Program's statute is that a hospital cited for deficiencies that pose immediate jeopardy during any part of the finalized performance period for the applicable program year does not meet the definition of the term ''hospital,'' and thus is excluded from the Hospital VBP Program for that program year. Because the Hospital VBP Program currently uses measures with 12-month, 24-month, and 36-month performance periods, a hospital's immediate jeopardy citations could result in its exclusion from the Hospital VBP Program for multiple program years.

b. Increase of Immediate Jeopardy Citations From Two to Three Surveys

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25111 through 25112), we proposed to amend our regulations at 42 CFR 412.160 to change the definition of the term ''Cited for deficiencies that pose immediate jeopardy'' to increase the number of surveys where a hospital must be cited for immediate jeopardy before being excluded from the Hospital VBP Program pursuant to section 1886(o)(1)(C) of the Act from 2 to 3. In other words, we proposed that a hospital must be cited on Form CMS–2567, Statement of Deficiencies and Plan of Correction, for immediate jeopardy on at least three surveys during the performance period in order to meet the standard for exclusion from the Hospital VBP Program under section 1886(o)(1)(C)(ii)(II) of the Act. Beginning on the effective date of this change, hospitals would be excluded from the Hospital VBP Program for a particular program year if, during the performance period for that fiscal year, they were cited three times by the Secretary for deficiencies that pose immediate jeopardy to the health or safety of patients. Because we expect that the effective date of this change will be October 1, 2016 (the first day of the FY 2017 Hospital VBP program year), only hospitals that were cited 3 times during the performance period that applies to the FY 2017 program year would be excluded from the Hospital VBP Program. Hospitals that were, as of October 1, 2016, cited for immediate jeopardy on 2 surveys during the performance period that applies to the FY 2017 program year could participate in the Hospital VBP Program for the FY 2017 program year.

We proposed this change to be more inclusive of hospitals and to ensure that we are not too quickly excluding a hospital from participation in the Hospital VBP Program. After reviewing the survey and certification data, we have determined that limiting exclusion to those hospitals that have been cited for immediate jeopardy 3 or more times during the applicable performance period, rather than 2, would continue to appropriately exclude hospitals that are cited for jeopardizing patient safety while allowing hospitals with a lower number of immediate jeopardy citations over significantly longer performance periods to continue to participate in the Hospital VBP Program. Many immediate jeopardy citations involve systematic issues of patient safety, and we believe that hospitals that are, during the performance period, cited by the Secretary for 3 or more deficiencies that pose immediate jeopardy should be excluded from the Hospital VBP Program. We stated in the proposed rule that this proposal would ensure that we continue to assure high quality care while being as inclusive of hospitals as possible.

We invited public comments on this proposal.

Comment: Many commenters supported CMS' proposal to increase the number of immediate jeopardy citations required to trigger Hospital VBP Program exclusion from 2 to 3 during the applicable performance period because hospitals should be encouraged to participate in the program and because such citations could result in excluding a hospital from the program for several program years. One commenter supported the proposal to increase the number of citations, and noted that an immediate jeopardy citation could be too broad and far-reaching under the current policy.

Response: We thank the commenters for their support.

Comment: One commenter did not support the proposal to increase the number of citations before being excluded from the program because it sets a low bar so that hospitals that average 1 immediate jeopardy citation per year or less can participate in the Hospital VBP Program. The commenter noted that an immediate jeopardy situation is a serious citation for a hospital to receive.

Response: We agree with the commenter that an immediate jeopardy citation should be considered seriously. Many immediate jeopardy citations have involved systematic issues of patient safety. However, they can also vary by level of patient safety risk and by location. We therefore believe that limiting exclusion from the Hospital VBP Program to those hospitals that have been cited for immediate jeopardy 3 or more times during the applicable performance period, rather than 2, would continue to appropriately

exclude hospitals that are cited for jeopardizing patient safety without excluding a hospital from participation in the Hospital VBP Program prematurely. In addition, when the immediate jeopardy policy was initially implemented in the Hospital VBP Program, the performance periods were shorter. Now, with significantly longer performance periods (up to 36 months), we believe it is more appropriate to allow hospitals with up to 3 immediate jeopardy citations to continue to participate in the Hospital VBP Program.

Comment: One commenter recommended that CMS limit ineligibility for hospitals cited for deficiencies that pose immediate jeopardy to one fiscal year at most because commenter believed this reflects Congress' statutory intent in the Act.

Response: In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53611), we interpreted the statute to mean that a hospital that meets the definition of ''cited for deficiencies that pose immediate jeopardy'' during any of the finalized performance periods for any measure in a given program year would be excluded from participating in that program year. Several commenters objected to the interpretation of the statute based on the possibility of immediate jeopardy citations during a relatively wide date range, resulting in hospitals being excluded from several program years (77 FR 53614). We responded by stating in that final rule (77 FR 53614) that ''we believe that we must exclude hospitals so cited during any finalized performance period for a fiscal year regardless of the length of the applicable performance period.'' We continue to believe that is the correct interpretation of section 1886(o)(1)(C) of the Act.

Comment: One commenter recommended several additional policies for CMS to consider with regard to the immediate jeopardy policy in the Hospital VBP Program. First, commenter recommended that CMS adopt an immediate jeopardy appeals process through which hospitals can appeal citations before an objective entity outside of HHS without being excluded from Medicare or the Hospital VBP Program because commenter believed this reflects Congress' statutory intent in the Act. Second, commenter requested that CMS interpret and change the regulatory definitions at 42 CFR 412.160 such that the word ''cited'' would mean after appeal rights have been exhausted and the citation has been upheld as valid. The commenter also requested that appeal rights be guaranteed separate from any appeal rights under the Medicare condition of participation (CoP) and EMTALA. Third, commenter requested that when a hospital is issued multiple immediate jeopardy citations for the same factual findings, that is, the same patient issues, they be counted as one immediate jeopardy citation.

Response: We thank the commenter for its suggestions and we will take them into consideration if we decide to make additional changes to the immediate jeopardy policies in the future.

After consideration of the public comments we received, we are finalizing our proposal to amend our regulations at 42 CFR 412.160 to change the definition of the term ''Cited for deficiencies that pose immediate jeopardy'' to increase the number of surveys where a hospital must be cited for immediate jeopardy before being excluded from the Hospital VBP Program pursuant to section 1886(o)(1)(C) of the Act from 2 to 3.

c. EMTALA-Related Immediate Jeopardy Citations

Hospitals are often alerted to immediate jeopardy situations when a surveyor or team of surveyors is in the process of conducting a survey of compliance with the Medicare CoP at the hospital and identifies those situations that immediately jeopardize the health and safety of patients (77 FR 53610). Following the survey, the Form CMS–2567, Statement of Deficiencies and Plan of Correction, is sent to the hospital, which contains the survey findings, including any immediate jeopardy situations. For EMTALA-related immediate jeopardy situations, however, the CMS Regional Office determines whether there was an EMTALA violation after reviewing the State Survey Agency's report and an expert physician review's findings, and, if so, whether it constituted an immediate jeopardy (77 FR 53610). The CMS Regional Office then sends the Form CMS–2567 to the hospital. Currently, the Automated Survey Processing Environment (ASPEN) system, an electronic system that supports our survey and certification activity, catalogs deficient practices (that is, noncompliance) identified during a survey and generates the Form CMS–2567 that is sent to the hospital after the survey. The survey end date generated in ASPEN is currently used as the date for assignment of the immediate jeopardy citation to a particular performance period (77 FR 53613). The additional processes for EMTALA-related immediate jeopardy citations can result in significant notification delays to hospitals (often several months or longer).

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25112), in the case of EMTALA-related immediate jeopardy citations only, we proposed to change our policy regarding the date of the immediate jeopardy citation for possible exclusion from the Hospital VBP Program from the survey end date generated in ASPEN to the date of CMS' final issuance of Form CMS–2567 to the hospital. Form CMS–2567 is not considered final until it is transmitted to the healthcare facility, either by the State Survey Agency, or, in all EMTALA cases and certain other cases, by the CMS Regional Office. The date of final issuance is also tracked in ASPEN. The date the Form CMS–2567 is sent by the CMS Regional Office to the hospital (via mail, electronically, or both) is the date of final issuance recorded in ASPEN. We believe this change would accurately reflect the date hospitals receive official notification of an immediate jeopardy citation based on the issuance date of Form CMS–2567 as this date will be weeks, if not months, after the survey end date. Hospitals may continue to receive preliminary notice during the onsite EMTALA investigation survey that they may receive an immediate jeopardy citation based on survey findings. However, because the decision-making responsibility in EMTALA investigations always rests with the CMS Regional Office, the final determination and notification of immediate jeopardy citations will always be delayed. The Form CMS–2567 constitutes the official notice to a healthcare facility of the survey findings.

Finally, in instances where one onsite hospital survey resulted in both hospital CoP immediate jeopardy citation(s) as well as EMTALA immediate jeopardy citation(s), the survey end date would be the default date for potential exclusion from the Hospital VBP Program. We recognize the hospital will receive notification of the EMTALA immediate jeopardy citation(s) at a later date than the CoP immediate jeopardy citation(s). However, because the hospital was notified of the CoP immediate jeopardy citation(s) at the time of survey, this date will be used for the performance period for potential exclusion from the Hospital VBP Program. Even though there may be separate enforcement actions resulting from the same survey, we will consider each Form CMS–2567 with immediate jeopardy findings to be one citation for purposes of the Hospital VBP Program (77 FR 53613).

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25112), we proposed to revise our regulations at 42 CFR 412.160 to reflect the above proposal and specify use of the date of CMS' final issuance of Form CMS–2567 to the hospital for EMTALA immediate jeopardy citation(s). We also proposed to specify that in instances where one onsite hospital survey resulted in both hospital CoP immediate jeopardy citation(s) as well as EMTALA immediate jeopardy citation(s), the survey end date would be the default date for potential exclusion from the Hospital VBP Program.

We invited public comments on this proposal.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to amend our regulations at 42 CFR 412.160 to change our policy regarding the date of the immediate jeopardy citation for possible exclusion from the Hospital VBP Program from the survey end date generated in ASPEN to the date of CMS' final issuance of Form CMS–2567 to the hospital. We are also finalizing our proposal to use the survey end date as the default date for potential exclusion from the Hospital VBP Program when one onsite hospital survey results in both hospital CoP immediate jeopardy citation(s) as well as EMTALA immediately jeopardy citations(s).

8. Performance Standards for the Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established no later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program.

In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

We refer readers to the FY 2013, FY 2014, and FY 2015 IPPS/LTCH PPS final rules (77 FR 53604 through 53605; 78 FR 50694 through 50698; and 79 FR 50077 through 50079) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program.

We note that the performance standards for the following measures are calculated with lower values representing better performance:

- The NHSN measures (the CLABSI, CAUTI, CDI, Colon and Abdominal Hysterectomy SSI, and MRSA Bacteremia measures);
- The PSI 90 measure;
- The THA/TKA measure;
- The PC–01 measure;
- The MSPB measure; and
- The HF and AMI Payment measures.

This distinction is made in contrast to other measures for which higher values indicate better performance. As discussed further in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50684), the performance standards for the Colon and Abdominal Hysterectomy SSI measure are computed separately for each procedure stratum, and we first award achievement and improvement points to each stratum separately, then compute a weighted average of the points awarded to each stratum by predicted infections.

The numerical values for the performance standards displayed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25113 through 25116) represented estimates based on the most recently available data, and we have updated the numerical values in this final rule to reflect new data in the charts below.

Comment: A few commenters did not support the PC–01 benchmark of 0 because The Joint Commission states that 2 to 4 percent is an expected rate for early elective delivery and commenters believed that some hospitals (such as academic medical centers and obstetric hospitals) experience a higher number of uncommon or rare conditions justifying the need for early-term elective delivery and are, therefore, unable to meet the current benchmark.

Response: As stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49549), in response to similar comments, we disagree with the assertion that the benchmark of 0 percent is unrealistic because not all justifications for an elective delivery are included in the ICD–10–CM Justification Table. As we previously noted, the benchmark is intended to represent a level of excellent performance to which hospitals generally should aspire. While no measure can account for every possible situation, the measure specifications (available at: *https://manual.jointcommission.org/releases/TJC2015B2/MIF0166.html*) provide a large number of ICD–10–CM Principal Diagnosis Code or Other Diagnosis Codes for conditions possibly justifying elective delivery prior to 39 weeks gestation. Furthermore, the 0 percent benchmark for PC–01 was calculated from the mean of the top 10 percent for all hospitals during the baseline period; therefore, attaining this benchmark is not unrealistic. We continue to believe that hospitals should aspire to prevent elective deliveries from being performed before the gestational age of 39 weeks without a medical indication.

b. Previously Adopted and Newly Finalized Performance Standards for the FY 2019 Program Year

In accordance with our finalized methodology for calculating performance standards (discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513)), in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25113), we proposed to adopt the following additional performance standards for the FY 2019 program year. We noted that the numerical values for the performance standards displayed in the proposed rule represented estimates based on the most recently available data, and that we intended to update the numerical values in this final rule. We noted further that the MSPB measure's performance standards are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time. The table below has been updated from the FY 2017 IPPS/LTCH PPS proposed rule and represents the most recently available data.

PREVIOUSLY ADOPTED AND NEWLY FINALIZED PERFORMANCE STANDARDS FOR THE FY 2019 PROGRAM YEAR: SAFETY, CLINICAL CARE, AND EFFICIENCY AND COST REDUCTION MEASURES

Measure ID	Description	Achievement threshold	Benchmark
Safety Measures			
CAUTI *	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0.464	0.000
CLABSI *	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure.	0.427	0.000
CDI *	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium Difficile* Infection (CDI) Outcome Measure.	0.816	0.012
MRSA Bacteremia *	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	0.823	0.000
Colon and Abdominal Hysterectomy SSI **.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	• 0.832 • 0.698	• 0.000 • 0.000
PC–01 *	Elective Delivery	0.010038	0.000000
PSI 90 *±	Patient Safety for Selected Indicators (Composite)	0.840335	0.589462
Clinical Care Measures			
MORT–30–AMI ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0.850671	0.873263
MORT–30–HF ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0.883472	0.908094
MORT–30–PN ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0.882334	0.907906
THA/TKA *±	Hospital-Level Risk-Standardized Complication Rate (RSMR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	0.032229	0.023178
Efficiency and Cost Reduction Measure			
MSPB *	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	Median Medicare Spending Per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending Per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.
± Previously adopted performance standards.

In the past, we have used the ''normalization'' approach to scoring the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain (which we are renaming the Person and Community Engagement domain beginning with the FY 2019 program year, as discussed in section IV.H.3.b. of the preamble of this final rule). The 9 dimensions of the HCAHPS measure, one of which is the CTM–3 measure, are calculated to generate the HCAHPS Base Score. For each of the 9 dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is summed across the 9 dimensions to create a prenormalized HCAHPS Base Score (0–90 points). The prenormalized HCAHPS Base Score is then multiplied by 8/9 (0.88888) and rounded according to standard rules (values of 0.5 and higher are rounded up, values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the 9 dimensions is of equal weight, so that the normalized HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points are then calculated and range from 0 to 20 points. The Consistency Points consider scores across all 9 of the Person and Community Engagement dimensions. The final element of the scoring formula is the sum of the HCAHPS Base Score and the HCAHPS Consistency Points and ranges from 0 to 100 points. The table below has been updated from the FY 2017 IPPS/LTCH PPS proposed rule and represents the most recently available data.

PERFORMANCE STANDARDS FOR THE FY 2019 PROGRAM YEAR
PERSON AND COMMUNITY ENGAGEMENT DOMAIN *

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Communication with Nurses	28.10	78.69	86.97

PERFORMANCE STANDARDS FOR THE FY 2019 PROGRAM YEAR—Continued
PERSON AND COMMUNITY ENGAGEMENT DOMAIN *

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Communication with Doctors	33.46	80.32	88.62
Responsiveness of Hospital Staff	32.72	65.16	80.15
Pain Management **	22.31	70.01	78.53
Communication about Medicines	11.38	63.26	73.53
Hospital Cleanliness & Quietness	22.85	65.58	79.06
Discharge Information	61.96	87.05	91.87
3-Item Care Transition	11.30	51.42	62.77
Overall Rating of Hospital	28.39	70.85	84.83

* We are finalizing the re-naming of this domain from Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to Person and Community Engagement domain beginning with the FY 2019 program year, as discussed in section IV.H.3.b. of the preamble of this final rule.

** For more information on the Pain Management dimension, please refer to the Hospital VBP Program proposal in the CY 2017 OPPS/ASC PPS proposed rule (81 FR 45755 through 45757).

We invited public comments on the proposed HCAHPS performance standards.

Comment: One commenter recommended reweighting the Communication about Medicines dimension of the proposed performance standards within the HCAHPS Survey because this commenter believed that medication mix-ups with opioid drugs are a leading cause of readmissions of senior citizens after a hospital stay.

Response: We disagree with the commenter that we should reevaluate the weighting of the Communication about Medicines dimension within the HCAHPS Survey because we do not believe there is a link between the three questions on the HCAHPS Survey that comprise the Communication about Medicines dimension and the rate of senior citizens' readmission to hospitals. The three questions include: ''During this hospital stay, were you given any medicine that you had not taken before?;'' ''Before giving you any new medicine, how often did hospital staff tell you what the medicine was for?;'' and ''Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand?'' We believe that asking questions on communications about medicines will encourage hospitals to ensure their staff are properly communicating medication information to patients. Patients' understanding of their medication is critical to reducing medication errors and improving quality and safety.

Comment: One commenter expressed concern about the HCAHPS Survey's ability to form a valid assessment of patient experience, based in part on its low response rate.

Response: Hospitals must report a minimum number of 100 completed HCAHPS surveys for a hospital to receive a Patient and Community Engagement domain score (see section IV.H.9.b. of the preamble of this final rule). We continue to believe that this requirement appropriately balances our desire to enable as many hospitals as possible to participate in the Hospital VBP Program and the need for the TPSs to be sufficiently reliable to provide meaningful distinction between hospitals' performance on quality measures.

Comment: Several commenters recommended disassociating the Pain Management dimension questions from the HCAHPS Survey because commenters believe it is linked to the over-prescription of pain medication in the United States. One commenter suggested modifying the question based on the Emergency Department Patient Experience of Care (ED PEC) survey tool (currently being developed) which allows for different levels of pain and discomfort.

Response: With regard to comments related to the Pain Management dimension in the Hospital VBP Program, we refer readers to the Hospital VBP Program proposal in the CY 2017 OPPS/ASC PPS proposed rule (81 FR 45755 through 45757) and request that they resubmit their comments to that proposed rule before the comment period closes on September 6, 2016. For more details on that proposal and on how to submit comments for CMS' consideration, we refer readers to that proposed rule (81 FR 45755 through 45757).

c. Previously Adopted Performance Standards for Certain Measures for the FY 2020 Program Year

As discussed above, we have adopted certain Safety and Clinical Care domain measures for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50062 through 50065), we adopted the PSI 90 measure in the Safety domain and the THA/TKA measure in the Clinical Care domain for the FY 2019 program year and subsequent years. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50077), we adopted performance standards for the MORT–30–AMI, MORT–30–HF, MORT–30–PN, and THA/TKA for the FY 2020 program year. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49566), we also adopted performance standards for the PSI 90 measure.

PREVIOUSLY ADOPTED PERFORMANCE STANDARDS FOR CERTAIN CLINICAL CARE DOMAIN AND SAFETY DOMAIN MEASURES FOR THE FY 2020 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
Safety Domain			
PSI 90 *	Patient Safety for Selected Indicators (Composite)	0.778761	0.545903

PREVIOUSLY ADOPTED PERFORMANCE STANDARDS FOR CERTAIN CLINICAL CARE DOMAIN AND SAFETY DOMAIN MEASURES FOR THE FY 2020 PROGRAM YEAR—Continued

Measure ID	Description	Achievement threshold	Benchmark
Clinical Care Domain			
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0.853715	0.875869
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0.881090	0.906068
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0.882266	0.909532
THA/TKA *	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	0.032229	0.023178

* Lower values represent better performance.

d. Previously Adopted and Newly Finalized Performance Standards for Certain Measures for the FY 2021 Program Year

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49567), we adopted performance standards for the FY 2021 program year for the Clinical Care domain measures (THA/TKA, MORT–30–HF, MORT–30–AMI, MORT–30–PN, and MORT–30–COPD). In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25103 through 25105), we proposed to add 2 measures, AMI Payment and HF Payment, beginning with the FY 2021 program year, which we are adopting as discussed in section IV.H.4.a. of the preamble of this final rule. The table below has been updated from the FY 2017 IPPS/LTCH PPS proposed rule and represents the most recently available data. The previously adopted and newly finalized performance standards for these measures are set out below.

PREVIOUSLY ADOPTED AND NEWLY FINALIZED PERFORMANCE STANDARDS FOR THE FY 2021 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
Clinical Care Measures			
MORT–30–AMI ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0.860355	0.879714.
MORT–30–HF ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0.883803	0.906144.
MORT–30–PN ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0.886443	0.910670.
MORT–30–COPD ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	0.923253	0.938664.
THA/TKA *±†	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	0.031157	0.022418.
Efficiency and Cost Reduction Measures			
AMI Payment *#	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.
HF Payment *#	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF).	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.

± Previously adopted performance standards.
* Lower values represent better performance.

† After publication of the FY 2016 IPPS/LTCH PPS final rule, we determined there was a display error in the performance standards for this measure. We have since undertaken a technical update for these performance standards in order to ensure that hospitals have the correct performance standards for the applicable performance period. The corrected performance standards are displayed here.
# Finalized to be scored the same as the MSPB measure, as discussed in section IV.H.4.a.(3) of the preamble of this final rule.

We did not receive any public comments on the proposed performance standards for the FY 2021 program year. Therefore, we are adopting the performance standards listed above.

e. Performance Standards for Certain Measures for the FY 2022 Program Year

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25116), we proposed the following performance standards for the FY 2022 program year for the Clinical Care domain measures (THA/TKA, MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD), and the proposed MORT–30–CABG, which we are adopting as discussed in section IV.H.5. of the preamble of this final rule. The table below has been updated from the FY 2017 IPPS/LTCH PPS proposed rule and represents the most recently available data.

NEWLY FINALIZED PERFORMANCE STANDARDS FOR THE FY 2022 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
Clinical Care Measures			
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following (RSMR) Acute Myocardial Infarction (AMI) Hospitalization.	0.861793	0. 881305.
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0.879869	0.903608.
MORT–30–PN (updated cohort).	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0.836122	0.870506.
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	0.920058	0.936962.
THA/TKA *	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	0.029833	0.021493.
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	0.979000	0.968210.
Efficiency and Cost Reduction Measures			
AMI Payment *#	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.
HF Payment *#	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF).	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.

* Lower values represent better performance.
# Finalized to be scored the same as the MSPB measure, as discussed in section IV.H.4.a.(3) of the preamble of this final rule.

We did not receive any public comments on the proposed FY 2022 performance standards. Therefore, we are finalizing our proposal to adopt the performance standards listed above.

9. FY 2019 Program Year Scoring Methodology

a. Domain Weighting for the FY 2019 Program Year for Hospitals That Receive a Score on All Domains

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49568 through 49570), we adopted equal weight of 25 percent for each of the 4 domains in the FY 2018 program year for hospitals that receive a score in all domains. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25117), for the FY 2019 program year, we noted that we did not propose to remove any measures nor did we propose to adopt any new measures. We

also did not propose any changes to the domain weighting for hospitals receiving a score on all domains.

DOMAIN WEIGHTS FOR THE FY 2019 PROGRAM YEAR FOR HOSPITALS RECEIVING A SCORE ON ALL DOMAINS

Domain	Weight (percent)
Safety	25
Clinical Care	25
Efficiency and Cost Reduction	25
Person and Community Engagement*	25

*We are finalizing the re-naming of this domain from Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to Person and Community Engagement domain beginning with the FY 2019 program year, as discussed in section IV.H.3.b. of the preamble of this final rule.

Comment: One commenter supported CMS' weighting of the Efficiency and Cost Reduction domain in the scoring methodology.

Response: We thank the commenter for its support.

Comment: A few commenters did not support the proposed weighting of the Person and Community Engagement domain for the FY 2018 program year because evidence has shown significant variation in scores due to differences in acuity level and region of the country and because one study found that patient satisfaction was independent of hospital compliance with quality of care processes and safety culture. The commenters recommended that CMS conduct a patient-level study to better understand the relationship between HCAHPS scores and outcomes, looking at factors like patient severity, SDS factors, and region.

Response: We disagree that the Person and Community Engagement domain is weighted too heavily in hospitals' TPSs because we believe this domain measures important elements of the patient's experience of inpatient care. We have adjusted HCAHPS scores for certain patient-level factors that are beyond the hospital's control but which affect survey responses. These factors include patient severity, as indicated by self-reported overall health, and patient's highest level of education, considered the most accurate single measure of socioeconomic status for older adults. Meterko, Wright et al. found that clinical measures of severity mattered little in adjusting patient experience scores that already accounted for standard HCAHPS adjustors.[56] Because valid adjustors must vary within hospitals, it is not possible to adjust for region without removing true regional variation in quality.[57] More information about HCAHPS patient-mix adjustment can be found on the official HCAHPS Web site at: *http://www.hcahpsonline.org/modeadjustment.aspx*. HCAHPS scores are not adjusted for hospital-level factors. While we have conducted and published research on the relationship between HCAHPS scores and hospital-level factors, patient outcomes cannot be directly assessed because the HCAHPS surveys submitted to CMS are not patient-identifiable.

Comment: One commenter recommended that, in the future, CMS increase the weight of the Efficiency and Cost Reduction domain to equal that of the Clinical Care and Safety domains because the commenter believed doing so would balance the Hospital VBP Program's focus on cost and quality equally.

Response: We appreciate the commenter's suggestion and will take that into consideration in future rulemaking. For the FY 2019 program year, we believe that the Efficiency and Cost Reduction domain at 25 percent of hospitals' TPSs appropriately weights cost and quality in the Hospital VBP Program.

Comment: One commenter did not support the 25 percent weight for the Efficiency and Cost Reduction domain because it overlaps with the HAC Reduction Program's penalties. The commenter expressed concern that the high weighting of the domain may encourage hospitals to avoid taking high-risk patients or to sacrifice quality of care following discharge by placing patients in a lower cost postacute care setting.

Response: We disagree with the commenter that the weighting of the Efficiency and Cost Reduction domain is too high. We believe the HAC Reduction Program and the Hospital VBP Program are both important quality programs but have different objectives. We do not have reason to believe that the weighting of the domain has caused hospitals to avoid high-risk patients or sacrifice quality of care in order to improve their score on the MSPB measure.

Comment: A few commenters recommended that CMS reallocate domain weights to emphasize the importance of measures of patient outcomes, which is where hospitals have the greatest ability to control and effectuate change. The commenters specifically recommended reducing the weight of the Efficiency and Cost Reduction domain because the current 25 percent weighting assigns a high amount of weight to a single measure, MSPB, which does not directly address patient outcomes. One commenter noted that the Efficiency and Cost Reduction domain can sometimes be driven more by the physician's orders and the Person and Community Engagement domain can fluctuate based on trivial matters not related to healthcare delivery.

Response: While we agree that the Hospital VBP Program should encourage providers to improve patient outcomes, we believe that equally weighting the 4 domains is appropriate for the FY 2019 program year based on the distribution of the measures we are finalizing in this final rule. We believe the Efficiency and Cost Reduction domain is appropriately weighted, despite not directly addressing patient outcomes, because it encourages hospitals to assess cost in conjunction with quality of care. We note that we are adopting the AMI and HF Payment measures, as discussed in section IV.H.4. of the preamble of this final rule, so that beginning with the FY 2021 program year, MSPB will no longer be the only measure in the Efficiency and Cost Reduction domain. We believe expanding the number of measures in this domain will further improve the link between payment and patient health outcomes as the program moves towards value scoring. We also believe that hospitals can effect change through the measures in each of the four domains in the Hospital VBP Program.

b. Domain Weighting for the FY 2019 Program Year and Future Years for Hospitals Receiving Scores on Fewer Than Four Domains

For the FY 2017 program year and subsequent years, we adopted a policy that hospitals must receive domain scores on at least 3 of 4 quality domains in order to receive a TPS, and hospitals with sufficient data on only 3 domains will have their TPSs proportionately reweighted (79 FR 50084 through 50085). We did not propose any changes in the FY 2017 IPPS/LTCH PPS proposed rule.

Under these policies, in order to receive a TPS for the FY 2019 program year and future years:

[56] ''Mortality among Patients with Acute Myocardial Infarction: The Influences of Patient-Centered Care and Evidence-Based Medicine.'' M. Meterko, S. Wright, H. Lin, E. Lowy, and P.D. Cleary. Health Services Research, 45 (5): 1188–1204. 2010.

[57] The Effects of Survey Mode, Patient Mix, and Nonresponse on CAHPS Hospital Survey Scores.'' M.N. Elliott, A.M. Zaslavsky, E. Goldstein, W. Lehrman, K. Hambarsoomian, M.K. Beckett and L. Giordano. Health Services Research, 44 (2): 501–518. 2009.

• Hospitals must report a minimum number of 100 completed HCAHPS surveys for a hospital to receive a Patient- and Caregiver-Centered Experience of Care/Care Coordination domain score (which, in section IV.H.3.b. of the preamble of this final rule, we are renaming to the Person and Community Engagement domain beginning with the FY 2019 program year).

• Hospitals must meet the requirements to receive a MSPB measure score in order to receive an Efficiency and Cost Reduction domain score. Hospitals must report a minimum number of 25 cases for the MSPB measure (77 FR 53609 through 53610) and the AMI Payment and HF Payment measures.

• Hospitals must receive a minimum of 2 measure scores within the Clinical Care domain. Hospitals must report a minimum number of 25 cases for each of the mortality measures (77 FR 53609 through 53610) and the THA/TKA measure.

• Hospitals must receive a minimum of 3 measure scores within the Safety domain.

++ Hospitals must report a minimum of 3 cases for any underlying indicator for the PSI 90 measure based on AHRQ's measure methodology (77 FR 53608 through 53609).

++ Hospitals must report a minimum of 1 predicted infection for NHSN-based surveillance measures based on CDC's minimum case criteria (77 FR 53608 through 53609).

++ Hospitals must report a minimum of 10 cases for the PC–01 measure (76 FR 26530).

We did not propose any changes to the minimum numbers of domain scores, cases, and measures outlined above. We continue to believe that these requirements appropriately balance our desire to enable as many hospitals as possible to participate in the Hospital VBP Program and the need for TPSs to be sufficiently reliable to provide meaningful distinctions between hospitals' performance on quality measures.

I. Changes to the Hospital-Acquired Condition (HAC) Reduction Program

1. Background

We refer readers to section V.I.1.a. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program. For a detailed discussion of the statutory basis of the HAC Reduction Program we refer readers to section V.I.2. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50708 through 50709). For a further description of our policies for the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581). These policies describe the general framework for implementation of the HAC Reduction Program, including: (a) The relevant definitions applicable to the program; (b) the payment adjustment under the program; (c) the measure selection and conditions for the program, including a risk-adjustment and scoring methodology; (d) performance scoring; (e) the process for making hospital-specific performance information available to the public, including the opportunity for a hospital to review the information and submit corrections; and (f) limitation of administrative and judicial review.

We also have codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

2. Implementation of the HAC Reduction Program for FY 2017

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the following measures for use in the FY 2017 program: PSI 90 measure for Domain 1 and the CDC NHSN measures CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI for Domain 2. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25117 through 25118), we did not propose any changes to this measure set for FY 2017. We also did not propose to make any changes to the measures that were finalized for use in the FY 2016 program (CAUTI, CLABSI, and Colon and Abdominal Hysterectomy SSI) or the FY 2017 program (MRSA Bacteremia and CDI).

HAC Reduction Program Measures for FY 2017

Short name	Measure name	NQF No.
Domain 1		
PSI 90	Patient Safety for Selected Indicators (Composite Measure)	0531
Domain 2		
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized and codified at 42 CFR 412.170 a 2-year period during which we collect data used to calculate the Total HAC Score. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49574), we finalized the 2-year time periods for the calculation of HAC Reduction Program measure results for FY 2017. For the Domain 1 measure (PSI 90 measure), we will use the data collected during the 24-month period from July 1, 2013 through June 30, 2015. Claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculations of measure results for FY 2017. For the CDC NHSN measures previously finalized for use in the FY 2017 HAC Reduction Program (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), we are using data collected during CYs 2014 and 2015.

We anticipate we will be able to provide hospitals with their confidential hospital-specific reports and discharge level information used in the calculation of their FY 2017 Total HAC Score in late summer 2016 via the QualityNet Secure Portal.[58] In order to access their hospital-specific reports, hospitals must register for a QualityNet Secure Portal account. We did not make any changes to the review and correction policies for FY 2016. Hospitals have a period of 30 days after the information is posted to the QualityNet Secure Portal to review and submit corrections for the calculation of their HAC Reduction Program measure scores, domain scores, and Total HAC Score for the fiscal year.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25118 through 25119), for FY 2017, we proposed updates to the following HAC Reduction Program policies: (1) A proposal to clarify data requirements for Domain 1; and (2) a proposal for NHSN CDC HAI data submission requirements for newly opened hospitals. Each policy is described in more detail below.

We note that we received public comments on the design of the HAC Reduction Program, requests to modify the payment adjustment computation, and for CMS to work with Congress to amend the law to create a phased-in or sliding-scale penalty. While we appreciate the commenters' feedback, we consider these topics to be out of the scope of the proposed rule. Therefore, we are not addressing most of them in this final rule. All other topics out of scope of the proposed rule will be taken into consideration when developing policies and program requirements for future years.

a. Clarification of Complete Data Requirements for Domain 1

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50722) we finalized our plan to use the PSI 90 measure for Domain 1. Because hospitals may not have complete data for every AHRQ indicator in the PSI 90 measure, we decided to use the same methodology used for the Hospital VBP Program to determine the minimum number of indicators with complete data to be included in the calculation of the Domain 1 measure. In addition, we finalized the following rules to determine the number of AHRQ indicators to be included in the calculation for a hospital's Domain 1 score. For Domain 1, we defined ''complete data'' as whether a hospital has enough eligible discharges to calculate a rate for a measure. In order to have complete data for the PSI 90 measure, a hospital must have three or more eligible discharges for at least one component indicator.

In establishing the performance period for the PSI 90 measure, we relied upon an analysis by Mathematica Policy Research, a CMS contractor, which found the measure was most reliable with a 24-month performance period. This analysis also indicated the measure was unreliable with a performance period of less than 12 months.[59] We have since determined that the current definition for ''complete data'' may result in facilities with less than 12 months of data being eligible to receive a score on the PSI 90 measure, and that the resulting score may not be reflective of the hospital's clinical performance. While the PSI 90 measure continues to play a vital role in patient safety and is an integral part of the HAC Reduction Program, we believe that reliable data is a critical component of accurately assessing hospital performance.

To address this concern, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25118 through 25119), we proposed to clarify the term ''complete data'' for the PSI 90 measure within Domain 1 to require that hospitals have three or more eligible discharges for at least one component indicator and 12 months or more of data to receive a Domain 1 score. Under this proposal, hospitals with less than 12 months of PSI 90 data would not receive a Domain 1 score, regardless of the number of eligible discharges at the hospital. If a hospital has 12 months or more of PSI 90 data, the hospital would need to have three or more eligible discharges for at least one component indicator to receive a Domain 1 score. We believe this is the most favorable method for scoring measure results for hospitals.

We believe, after weighing the considerations, that this additional policy should be incorporated into the HAC Reduction Program for FY 2017 and subsequent years, primarily because this approach greatly improves the measure's assessment of quality and, therefore, its implementation should not be unnecessarily delayed. This clarification would be a change to the Domain 1 criteria and would not change our current scoring policy for Domain 2. As previously finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50722 through 50723), if a hospital does not have enough data to calculate the PSI 90 measure score for Domain 1 but has ''complete data'' for at least one measure in Domain 2, its Total HAC Score will depend entirely on its Domain 2 score. Similarly, if a hospital has ''complete data'' to calculate the PSI 90 measure score in Domain 1 but none of the measures in Domain 2, its Total HAC Score will be based entirely on its Domain 1 score. If a hospital does not have ''complete data'' to calculate the PSI 90 measure score for Domain 1 or any of the measures in Domain 2, we will not calculate a Total HAC Score for this hospital. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50722 through 50723) for a detailed discussion of Domain 2 scoring.

We invited public comments on our proposal to require that hospitals have three or more eligible discharges for at least one component indicator and 12 months or more of data to receive a Domain 1 score beginning in the FY 2017 HAC Reduction Program.

Comment: Many commenters supported the proposal to clarify the term ''complete data'' and agreed that using less than 12 months of measure data may not provide a statistically valid reflection of hospital performance. Commenters commended CMS' efforts to ensure data reliability as a critical component of accurately assessing performance. One commenter recommended that complete data should require at least 24 months of data. Commenters noted that in the proposed rule, CMS stated that the PSI 90 measure was most reliable with a 24-month performance period.

Response: We understand that reliable data is a critical component of accurately assessing hospital performance and thank commenters for their support. We note that the analysis performed by Mathematica showed that PSI composite achieves moderate reliability at a majority of hospitals for reporting periods of 6 months or longer. We further note that the proposed data requirements establish a minimum data requirement of at least 12 months.[60] We believe the proposed requirements balance the needs of the program and allows the composite measure to continue to play a vital role in ensuring patient safety and provide alignment across our value-based and quality reporting programs.

After consideration of the public comments we received, we are finalizing the definition of complete data discussed above as proposed.

[58] Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228773343598.*

[59] Mathematica Policy Research (November 2011). Reporting period and reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf.*

[60] Ibid.

b. Clarification of NHSN CDC HAI Data Submission Requirements for Newly Opened Hospitals

We have encountered issues with some newly opened hospitals that do not appear to understand that they must submit CDC NHSN HAI data for the HAC Reduction Program, even when they may not be required to report under the Hospital IQR Program. As set forth in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50098), a hospital that does not have an ICU waiver *or other waiver* for the CDC NHSN HAI measures and does not submit data will receive the maximum of 10 points for that measure. We noted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723) that, for Domain 2, we will obtain measure results that hospitals submitted to the CDC NHSN from the Hospital IQR Program.[61] However, we note that participation in the Hospital IQR Program is voluntary, while participation in the HAC Reduction Program is mandatory for almost all IPPS hospitals (we refer readers to section 1886(d)(1)(B) of the Act; 42 CFR 412.170 (definition of the term ''applicable hospital''); and 42 CFR 412.172(e)). The HAC Reduction Program does not apply to hospitals and hospital units that are excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, IPFs, CAHs, and Puerto Rico hospitals (79 FR 50087 through 50088).

We believe that it is important to establish data submission requirements for all applicable hospitals under the HAC Reduction Program. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25119), we proposed the following requirements for newly opened hospitals for CDC NHSN HAI data submissions. We note that these requirements do not affect any requirements for facilities in States that are required by law to report HAI data to NHSN.

- If a hospital files a notice of participation (NOP) with the Hospital IQR Program within 6 months of opening, the hospital would be required to begin submitting data for the CDC NHSN HAI measures no later than the first day of the quarter following the NOP.
- If a hospital does not file a NOP with the Hospital IQR Program within 6 months of opening, the hospital would be required to begin submitting data for the CDC NHSN HAI measures on the first day of the quarter following the end of the 6-month period to file the NOP.

For example, if a subsection (d) hospital opened on January 1 and it intended to participate in the Hospital IQR Program, the hospital would be required to file a Hospital IQR Program NOP no later than July 1, and begin submitting data to NHSN no later than October 1. If a subsection (d) hospital opened on January 1 and it did not intend to participate in the Hospital IQR Program (that is, no NOP is filed), it would have to begin submitting data to NHSN no later than July 1 of that year. We believe that these data submission requirements are clear, align with the Hospital IQR Program, and are fair and equitable for all newly opened hospitals. Hospitals that are not required to submit data within the respective HAC Reduction Program year will not receive a score. These hospitals will receive a designation of ''NEW,'' and will not receive any points for CDC NHSN HAI measures.

We further note that this clarification does not affect the narrative rules used in calculation of the Domain 2 Score. We will continue to follow all Domain 2 scoring procedures as previously finalized, and we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49575) for further discussion of the narrative rules used in calculation of the Domain 2 Score. We believe that this proposal should be incorporated into the HAC Reduction Program for FY 2017 and subsequent years.

We invited public comments on our proposal to adopt these policies related to the data submission requirements beginning in the FY 2017 HAC Reduction Program.

Comment: Commenters supported and applauded CMS for establishing a reasonable deadline for beginning the submission of measure data following the opening of a new hospital. Commenters noted that clarifying and establishing a process for new hospitals affords patients who receive care at those facilities the same benefits to transparent quality data that has been available in long established facilities. One commenter recommended that CMS establish a single date under which HAC Reduction Program reporting must begin, regardless of a hospital's decision about participation in the Hospital IQR Program.

Response: We thank commenters for their input and support. We believe these submission requirements support our continued goal of aligning our value-based and quality reporting programs in order to minimize provider burden and incentivize high-quality care. We note that the intention of the submission requirements is to make use of the available data for each hospital and encourage hospitals to report HAI data to CDC NHSN.

After consideration of the public comments we received, we are finalizing the data submission requirements discussed above as proposed.

3. Implementation of the HAC Reduction Program for FY 2018

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25119 through 25123), for FY 2018, we proposed the following HAC Reduction Program policies: (1) Adoption of the modified version of the NQF-endorsed PSI 90: Patient Safety and Adverse Events Composite; (2) defining the applicable time periods for the FY 2018 HAC Reduction Program and the FY 2019 HAC Reduction Program; (3) changes to the scoring methodology; and (4) a request for comments on additional measures for potential future adoption.

a. Adoption of Modified PSI 90: Patient Safety and Adverse Events Composite (NQF #0531)

(1) Background

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25119 through 25121) we proposed to adopt refinements to the Agency for Healthcare Research and Quality (AHRQ) Patient Safety and Adverse Events Composite (NQF #0531) for the HAC Reduction Program beginning with the FY 2018 payment determination and subsequent years. In summary, the PSI 90 measure was refined to reflect the relative importance and harm associated with each component indicator to provide a more reliable and valid signal of patient safety events. We believe the modified PSI 90 will provide strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, a critical consideration in quality improvement.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50712 through 50717), we adopted the PSI 90 measure (NQF #0531) in the HAC Reduction Program as an important measure of patient safety and adverse events. As previously adopted, PSI 90 consisted of eight component indicators: (1) PSI 03 Pressure Ulcer Rate; (2) PSI 06 Iatrogenic Pneumothorax Rate; (3) PSI 07 Central Venous Catheter-Related Blood Stream Infections Rate; (4) PSI 08 Postoperative Hip Fracture Rate; (5) PSI 12 Perioperative Pulmonary Embolism/Deep Vein Thrombosis Rate; (6) PSI 13 Postoperative Sepsis Rate; (7) PSI 14 Postoperative Wound Dehiscence Rate;

[61] For a further discussion of CDC NHSN HAI Data submission requirements for the Hospital IQR Program, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536) and 42 CFR 412.140(a)(3)(i) and 412.140(b).

and (8) PSI 15 Accidental Puncture and Laceration Rate.[62]

The currently adopted eight-indicator version of the measure underwent extended NQF maintenance reendorsement in the 2014 NQF Patient Safety Committee due to concerns with the underlying component indicators and their composite weights. In the NQF-Endorsed Measures for Patient Safety, Final Report,[63] the NQF Patient Safety Committee deferred its final decision for the PSI 90 measure until the following measure evaluation cycle. In the meantime, AHRQ worked to address many of the NQF stakeholders' concerns about PSI 90, which subsequently completed NQF maintenance re-review and received reendorsement on December 10, 2015.

The PSI 90 measure's extended NQF reendorsement led to several changes to the measure.[64] First, the name of the PSI 90 measure has changed to ''Patient Safety and Adverse Events Composite'' (NQF #0531) (herein referred to as the ''modified PSI 90''). Second, the modified PSI 90 measure includes three new indicators: (1) PSI 09 Perioperative Hemorrhage or Hematoma Rate; (2) PSI 10 Postoperative Acute Kidney Injury Requiring Dialysis Rate (formerly titled ''Physiologic and Metabolic Derangement Rate''); and (3) PSI 11 Postoperative Respiratory Failure Rate. Third, the measure PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate and PSI 15 Accidental Puncture or Laceration Rate have been respecified in the modified PSI 90. Fourth, PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate has been removed in the modified PSI 90. Fifth, the weighting of component indicators in the modified PSI 90 is based not only on the volume of each of the patient safety and adverse events, but also the harms associated with the events.

We consider these changes to the modified PSI 90 to be substantive changes to the measure. Therefore, we proposed to adopt the modified PSI 90 for the HAC Reduction Program beginning with the FY 2018 payment determination and subsequent years. We explain the modified PSI 90 more fully below, and also refer readers to the measure description on the NQF Web site at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3*.

We note that the proposed modified PSI 90 (MUC ID 15–604) was included on a publicly available document entitled ''2015 Measures Under Consideration for December 1, 2015'' [65] in compliance with section 1890A(a)(2) of the Act, and was reviewed by the Measures Application Partnership (MAP). The MAP supported this measure, stating that ''the PSI measures were developed to identify harmful healthcare related events that are potentially preventable. Three additional PSIs have been added to this updated version of the measure. PSIs were better linked to important changes in clinical status with 'harm weights' that are based on diagnoses that were assigned after the complication. This is intended to allow the measure to more accurately reflect the impact of the events.'' [66] The measure received support for inclusion in the HAC Reduction Program as referenced in the MAP Final Recommendations Report.[67]

(2) Overview of the Measure Changes

First, the name of the PSI 90 measure has changed from the ''Patient Safety for Selected Indicators Composite Measure'' to the ''Patient Safety and Adverse Events Composite'' (NQF #0531) to more accurately capture the indicators included in the measure.

Second, the PSI 90 measure has expanded from 8 to 10 component indicators. The modified PSI 90 is a weighted average of the following 10 risk-adjusted and reliability-adjusted individual component PSI rates:

- PSI 03 Pressure Ulcer Rate;
- PSI 06 Iatrogenic Pneumothorax Rate;
- PSI 08 In-Hospital Fall With Hip Fracture Rate; [68]
- PSI 09 Perioperative Hemorrhage or Hematoma Rate; *
- PSI 10 Postoperative Acute Kidney Injury Requiring Dialysis Rate; * [69]
- PSI 11 Postoperative Respiratory Failure Rate; *
- PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate;
- PSI 13 Postoperative Sepsis Rate;
- PSI 14 Postoperative Wound Dehiscence Rate; and
- PSI 15 Unrecognized Abdominopelvic Accidental Puncture/Laceration Rate.[70] [71]

(* Denotes new component for the modified PSI 90 measure.)

As stated above, the modified PSI 90 measure also removed PSI 07, Central Venous Catheter-Related Blood Stream Infection Rate, because of potential overlap with the CLABSI measure (NQF #0139) which has been included in the Hospital IQR Program since the FY 2011 IPPS/LTCH PPS final rule (75 FR 50201 through 50202), the HAC Reduction Program since the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), and the Hospital VBP Program since the FY 2013 IPPS/LTCH PPS final rule (77 FR 53597 through 53598).

In response to stakeholder concerns, highlighted in the NQF 2014 Patient Safety Report,[72] the modified PSI 90 also respecified two component indicators, PSI 12 and PSI 15. Specifically, for PSI 12 Perioperative PE or DVT rate, the NQF received public comments concerning the inclusion of: (1) Extracorporeal membrane oxygenation (ECMO) procedures in the denominator; and (2) intra-hospital variability in the documentation of calf vein thromboses (which have uncertain clinical significance). As such, the revised PSI 12 component indicator no longer includes ECMO procedures in the denominator or isolated deep vein thrombosis of the calf veins in the numerator. PSI 15 was also respecified further to focus on the most serious intraoperative injuries—those that were unrecognized until they required a subsequent reparative procedure. The modified denominator of PSI 15 now is limited to discharges with an abdominal/pelvic operation, rather than including all medical and surgical discharges. In addition, to identify events that are more likely to be clinically significant and preventable, the PSI 15 numerator was modified to require both: (1) A diagnosis of an accidental puncture and/or laceration; and (2) an abdominal/pelvic reoperation one or more days after the index surgery.

[62] NQF-Endorsed Measures for Patient Safety, Final Report. Available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx*.

[63] NQF-Endorsed Measures for Patient Safety, Final Report. Available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx*.

[64] National Quality Forum QPS Measure Description for ''Patient Safety for Selected Indicators (modified version of PSI90) (Composite measure)'' found at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3*.

[65] 2015 Measures Under Consideration List available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[66] MAP Final Recommendations available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_Hospitals.aspx*.

[67] Ibid.

[68] Previously titled ''Postoperative Hip Fracture'' prior to v6.0.

[69] Previously titled ''Postoperative Physiologic and Metabolic Derangement'' prior to v6.0.

[70] Previously titled ''Accidental Puncture or Laceration Rate'' prior to v6.0.

[71] *http://www.qualityforum.org/QPS/0531*.

[72] NQF Endorsed Measures for Patient Safety, Final Report. Available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx*.

Finally, the NQF Patient Safety Review Committee raised concerns about the weighting scheme of the component indicators. In prior versions of the measure, the weights of each component PSI were based solely on volume (numerator rates). In the modified PSI 90, the rates of each component PSI are weighted based on statistical and empirical analyses of volume, level of excess clinical harm associated with the PSI, and disutility (the measure of the severity of the adverse events associated with each of the harms, that is, outcome severity, or least preferred states from the patient perspective). The final weight for each component indicator is the product of harm weights and volume weights (numerator weights). Harm weights are calculated by multiplying empirical estimates of excess harms associated with the patient safety event by utility weights linked to each of the harms. Excess harms are estimated using statistical models comparing patients with a safety event to those without a safety event in a Medicare FFS sample. Volume weights are calculated based on the number of safety events for the component indicators in an all-payer reference population.

For more information on the modified PSI 90 measure and component indicators, we refer readers to the Quality Indicator Empirical Methods available online at: *www.qualityindicators.ahrq.gov*.

(3) Risk Adjustment

The risk adjustment and statistical modeling approaches of the models remain unchanged in the modified PSI 90. In summary, the predicted value for each case is computed using a modeling approach that includes, but is not limited to, applying a Generalized Estimating Equation (GEE) hierarchical model (logistic regression with hospital random effect) and covariates for gender, age, Modified MS–DRG (MDRG), Major Diagnostic Category, transfer in, point of origin not available, procedure days not available, and AHRQ Elixhauser Comorbidity Software (COMORB).

The expected rate for each of the indicators is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (that is, hospital). The risk-adjusted rate for each of the indicators is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate. For more details about risk adjustment, we refer readers to: *http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf*.

(4) Adoption of the NQF-Endorsed Version of the Modified PSI 90

In summary, the PSI 90 measure was revised to reflect the relative importance and harm associated with each component indicator to provide a more reliable and valid signal of patient safety events. We believe that adopting the modified PSI 90 would continue to provide strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, which is a critical consideration in quality improvement. We proposed to adopt the modified PSI 90 for the HAC Reduction Program for FY 2018 and subsequent years. We will continue to use the currently adopted eight-indicator version of the PSI 90 measure for the HAC Reduction Program for FY 2017. We invited public comment on our proposal to adopt the modified PSI 90 measure (NQF #0531) for the HAC Reduction Program for FY 2018.

Comment: Many commenters supported adopting the modified measure, noting that the modified PSI 90 measure was recently endorsed by NQF, addresses past measure concerns, and reflects events within the hospital's control. Commenters appreciated that the measure was modified to incorporate harms associated with safety events into the weighting of the component indicators. Commenters also noted that the components currently include significant indicators of patient safety events that hospitals could prevent through incorporation of evidence-based processes including enhanced patient monitoring. Finally, commenters stated that this modified version is an improvement and strongly supported its use as a component for evaluation of safety and payment incentives for the reduction of medical harm.

Response: We thank commenters for their support and continue to believe that the HAC Reduction Program encourages improvement in patient safety over the long-term for all hospitals. HACs are often preventable conditions like central line associated bloodstream infections, catheter associated urinary tract infections, and other complications or conditions that arise after a patient was admitted to the hospital for the treatment of another condition. These conditions cost Medicare and the private sector billions of dollars each year and take a significant toll on patients and families. In most cases, hospitals can prevent HACs when they follow protocols, procedures and evidenced-based guidelines. We base our measure selection decisions for the HAC Reduction Program on measures currently available, risk adjusted, and reflective of hospital performance. Factors such as endorsement by the NQF and support by the NQF-convened MAP, which represents stakeholder groups, are also taken into account in deciding which measures to adopt. All the measures finalized for inclusion in the HAC Reduction Program are NQF-endorsed and were recommended for inclusion in the program by the MAP. We have identified patient safety and the reduction of HACs as a high priority through our CMS and National Quality Strategies.

Comment: One commenter thanked CMS for the proposed removal of PSI 07 from the PSI 90 measure.

Response: We thank the commenter for its support.

Comment: Commenters appreciated that the revised measure re-weights individual component PSIs to better reflect the importance and preventability of particular safety events. However, numerous commenters stated that these updates do not address the serious deficiencies with the measure noted by MedPAC and academic researchers. Commenters also expressed concern that CMS continues to use claims data to determine payment adjustments. Commenters specifically noted that claims-based measures are risk-adjusted based on diagnostic codes and specificity of coding on an administrative claim, not on any clinical data related to a patient. These commenters stated that claims data cannot and do not fully reflect the details of a patient's history, course of care and clinical risk factors. As a result, the commenters stated that the rates derived from the measures are highly inexact. Commenters stated that PSI data may assist hospitals in identifying patients whose particular cases merit deeper investigation, but that they are poorly suited to drawing meaningful conclusions about hospital performance on safety issues. These commenters stated that the measure does not drive quality improvement. Commenters recommended that CMS review this measure to determine the appropriateness of both the current and modified measures in the performance programs moving forward and strongly urged CMS to phase the measure out of the HAC Reduction Program and other programs.

Response: We continue to believe the PSI 90 measure is an important measure of patient safety and these modifications help to broaden and strengthen the measure. We disagree with commenters

that claims-based measures in general and PSIs in particular have not demonstrated that they are accurate, reliable, and valid indicators of quality and safety of care. Regarding the administrative data elements of PSI 90, we note that there are previously conducted studies that validate the relationship between administrative claims data and medical records.[73] These studies demonstrate that administrative claims data can provide sufficient clinical information to assess patient safety. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50091) for a further discussion of this issue. Further, over the past decade, AHRQ has supported a series of validation studies based on detailed abstraction of medical records.[74] These studies informed AHRQ's PSI development process, including further refinements to indicators, working with others to improve coding practices, and retirement of a few indicators.

We disagree with commenters that the PSIs are not are accurate, reliable, and valid indicators of quality and safety of care. Many of these claims-based indicators have been endorsed by the NQF, which includes a review process that assesses reliability and validity.[75] We note that NQF endorsed the modified PSI 90, including the risk-adjustment methodology of the component indicators, as reliable and valid (NQF #0531).[76] Further, we believe the modified PSI 90 does provide actionable information and specific direction for prevention of patient safety events, because hospitals can track and monitor individual PSI rates and develop targeted improvements to improve patient safety. For further guidance on PSI monitoring and strategies for applying quality improvements to PSI data, we refer readers to the Toolkit for Using the AHRQ quality indicators available at: *http://www.ahrq.gov/professionals/systems/hospital/qitoolkit/index.html*.

We emphasize that improving patient safety is our primary objective for the HAC Reduction Program

Comment: One commenter noted that a recent study published in Medical Care[77] found there was limited validity for the AHRQ PSI and HAC Reduction Program measures when measured against the reference standard of a medical chart review. Commenters stated that only 5 of the measures had sufficient data for pooled meta-analysis. These commenters stated that only PSI 15 (Accidental Puncture and Laceration) met the proposed threshold for validity, based on a positive predictive value (PPV) of 0.80 and higher. Commenters also stated that coding errors were found to be the most common reasons for discrepancies between the medical record review and administrative databases. Commenters requested that CMS reevaluate the appropriateness of including the PSI 90 measure for use in its future public reporting and pay-for-performance programs.

Response: We appreciate the commenters' input and would like to emphasize that improving patient safety is our primary objective for the HAC Reduction Program. We note that NQF endorsed the modified PSI 90 measure as a valid measure (NQF #0531); further, experts agree that this measure is scientifically rigorous. We also note that NQF reviewed the risk-adjustment methodology of the component indicators during its last cycle of NQF endorsement, and endorsed the modified PSI 90 measure as valid and reliable. We continue to work with the measure steward to improve the measure. We also continually review alternative measures, related to patient safety, to determine their appropriateness for inclusion in the HAC Reduction Program. We also refer readers to the AHRQ Quality Improvement Toolkit for additional guidance to facilitate improvements to documentation and coding at: *http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/systems/hospital/qitoolkit/b4-documentationcoding.pdf*.

Comment: Commenters recommended that use of the modified PSI 90 measure in any of the CMS pay-for-performance programs start no sooner than October 1, 2016, noting that this timeline will give organizations time to understand and prepare for the newly revised measure. Commenters further noted that the software which AHRQ has made available to hospitals for the purpose of monitoring performance has not been updated to reflect ICD–10 coding. Commenters expressed concern about the proposed performance period, claiming that adding indicators after the performance period has ended do not allow for concurrent coding correction or concurrent process improvement. Commenters recommended CMS work with AHRQ to make this software available as soon as possible so that hospitals are able to monitor performance in an ongoing way in order to provide for continuous quality improvement. Commenters further recommended that CMS temporarily remove this measure from public reporting and inclusion in any pay-for-performance scoring and reimbursement until the ICD–10 version of PSI 90 is available.

Response: We understand that there are concerns regarding the transition to ICD–10. However, we disagree that the use of the modified PSI 90 measure should start no sooner than October 1, 2016. Hospitals and other healthcare facilities have known about ICD–10 coding for some time and have had the opportunity to implement ICD–10 coding procedures. All measure specifications have been translated to and updated for corresponding ICD–10 code specifications and we were fully prepared to accept ICD–10-based claims data beginning October 1, 2015 in accordance with established program timelines. AHRQ originally sought public comment in the **Federal Register** on November 26, 2013 (78 FR 70558 through 70559) on the proposed conversion of the AHRQ QIs to ICD–10 CM/PCS codes. At that time, the proposed ICD–10 CM/PCS mappings and specifications were posted on the AHRQ QI Web site for review at: *http://www.qualityindicators.ahrq.gov/icd10/default.aspx*. Since that time, the AHRQ QIs and the ICD–10 mappings have been continuously updated and refined, as new ICD–10 codes are released and CMS' MS–DRG classification of ICD–10 codes is refined.

We further note that we are finalizing the proposal to use only ICD–9 claims data for FY 2018. This will provide the necessary time for AHRQ to develop a

[73] (1) Zrelak PA, Romano PS, Tancredi DJ, Geppert JJ, Utter GH. Validity of the AHRQ Patient Safety Indicator for Postoperative Physiologic and Metabolic Derangement based on a national sample of medical records. Medical Care 2013; 51(9):806–11. (2) Utter GH, Zrelak PA, Baron R, Tancredi DJ, Sadeghi B, Geppert JJ, Romano PS. Detecting postoperative hemorrhage or hematoma from administrative data: The performance of the AHRQ Patient Safety Indicator. Surgery 2013; 154(5):1117–25. (3) Borzecki AM, Cevasco M, Chen Q, Shin M, Itani KM, Rosen AK. How valid is the AHRQ Patient Safety Indicator ''postoperative physiologic and metabolic derangement''? J Am Coll Surg. 2011 Jun; 212(6):968–976. (4) Borzecki AM, Kaafarani H, Cevasco M, Hickson K, Macdonald S, Shin M, Itani KM, Rosen AK. How valid is the AHRQ Patient Safety Indicator ''postoperative hemorrhage or hematoma''? J Am Coll Surg. 2011 Jun; 212(6):946–953.

[74] A list of all AHRQ validation studies is available at: *http://www.qualityindicators.ahrq.gov/Resources/Publications.aspx*.

[75] More information on the NQF endorsement process is available in the NQF Review and Update of Guidance for Evaluating Evidence and Measure Testing- Technical Report available at: *http://www.qualityforum.org/Publications/2013/10/Review_and_Update_of_Guidance_for_Evaluating_Evidence_and_Measure_Testing_-_Technical_Report.aspx*.

[76] Measure information is available at: *http://www.qualityforum.org/QPS/0531*.

[77] Winters BD, Bharmal A, Wilson RF, et al. Validity of the Agency for Health Care Research and Quality Patient Safety Indicators and the Centers for Medicare and Medicaid Hospital-acquired Conditions: A Systematic Review and Meta-Analysis. Medical Care. 2016 [ePub ahead of print].

risk adjusted software version capable of using ICD–10 claims data for FY 2019. One of the factors in the decision to delay the use of ICD–10 claims data until FY 2019 was to allow for the necessary one year of ICD–10 data collection required for AHRQ to create a risk adjusted software version. We will also monitor and assess measure specifications with respect to ICD–10 code specifications and potential impacts on measure performance and payment incentive programs.

Comment: Commenters recommended that CMS revise ICD–10 codes to more appropriately capture PSI measures. For PSI 12, commenters noted that ICD–10 codes do not currently exist to appropriately code DVT in the soleal vein or peroneal vein. Commenters recommended the addition of codes for the appropriate capture of PSI 12. For PSI 13, commenters noted the Third International Consensus Definition Task Force published a recommended new definition of sepsis in March 2016.[78] These commenters recommended that, as this new definition is adopted as a medical standard, revised ICD–10 codes be developed that reflect the new definition, to appropriately capture and report PSI 13.

Response: Many claims-based measures have updated ICD–10 codes contained in the Measure Information Forms (MIFs) on the NQF Web site. We also note that AHRQ's proposed changes for ICD–10–CM/PCS conversion of its quality indicators are available at: *http://www.qualityindicators.ahrq.gov/icd10/default.aspx*. AHRQ reviews all ICD–10–CM/PCS coding updates and integrates new codes regularly. AHRQ is also working with CMS to align coding classification systems.

Comment: One commenter expressed concern with the inclusion of PSI 03. Commenters noted that the measure is inconsistent with recent work completed by the National Pressure Ulcer Advisory Panel (NPUAP) in April 2016 and may be providing misleading information to the public if not corrected. In addition, commenters stated that the reporting of data is further complicated by inconsistencies between existing ICD codes and current practice, making it difficult to report accurately. Commenters believed that it would be a serious error to continue to collect misleading information, which arbitrarily skews reports and can hinder rather than facilitate patient understanding in their review of this measure. Commenters requested CMS suspend data collection for PSI 03 until such time this measure can be brought in line with NPUAP's definitions. Commenters further requested CMS request of AHRQ the following: Modification of PSI 03 to include only stage III and IV pressure injuries (ulcers); modification of pressure injuries (ulcers) to be consistent with the April 2016 NPUAP definitions, in particular, the consideration that not all deep tissue pressure injury (DTP) wounds evolve into a significant tissue injury; and that DPTI should be generally excluded from the PSI 03 measure definition and only included once they reveal the actual extent of pressure injury.

Response: As noted in the technical specifications (*http://www.qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx* and *http://www.qualityindicators.ahrq.gov/Modules/PSI_TechSpec_ICD10.aspx*), PSI 03 is currently limited to stage III and IV pressure injuries as well as unstageable injuries (which are considered clinically equivalent to stage III or IV, because they represent ''obscured full-thickness skin and tissue loss''). We appreciate the suggestion to review the April 2016 revisions by the NPUAP. AHRQ has already considered the revisions and its potential impact on PSI 03 with ICD–10 coding guidelines. At this time, we do not believe the revisions have a material impact on the incidence of PSI 03. Because it is not yet clear whether all deep tissue pressure injuries (DTPI) should be counted in quality measurement programs, or only those that evolve into ulcers, and NPUAP noted that DPTI ''results from intense and/or prolonged pressure and shear forces at the bone-muscle interface,'' AHRQ believes that it is still appropriate to count DPTI as a significant pressure-related soft tissue injury and to capture it in PSI 03 based on current ICD–10 indexing. All of the PSIs are reviewed, refined, and updated annually. AHRQ will continue to monitor the coding guidelines with respect to the NPUAP revisions and its potential impact on the technical specifications of PSI 03.

Comment: One commenter recommended that the exclusion criteria of PSI 04 Stratum 4A be broadened to include diagnoses that reflect a hypercoagulable state. The commenter recommended broadening the exclusion criteria in Stratum 04B to include cases that started in MDC 4, but advanced to the Pre-MDC. The commenter recommended broadening the exclusion criteria in Stratum 4C to include sepsis diagnosis codes that are present on admission. The commenter also recommended broadening the exclusion criteria of Stratum 4D to include cases that started in MDC 4 or 5 but advanced to the Pre-MDC and cases that are present on admission. In addition, the commenter recommended removing inclusion criteria of K921 melena in Stratum 04E. The commenter also recommended broadening the exclusion criteria for Stratum 04E to focus on the Present on Admission Indicator rather than the principal diagnosis position and also excluding Pre-MDC.

Response: We will continue to monitor and analyze the impact of our measure selection for further adjustments to the HAC Reduction Program. Suggestions regarding potential PSI measure revisions can be made directly to *QIsupport@ahrq.hhs.gov*.

Comment: One commenter supported the inclusion of PSI 09 in the modified PSI 90 measure. This commenter noted that perioperative hemorrhage is a high-volume condition, with up to five percent of cardiac surgery patients potentially requiring additional surgery to control bleeding. The commenter also noted that perioperative hemorrhage is a high-cost condition, with complications that require an increased hospital length of stay and longer ICU time resulting in an increased economic burden relative to patients without these events. The commenter stated that in many instances these conditions can be prevented in many surgeries through appropriate use of a flowable hemostatic matrix which will help to improve patient safety and reduce the costs of care.

Response: We thank the commenter for its feedback and we continue to believe that the HAC Reduction Program encourages improvement in patient safety over the long-term for all hospitals.

Comment: Commenters expressed concern that the PSI 09 component may apply to a number of transplant patients. Commenters indicated that perioperative hemorrhage or hematoma is normal after liver transplant, and is frequent after kidney transplant, and the repercussions of these and other transplantation procedures are not indicative of poor quality care. Commenters further noted that liver transplants result in significant blood loss in nearly every case, and poor performance on this measure can be driven by the number of liver transplants performed. Commenters recommend that transplantation should be added to the exclusion list a priori

[78] Singer M, Deutschman CS, Seymour CW, et al: The Sepsis Definitions Task Force The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). Journal of the American Medical Association (JAMA, Feb 22, 2016). Accessed at: *http://jama.jamanetwork.com/article.aspx?articleid=2492881#Abstract*.

and requested that that liver transplant patients be excluded from the PSI 09 denominator.

Response: We do not agree with the commenters' recommendation that liver transplant patients should be excluded from the PSI 09 denominator. While we appreciate commenters' observation that transplant patients may have an elevated risk of hemorrhage or hematoma, we note that the risk-adjustment model for PSI 09 explicitly accounts for the increased risk associated with solid organ transplantation. For more information on the PSI 09 risk model, we refer readers to: *http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V50/Parameter_Estimates_PSI_50.pdf*).

Comment: One commenter expressed concern that the PSI 10 component of the measure is inappropriate for liver transplantation. The commenter stated that while the measure excludes patients with preoperative renal failure, many liver transplant patients with relatively normal baseline renal function get Acute Renal Failure after transplant despite high quality care, due to hemodynamic factors and the nature of the drugs involved in the performance of the procedure and its aftermath. The commenter recommended that liver transplantation be added to the exclusion list.

Response: We do not agree with commenter that liver transplant patients should be excluded from the PSI 10 denominator. While we appreciate commenter's observation that liver transplant patients may have an elevated risk of acute kidney failure, we note that the risk-adjustment model for PSI 10 explicitly accounts for the increased risk associated with hepatic failure. For more information on the PSI 10 risk model, we refer the commenter to: *http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V50/Parameter_Estimates_PSI_50.pdf*.

Comment: One commenter expressed concern with the PSI 11 component of the measure because acute respiratory failure, mechanical ventilation, and reintubation are fairly common for both liver and kidney procedures and do not suggest poor quality of care. This commenter stated that transplants have high incidences of acute respiratory failure, mechanical ventilation, and reintubation meeting the specifications set forth in this measure, due to the fluid shifts, medication, neurological status, and potential for infection involved in this complex surgery. The commenter recommend that liver and kidney transplantation should be added to the exclusion list for this measure.

Response: We understand commenter's concerns, however, we disagree with the commenter that liver and kidney transplantation should be added to the exclusion list. We note that the risk-adjustment model for PSI 11 explicitly accounts for the increased risk associated with solid organ transplantation. Liver transplantation (MDRG 7702) is associated with an adjusted odds ratio of 48.3 in AHRQ's v5.0 risk model for PSI 11, whereas kidney transplantation (MDRG 1101) is not empirically associated with increased odds of PSI 11. For more information, we refer the commenter to: *http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V50/Parameter_Estimates_PSI_50.pdf*.

Comment: Commenters thanked CMS for the proposed changes to PSI 12 and appreciated that the modified weighting methodology that accounts for patient harm dropped from 34 to 18 percent. However, commenters expressed concern about the vulnerability of PSI 12 to surveillance bias. Commenters noted that studies have shown that hospitals with increasing numbers of structural quality characteristics (that is, larger hospitals with more accreditations, more complex patients, and engagement in quality initiatives that typically suggest high quality care) have better venous thromboembolism (VTE) prophylaxis, but actually have higher VTE rates, or an increase in PSI 12 event rates.[79] Commenters stated that hospitals with more sophisticated tools and technology used to track VTE show higher rates of VTE and are being penalized for doing a better job at detection. Commenters stated that performance on PSI 12 may reflect differences in VTE imaging use rather than differences in quality of care, and the inclusion of PSI 12 could unfairly penalize hospitals with increased vigilance in VTE detection. One commenter recommended that PSI 12 be removed from pay-for-performance programs.

Response: CMS and AHRQ recognize the commenters' concerns about surveillance bias for PSI 12 Perioperative PE or DVT Rate and the issue was addressed in the NQF Patient Safety Steering Committee in 2015. Surveillance bias is a non-random type of systemic bias where a diagnosis is more likely to be observed the more vigilant one is in looking for it. In the case of DVT or PE, hospitals may underdiagnose or over diagnose DVT or PE depending how often they screen or perform diagnostic testing to look for these diagnoses. Several research teams have examined DVT and PE rates and surveillance bias.[80] However, studies have not specifically examined whether the observed rates reflect underdiagnoses of DVT or PE at low-testing hospitals, over diagnosis of DVT or PE at high-testing hospitals, or the underlying true incidence of symptomatic DVT or PE.

While some hospitals might hypothesize that increased surveillance is desirable, there is no evidence to support the hypothesis that ''increased vigilance in DVT or PE detection'' is desirable, from the perspective of patients and their families. Over diagnosis of DVT or PE among patients may lead to overtreatment, and overtreatment is not inconsequential as there are known adverse effects associated with treatment of DVT and PE. Thus, while we acknowledge commenter's concerns regarding surveillance bias, we believe that PSI 12 is an important component indicator of the modified PSI 90 measure, because it encourages hospitals not only to prevent DVT or PE, but also to appropriately assess a patient's risk for DVT and PE to prevent over diagnosis and underdiagnoses. Because of the negative economic and health consequences associated with DVT or PE diagnosis, we believe that preventing underdiagnoses and over diagnosis is critical to improving patient safety.

Lastly we disagree with commenter that PSI 12 Perioperative PE or DVT Rate lacks appropriate exclusions. Measure exclusions were reviewed by the NQF Patient Safety Steering Committee in 2015 and the measure was re-endorsed as reliable and valid. We note that AHRQ removed isolated thrombosis of calf veins (ICD–9–CM

[79] Bilimoria, Karl Y., Jeanette Chung, Mila H. Ju, Elliott R. Haut, David J. Bentrem, Clifford Y. Ko, and David W. Baker. ''Evaluation of Surveillance Bias and the Validity of the Venous Thromboembolism Quality Measure.'' JAMA 310.14 (2013): 1482–489. Web. 26 May 2016.

[80] Bilimoria KY, Chung J, Ju MH, et al. Evaluation of surveillance bias and the validity of the venous thromboembolism quality measure. JAMA. 2013;310(14):1482–1489; Holcomb CN, DeRussy A, Richman JS, Hawn MT. Association Between Inpatient Surveillance and Venous Thromboembolism Rates After Hospital Discharge. JAMA Surg. 2015;150(6):520–527; Ju MH, Chung JW, Kinnier CV, et al. Association between hospital imaging use and venous thromboembolism events rates based on clinical data. Ann Surg. 2014;260(3):558–566 and Pierce CA, Haut ER, Kardooni S, et al. Surveillance bias and deep vein thrombosis in the national trauma data bank: The more we look, the more we find. The Journal of Trauma. 2008;64(4):932–936; discussion 936–937. Haut ER, Chang DC, Pierce CA, et al. Predictors of posttraumatic deep vein thrombosis (DVT): Hospital practice versus patient factors-an analysis of the National Trauma Data Bank (NTDB). The Journal of trauma. 2009;66(4):994–9.

453.42) from the version 6.0 specification reviewed by the NQF Patient Safety Steering Committee in 2015 in order to minimize the impact of clinically unimportant distal thromboses on hospital-specific PSI 12 rates. However, suggestions regarding potential PSI measure revisions can be made directly to: *QIsupport@ahrq.hhs.gov*.

Comment: One commenter suggested using a comprehensive prophylaxis measure because it is a better measure of quality in VTE prevention and more widely used.

Response: CMS and external stakeholders believe measures in the hospital reporting programs should focus on the outcomes of care rather than processes of care, which is consistent with PSI 12. The AHRQ PSIs are based on actual clinical events or outcomes rather than processes of care. Focusing on outcomes has the advantages of representing clinically meaningful events that: Affect the care and outcomes of hospitalized patients, often leading to lost time from work, school, or family responsibilities (or even death); have significant public health and economic implications, require additional resources for treatment and follow-up care; are better aligned with the preferences and values of patients and families; and are sensitive to a variety of different care processes and ''bundles'' of processes, not just pharmacologic prophylaxis.

Comment: One commenter expressed concern regarding the PSI 12 respecifications and noted that it is important within these specifications to identify the exact ICD–10 codes that represent ''isolated deep venous thrombosis of calf veins.'' The commenter noted that, in ICD–10, there are codes for deep venous thrombosis of distal lower extremity, calf veins, and tibial vein, all of which are considered ''calf veins.'' The commenter recommend that CMS consider these codes in PSI 12.

Response: CMS and AHRQ are aware of the issue and are working to clarify the diagnosis codes for DVT involving distal deep veins of the lower extremity in ICD–10–CM coding. In the meantime, we note that version 6.0 of PSI 12 excludes the following ICD–10–CM diagnosis codes from the numerator specification: I82.441–I82.443, I82.449, I82.491–I82.493, I82.499, I82.4Z1–I82.4Z3 and I82.4Z9 (acute embolism and thrombosis of the tibial vein and deep vein of the lower extremity).

Comment: One commenter expressed concern that changes in coagulation in the early postoperative period may lead to increased incidence of clotting disorders including DVT after transplant procedures and also may be caused by large bore IVs.[81] In addition, transplant patients often get products that promote clotting due to inherent coagulopathy, and some patients have clotting disorders that cause hypercoagulability. The commenter noted that this measure excludes surgeries involving interruption of the vena cava, and stated that all liver transplants involve such interruption. This commenter recommended that liver and kidney transplant be added to the exclusion list because DVT is not indicative of poor quality care for these procedures due to the frequency of DVT in transplantation.

Response: We appreciate commenter's observation that PSI 12 excludes cases where a procedure for interruption of the vena cava occurs before or on the same day of the first operating room procedure; cases meeting this criterion should be excluded, because inferior vena cava (IVC) filter placement (which is by far the most common example of surgical interruption of the vena cava) is appropriate only for patients who cannot tolerate, or have already failed, conventional pharmacologic prophylaxis. IVC filters are placed in high-risk patients with the knowledge that they increase the risk of deep vein thrombosis distal to the device while decreasing the risk of embolization to the pulmonary circulation.

We disagree with commenter that liver and/or kidney transplants must be placed on the exclusion list, just because these patients have an elevated risk of thrombosis. We note that the risk-adjustment model for PSI 12 explicitly accounts for the increased risk associated with solid organ transplantation. For example, liver transplantation (MDRG 7702) is associated with an adjusted odds ratio of 3.2 in AHRQ's v5.0 risk model for PSI 12. For more information, we refer the commenter to: *http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V50/Parameter_Estimates_PSI_50.pdf*.

Comment: One commenter requested that CMS add an exclusion for any patient who has a tracheostomy. The commenter noted that it is not the surgery that puts that patient at risk for PE or DVT, it is the medical problem that leads to the patient needing a tracheostomy that puts the patient at increased risk for PE or DVT.

Response: We will continue to monitor and analyze the impact of our measures selection for further adjustments to the HAC Reduction Program. We agree that some medical conditions which lead to a tracheostomy [82] may also increase patients' risk for PE or DVT. However, we do not believe that just because a patient has a tracheostomy they are at increased risk for PE or DVT and should be excluded. We note that most of the medical conditions that can lead to tracheostomy are already captured by the extensive set of risk factors variables used in the risk adjustment for PSI 12. Further suggestions regarding potential PSI measure revisions can be made directly to: *QIsupport@ahrq.hhs.gov*.

Comment: Commenters appreciated the modifications to PSI 15, but requested that CMS update its guidance regarding the correct coding of PSI 15 to ensure that abdominopelvic punctures or lacerations inherent to a surgery are not incorrectly coded as accidental.

Response: Suggestions regarding potential PSI measure revisions can be made directly to: *QIsupport@ahrq.hhs.gov*.

Comment: One commenter did not support PSI 15 because no large-scale assessment has been done to assess the validity of the measure component, and it is difficult to determine if a reoperation was directly related to the accidental puncture/laceration. The commenter recommended that PSI 15 (Accidental Puncture or Laceration) be improved considerably by adding the requirement for a reoperation to occur that is related to the accidental puncture or laceration.

Response: We thank the commenter for its feedback. Suggestions regarding potential PSI measure revisions can be made directly to: *QIsupport@ahrq.hhs.gov*.

Comment: One commenter recommended broadening the PSI 03 Pressure Ulcer Rate exclusion criteria to include those from Appendix I-Immunocompromised State Diagnosis and Procedure Code; broadening the PSI 06 Iatrogenic Pneumothorax Rate to include pneumothorax related to CPR; broadening the PSI 07 CVC Related Blood Stream Infection Rate exclusion criteria to include cases with a length of stay of less than 2 days; broadening the PSI 08 Post Op Hip Fracture exclusion criteria to include anything falling within Appendix H: Cancer Diagnosis Codes regardless of metastasis and regardless of Present on Admission status; broadening the PSI 09

[81] Bore refers to the size of a needle use for an IV.

[82] A tracheotomy or a tracheostomy is an opening surgically created through the neck into the trachea (windpipe) to allow direct access to the breathing tube and is commonly done in an operating room under general anesthesia. Definition obtained from: *http://www.hopkinsmedicine.org/tracheostomy/about/what.html*.

Perioperative Hemorrhage and Hematoma Rate exclusion criteria to include Abnormal Coagulation Profile R79.1 as an exclusion criterion with present on admission and creating a new seroma ICD–10 code; changing the exclusion criteria of PSI 10 Postoperative Physiologic and Metabolic Derangement Rate to a time based element in hours as opposed to the number of postoperative days and including Sinus Bradycardia and Sinus Tachycardia cardiac arrhythmias in the exclusion criteria; changing the inclusion criteria of the PSI 11 Postoperative Respiratory Failure Rate in the numerator inclusion criteria, vent time, reintubation criteria and broadening the exclusion criteria to include cases that started in MDC 4 or 5 but advanced to the Pre-MDC; broadening the PSI 12 Perioperative Pulmonary Embolism or Deep Vein Thrombosis exclusion criteria to include inheritable hypercoagulable conditions, acquired hypercoagulable conditions, present on admission status; excluding PSI 12 from public reporting and pay-for-performance programs; modifying the PSI 13 Postoperative Sepsis Rate to delete the inclusion criteria for post-procedural shock; and extending the exclusion criteria of PSI 14 Postoperative Wound Dehiscence Rate to a length of state of four days.

Response: We thank the commenter for its feedback. Suggestions regarding potential PSI measure revisions can be made directly to: *QIsupport@ahrq.hhs.gov*.

After consideration of the public comments we received, we are finalizing the adoption of the modified PSI 90: Patient Safety and Adverse Events Composite (NQF #0531) discussed above as proposed.

b. Applicable Time Periods for the FY 2018 HAC Reduction Program and the FY 2019 HAC Reduction Program

Section 1886(p)(4) of the Act gives the Secretary the statutory authority to determine the ''applicable period'' during which data are collected for the HAC Reduction Program. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized and codified at 42 CFR 412.170 that we would use a 2-year time period of performance data to calculate the Total HAC Score. We believe the 24-month performance period provides hospitals and the public with the most current data available, while allowing sufficient time to complete the complex calculation process for these measures. The 24-month performance period was chosen because it tended to show that between 50 to 90 percent of hospitals attained a moderate or high level of reliability for AHRQ measures (78 FR 50717). Although we believe the 24-month time is the preferred length of time for performance data, there may be situations, discussed in more detail below, where the collection of 24 months of data is not operationally feasible.

Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25121 through 25122), we proposed, beginning in FY 2017 and for subsequent years, to permit flexibility to use a period other than 2 years from which data are collected in order to calculate the Total HAC Score under the HAC Reduction Program. We also proposed to change the definition of ''applicable period,'' in 42 CFR 412.170, to reflect this proposed change.

Since the ICD–10 transition was implemented on October 1, 2015, we have been monitoring our systems and so far claims are processing normally. The measure steward, AHRQ, has been reviewing the measure for any potential issues related to the conversion of approximately 70,000 ICD–10 coded operating room procedures [83] (*https://www.cms.gov/icd10manual/fullcode_cms/P1616.html*), which could directly affect the modified PSI 90 component indicators. In addition, to meet program requirements and implementation schedules, our system would require an ICD–10 risk-adjusted version of the AHRQ QI PSI software [84] by December 2016 for the FY 2018 payment determination year. At this time, a risk-adjusted ICD–10 version of the PSI 90 Patient Safety and Adverse Events Composite software is not expected to be available until late CY 2017. A full year of nationally representative ICD–10 coded data must be available for the development risk-adjusted models based on a national reference population.

To address these issues, for the current Domain 1 measure (PSI 90 Patient Safety and Adverse Events Composite), we proposed to use the 15-month performance period from July 1, 2014 through September 30, 2015, for the FY 2018 HAC Reduction Program. This 15-month performance period would utilize only ICD–9–CM data and only apply to the FY 2018 payment year. The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculations of measure results for FY 2018. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25121), we erroneously referenced the incorrect date for the end of the FY 2019 performance period. We had stated that ''For the FY 2019 HAC Reduction Program, we proposed to use the 21-month performance period from October 1, 2015 through September 30, 2017.'' Accordingly, we issued a correction notice (81 FR 37176). The 21-month performance period should be October 1, 2015 through June 30, 2017. This 21-month performance period would utilize only ICD–10 data and only apply to the FY 2019 payment year. The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculations of measure results for FY 2019.

Prior to deciding to propose abbreviated data collection periods for the FY 2018 and the FY 2019 payment determinations, we took several factors into consideration. These included the recommendations of the measure steward, the feasibility of using a combination of ICD–9 and ICD–10 data, the impact of suspending the measure, minimizing provider burden, program implementation timelines, and the reliability of using shortened data collection periods, as well as the importance of continuing to publicly report this measure. We believe that using a 15-month data collection period for FY 2018 and a 21-month data collection period for FY 2019 best serve the need to provide important information on hospital patient safety and adverse events by allowing sufficient time to process the claims data and calculate the measures, while minimizing reporting burden and program disruption.

Because this issue only impacts the PSI 90 Patient Safety and Adverse Events Composite in Domain 1, for the CDC NHSN measures previously finalized for use in the FY 2017 HAC Reduction Program (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), we would use the 24-month performance period from January 1, 2015 through December 31, 2016 (CYs 2015 and 2016) for the FY 2018 HAC Reduction Program. For the FY 2019 HAC Reduction Program, we proposed to use the 24-month performance period from January 1, 2016 through December 31, 2017 (CYs 2016 and 2017).

We believe that using a 15-month (FY 2018 only) and a 21-month (FY 2019

[83] International Classification of Diseases, (ICD–10–CM/PCS) Transition—Background. Available at: *http://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm*.

[84] The AHRQ QI Software is the software used to calculate PSIs and the composite measure. More information is available at: *http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf*.

only) performance period for Domain 1 and a 24-month performance period for Domain 2 balances the needs of the HAC Reduction Program and allows sufficient time to process the claims data and calculate the measures. We will continue to test ICD–10 data that are submitted in order to ensure the accuracy of measure calculations and to monitor and assess the translation of measure specifications to ICD–10, potential coding variation, and impacts on measure performance and payment incentive programs.

We invited public comment on the proposals to update the definition of ''applicable period'' codified at 42 CFR 412.170 for FY 2017 and subsequent years and to use these updated performance periods for calculation of measure results for the FY 2018 and the FY 2019 HAC Reduction Programs.

Comment: Many commenters supported the proposal to limit the performance periods. Commenters stated that although many hospitals typically benefit from a longer reporting period, in this case they recognize that combining ICD–9 and ICD–10 data would create confusion. One commenter recommended that CMS transition quality measures to full ICD–10 and not rely upon ICD–9 codes in the new performance periods.

Response: We thank commenters for their feedback and agree that combining ICD–9 and ICD–10 data would create confusion. We believe this policy best serves the need to provide important information on hospital patient safety and adverse events by allowing sufficient time to process the claims data and calculate the measures, while minimizing reporting burden and program disruption.

Comment: Many commenters expressed concern that reducing the performance period to 15 months in FY 2018 will undermine the reliability of the results. Commenters supported CMS' decision of not combining claims data for ICD–9 and ICD–10. However, commenters believe that all measures should be reported first in the Hospital IQR Program for one year before the performance period in a payment program begins. Commenters stated that reporting measures in the Hospital IQR Program provides transparency, allows stakeholders to gain experience submitting measures, and allows time to identify errors and unintended consequences. Commenters recommended that CMS suspend PSI 90 from inclusion in calculating scores for the Hospital VBP Program and HAC Reduction Program and suspend it from public reporting on *Hospital Compare* until a 24-month performance period can be re-established, or until AHRQ has satisfactorily demonstrated that the shorter performance period will produce equitable results.

Response: We understand stakeholder concerns about the potential impacts to hospital performance on quality measures when ICD–10 was implemented on October 1, 2015, as well as suggestions for more extensive testing to understand the impacts before any payments or penalties are implicated. As part of the ICD–10 transition planning that has taken place over the past several years, we have performed testing and analyses across the agency with respect to system readiness and claims payment, and continue to provide extensive education and outreach to providers, vendors, and other payers through the CMS ICD–10 Web site.[85] All measure specifications have been translated to and updated for corresponding ICD–10 code specifications and we were fully prepared to accept ICD–10-based claims data beginning October 1, 2015 in accordance with established program timelines.

In response to commenters' specific concerns regarding PSI 90, we note that the NQF found the modified PSI 90 to be reliable using 12 months of data.[86] We further note that we base our measure selection decisions for the HAC Reduction Program on measures currently available, risk adjusted, and reflective of hospital performance. We also take NQF endorsement and support by the MAP into account in deciding which measures to adopt. All the measures finalized for inclusion in the HAC Reduction Program are NQF-endorsed and were recommended for inclusion in the HAC Reduction Program by the MAP.

We further note that the HAC Reduction Program and the other value-based and quality reporting programs are separate programs with different purposes and policy goals. We note that the PSI 90 measure covers topics of critical importance to quality improvement in the inpatient hospital setting and to patient safety. We selected this quality measure because we believe that hospital acquired conditions comprise some of the most critical patient safety areas, therefore justifying the use of the measure in more than one program. Although the measure exists in more than one program, the measure is used and calculated for very distinct purposes. Accordingly, we believe that the critical importance of this measure to patient safety warrants inclusion in the HAC Reduction Program.

Comment: One commenter noted that the reduced performance period of 21 months for FY 2019 payment determination listed in the proposed rule indicates the period October 1, 2015 through September 30, 2017, which is a total of 24 months. The commenter requested that CMS provide clarification as to which months will be used to determine performance for FY 2019.

Response: In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25121), we erroneously referenced the incorrect date for the end of the FY 2019 performance period. Accordingly, we issued a correction notice updating September 30, 2017 to read June 30, 2017 (81 FR 37176). We are confirming that the FY 2019 HAC Reduction Program will use the 21-month performance period from October 1, 2015 through June 30, 2017.

Comment: Commenters requested that CMS continue working with hospitals, measure developers and all other stakeholders to address the potential unintended consequences of combining measure data collected under ICD–9 and ICD–10. Commenters recommended that CMS undertake an analysis of any performance differences resulting from the transition to ICD–10 for all of the measures used in the pay-for-performance program, with the results of those analyses be made publicly available. Commenters noted that such data would help inform about any potential unintended biases and measure performance changes resulting from the use of the new codes.

Response: We will continue to work with stakeholders during the ICD–10 transition to monitor and assess impacts and to address any potential issues that may occur. We continue to publish comprehensive documentation of all ICD–10 resources by quality program and/or measure type. We also plan to continue to conduct national provider calls and other presentations to help stakeholders understand the potential impact of ICD–10 on their measure performance. We encourage stakeholders to subscribe to our listserv titled ''Hospital Inpatient Value-Based Purchasing (HVBP) and Improvement'' to receive notification of scheduled events. Stakeholders may join at: *https://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic/ListServe/Register*. For those individuals

[85] *https://www.cms.gov/Medicare/Coding/ICD10/index.html*.

[86] Modified_Version_of_PSI90_NQF0531_Composite_Measure_Testing_151022.pdf available in the Patient Safety for Selected Indicators (modified version of PSI90) zip file at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=77836*.

who are interested in participating in future ICD–10 Coordination and Maintenance Committee meetings, information on the Committee can be found on the CMS Web site at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*. We encourage public participation at these meetings either in person, by conference lines, or by the livestream provided by CMS.

After consideration of the public comments we received, we are finalizing the definition of applicable period at 42 CFR 412.170 and the 15-month FY 2018 performance period discussed above as proposed. We are finalizing the FY 2019 performance period as the 21-month performance period October 1, 2015 through June 30, 2017.

c. Changes to the HAC Reduction Program Scoring Methodology

(1) Current Scoring Policy

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50721), we finalized a scoring methodology that aligns with the achievement scoring methodology currently used in the Hospital VBP Program. Our intent was to reduce confusion associated with multiple scoring methodologies by aligning the scoring for the Hospital VBP Program and the HAC Reduction Program. We note that alignment benefits the hospital stakeholders who have prior experience with the Hospital VBP Program. Accordingly, we implemented a methodology for assessing the top quartile of applicable hospitals for HACs based on performance standards.

We indicated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50720 through 50725) that points will be assigned to hospitals' performance for each measure. We finalized a decile-based methodology for assigning points, depending on the specific measures.

- For Domain 1, point assignment is based on a hospital's score for the PSI 90 measure.
- For the Domain 1 score, 1 to 10 points are assigned to the hospital.
- For the measures in Domain 2, point assignment for each measure is based on the SIR for that measure.
- For each SIR, 1 to 10 points are assigned to the hospital for each measure.
- The Domain 2 score consists of the average of points assigned to each measure.

To calculate a Total HAC Score for each hospital, we multiply each domain score by a weighting and add together the weighted domain scores to determine the Total HAC Score (§ 412.172(e)(3)). We use each hospital's Total HAC Score to determine the top quartile of subsection (d) hospitals that are subject to the payment adjustment beginning with discharges on or after October 1, 2014.

(2) Program Evaluation Efforts

As part of our ongoing efforts to evaluate the HAC Reduction Program, we recently conducted a review of our scoring methodology and assessed opportunities to strengthen the program. As part of that review, our Hospital Quality Reporting Program Support (HQRPS) contractors convened a technical expert panel (TEP) on October 19–20, 2015, with a follow-up call on December 11, 2015. The TEP examined multiple areas of the HAC Reduction Program and focused on identifying a scoring methodology that provides an incentive to hospitals to reduce HACs and distinguishes top performers from low performers. The TEP identified concerns with the current decile-based scoring methodology that included: Ties at the penalty threshold; hospitals with a limited amount of data being identified as poor performers; and situations in which hospitals with no adverse events and no Domain 2 data nonetheless become eligible for penalty.

During the FY 2016 HAC Reduction Program, a small subset of hospitals that had zero adverse events in Domain 1 and no Domain 2 score were identified as part of the worst-performing quartile. These hospitals received Domain 1 scores of 7.0, meaning they were in the 7th decile of hospitals for the PSI 90 measure despite being close to the PSI 90 measure mean value. As this subset of hospitals had no Domain 2 scores, they received a Total HAC Score equal to their Domain 1 score of 7.0. This Total HAC Score was greater than the 75th percentile cutoff for penalty determination of 6.75. CMS waived the penalty for these zero adverse event hospitals so they would not be treated as poor performers. These hospitals were potentially disadvantaged because their Total HAC Scores were determined solely on their Domain 1 Score. Because Domain 2 scores tend to be lower on average than Domain 1 scores,[87] other hospitals without Domain 2 scores are potentially treated the same as low performers in the same decile.

In addition, scoring using deciles can make it more difficult to distinguish top performers from low performers by creating a large number of ties on measure scores. For example, two hospitals with meaningfully different measure results may fall into the same decile bin and therefore be ultimately indistinguishable under the current scoring methodology. Conversely, two hospitals with performance that is not statistically distinguishable may fall into different decile bins. Furthermore, ties at the penalty threshold complicate the adjudication of payment adjustments; in both the FY 2015 and FY 2016 programs, less than 25 percent of all hospitals had Total HAC Scores above the threshold for penalties. Specifically, only 21.9 percent of hospitals in FY 2015 and 23.7 percent of hospitals in FY 2016 were subject to a payment adjustment.

To address stakeholder concerns regarding the current scoring methodology, we evaluated a number of alternatives and recommendations from the TEP. We refer readers to the Project Title: Hospital-Acquired Condition (HAC) Reduction Program Scoring Methodology Reevaluation located at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html* for a summary of the TEP's discussion. These alternatives included replacement of the current decile-based scoring approach with the use of Winsorized [88] z-scores. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25122 through 25123), we proposed to use Winsorized z-scores for FY 2018.

(3) Winsorized Z-Score Method

The Winsorized z-score method (z-score) uses a continuous measure score rather than forcing measure results into deciles. Z-scores represent a hospital's distance from the national mean for a measure in units of standard deviations. Under the z-score approach, poor-performing hospitals earn a positive z-score, reflecting measure values above the national mean, and better-performing hospitals earn a negative z-score, reflecting measure values below

[87] This is because hospitals are assigned the minimum of one point for any measure for which they have a measure result of zero. For example, for the CAUTI measure, if 13 percent of hospitals have an SIR of zero, one point is assigned to each of these hospitals, even though the decile approach is intended to assign 10 percent of hospitals to each decile. Two points would be assigned to the remaining seven percent of hospitals that would fall in the second decile. This phenomenon does not affect Domain 1 scores, since the reliability-adjusted PSI 90 measure result is not equal to zero in any hospital.

[88] Winsorized measure results are truncated to the 5th and 95th percentiles, replacing values between the minimum and the 5th percentile with the 5th percentile value and replacing values between the 95th percentile and the maximum with the 95th percentile value. Z-scores are then calculated based on these values.

the national mean. For each measure, a hospital's z-score is based on the following equation that expresses the hospital's measure value minus the average value for that measure, divided by the standard deviation of the measure values across all hospitals:

Z-Score = (Hospital's Measure Performance—Mean Performance for All Hospitals) Standard Deviation for All Hospitals

To form the Total HAC Score, we would use the z-scores as hospitals' measure scores. In accordance with the current scoring methodology, we would then average the z-scores across measures within Domain 2 and assign the z-score for PSI 90 for Domain 1 to determine the domain scores. We would then multiply each domain score by the appropriate weighting and add together the weighted domain scores to determine the Total HAC Score. We would use each hospital's Total HAC Score to determine the top quartile of subsection (d) hospitals that are subject to the payment adjustment.

(4) Impact and Implementation

This z-score approach is straightforward to implement, easily adapted as measures are added or removed from the HAC Reduction Program, transparent, and familiar to a wide range of stakeholders. Continuous values address the limitations of decile scoring and preserve the magnitude of differences among hospitals' measure results. Thus, hospitals that differ meaningfully on their measure results will also differ meaningfully on their Total HAC Scores. Unlike the decile approach, continuous measure scores would substantially reduce ties of Total HAC Scores, which have prevented CMS from penalizing exactly 25 percent of hospitals in previous program years. The use of z-scores also improves alignment between Domains 1 and 2 and creates a more level playing field for hospitals with data in only Domain 1.

Based on FY 2016 data supplemented with MRSA Bacteremia and CDI results,[89] the z-score approach affects the penalty status of slightly more than 200 hospitals, relative to the decile approach. This approach brings 114 hospitals into the penalty zone and 103 hospitals out of the penalty zone and reduces the HAC Reduction Program's impact on the largest and smallest hospitals. Most importantly, because of the improvements in precision and standardization gained by implementing this approach, there is no penalization of hospitals that had zero adverse events and no Domain 2 score in either the actual results from FY 2016 or in the results based on the FY 2016 data supplemented with MRSA Bacteremia and CDI results.

Among the 184 hospitals with fewer than 25 beds, the proportion of hospitals penalized would fall from 33 percent to 18 percent. Among the 213 hospitals with more than 500 beds, the proportion of hospitals penalized would fall from 50 percent to 42 percent. The approach leaves the proportion of teaching, urban, and high-DSH hospitals penalized largely unchanged, with one exception. The z-score approach slightly increases the penalization rate among moderately high (50 to 64 percent) DSH hospitals, from 28 percent to 35 percent. Only 172 hospitals fall into this group; therefore, the increase reflects only 11 additional hospitals in that group being penalized.

We believe that differences in performance scores must reflect true differences in performance. In addition, hospitals must be able to clearly understand performance scoring methods and performance expectations to maximize their quality improvement efforts. Therefore, we invited public comments on our proposal to adopt the z-score method for calculating measure results beginning in the FY 2018 HAC Reduction Program.

Comment: Many commenters commended CMS' willingness to consider changes to the underlying scoring methodology. Commenters noted that the shift away from the decile-based scoring approach to a Winsorized z-score more accurately represents a hospital's performance in relation to the national mean, rather than forcing scores into deciles. Commenters stated that this transition promotes a better statistical methodology, resulting in a smoother distribution of scores and avoiding unintended anomalies that result from the current decile-based scoring method.

Response: We thank commenters for their support and agree that the transition promotes a better statistical methodology.

Comment: Commenters recommended that CMS closely monitor the effects the new scoring methodology may have among essential hospitals that serve a larger volume of vulnerable patients and to evaluate whether any particular category of hospital is disproportionately impacted by the change.

Response: We understand commenters' concerns and we believe these improvements mark progress towards enhancing our ability to distinguish hospital performance and we will continue to monitor the impacts of the scoring change.

Comment: Commenters requested that CMS provide robust guidance and support to hospitals to avoid confusion as the agency implements its new methodology. Commenters also requested CMS provide hospitals with the ability to compare their current performance scoring with the proposed methodology. One commenter asked if the z-scores would be publicly reported and how hospitals will receive their scores.

Response: We thank commenters for their input and note that we plan to provide education and outreach as we work with hospitals to inform them about the new methodology and any potential impacts of the scoring change. We note that each hospital will receive a Hospital-Specific Report (HSR) containing its results prior to public reporting. We will work to ensure that the HSRs and accompanying documents contain the information hospitals need to understand their performance in the program. The results will be publicly reported on *Hospital Compare* according to already established timelines. We appreciate commenters' suggestion of providing hospitals with the ability to compare their results under the current performance scoring and the proposed scoring and we will work to determine the feasibility of providing these data.

Comment: Commenters recommended that CMS reevaluate the scoring of Domain 2. Commenters stated they would like to see the same process used in Domain 2 as is used in Domain 1 if there are zero adverse events. Commenters noted that the current scoring of Domain 2 is ignoring perfect performance and puts some hospitals at an unfair advantage.

Response: We thank commenters for their input. We believe the z-score methodology further improves alignment between the HAC Reduction Program scoring domains by making the distributions of domain scores more comparable and placing them on the same scale. Neither the current nor the proposed methodology ignore hospitals with zero observed infections; in both cases they would receive a measure score of zero unless they have insufficient data. Under Domain 2, hospitals are considered to have insufficient data when they have less than one predicted infection for a given measure and do not receive a measure score in this scenario. We believe this criterion is comparable to the

[89] Results are a based on actual FY 2016 measure data with the addition of MRSA Bacteremia and CDI data for the reporting period spanning October 2012 through December 2014.

insufficient data requirements in Domain 1.

Comment: Commenters supported the proposal to change the scoring methodology. However, commenters expressed concern that this new methodology increases the penalization rate among moderately high DSH hospitals (50 to 64 percent) from 28 percent to 35 percent. Commenters noted that while this increase may only affect 11 additional hospitals, it shifts the penalties for this program towards academic hospitals, which are already at a disadvantage in other value-based programs.

Response: We appreciate commenters' concerns and note that rather than reducing the penalty burden on any particular category of hospitals, the proposed scoring change aims to correct an identified limitation in the HAC Reduction Program: The penalization of hospitals with no Domain 2 score and zero adverse events in Domain 1. Hospitals with only Domain 1 data received higher Total HAC Scores than hospitals contributing data in both domains contributing to a misalignment. We believe that the proposed scoring approach corrects this misalignment and along with previously finalized modifications to Domain 2, including additional measures, expansion of patient care locations, and re-baselining, will substantially reduce the number of hospitals with no Domain 2 score moving forward.

Comment: Some commenters did not support the use of Winsorized z-scores and expressed concern that neither the proposed z-score approach nor the current decile-based scoring is adequate to identify meaningful differences in performance across hospitals. These commenters stated that an AHA-commissioned analysis estimating the impact of the proposed scoring changes and comparing them to the current decile-based approach found that the percentages of large hospitals, high-DSH payment hospitals, and teaching hospitals penalized under the z-score method are minimally different from the current scoring method.

Commenters further conducted a simulation analysis to determine whether hospitals in particular performance categories had Total HAC Scores that are statistically different from the payment penalty threshold score. These commenters placed hospitals into ventiles (that is, division of the population into 20 approximately equal groups) (with higher ventiles indicating worse performance) of Total HAC Scores. Commenters then calculated the percentage of hospitals whose performance was statistically different from the penalty threshold score in each ventile. Commenters found that as the performance ventile increased, the percentage of hospitals whose performance scores are statistically different from the performance threshold score declined. In some cases, (that is, the 15th and 16th ventiles under the decile scoring method and the 17th ventile under the z-score method), virtually no hospitals had Total HAC Scores that were statistically different from the payment penalty threshold score.

Commenters also stated that it does not appear that the z-score approach would make it any more likely that CMS would penalize 25 percent of hospitals. Commenters stated their analysis showed that under either method, 25 percent of hospitals would be penalized in FY 2017. Commenters recommend that CMS consider adopting a scoring methodology that recognizes both improvement and achievement but noted that the current legislative language does not permit that kind of flexibility. Commenters stated they saw little merit to changing the scoring approach at this time, given that hospitals have gained an understanding of the decile-based scoring approach and that there are minimal differences in the distribution of penalties.

Response: We thank commenters for their input and note that a TEP convened in late 2015 and early 2016 supported this approach. Rather than reducing the penalty burden on any particular category of hospitals, the proposed scoring change aims to correct an identified limitation in the HAC Reduction Program: The penalization of hospitals with no Domain 2 score and zero adverse events in Domain 1. We note that under decile-based scoring, hospitals with insufficient data to calculate a Domain 2 score received higher Total HAC Scores due to only having a Domain 1 score. The proposed scoring change aims to correct this problem by applying Winsorized z-scores, a continuous scoring approach that brings the domains into alignment. The proposed approach essentially eliminates ties in Total HAC Scores, reduces effects on outliers, and enhances the ability to distinguish among hospitals of varying quality and ensuring consistent penalization of exactly 25 percent of hospitals. This approach also enhances our ability to distinguish among hospitals of varying quality, unlike deciles, where two hospitals with very different scores might be in the same decile. Coupled with Winsorization, which diminishes the impact of outlying measure scores on the program while preserving information about hospitals' relative performance, the proposed methodology represents a substantial improvement in the HAC Reduction Program.

Comment: Some commenters recommended that CMS explore additional scoring methods that could adjust for skewed distributions and avoid penalizing hospitals with no adverse events. Commenters agreed with CMS that the z-score will reduce ties. However, commenters noted that z-scores are best used with a normal distribution and are not appropriate for the CDC NHSN measures in Domain 2, which are skewed to the left (that is, many hospitals have low infection rates), unlike Domain 1, which has an approximately normal distribution. Commenters recommend CMS consider scoring methods that account for the skew in the distribution and do not penalize hospitals with zero adverse events, including p-values for the CDC NHSN measures in Domain 2.

Response: We thank commenters for their input and recommendations. Although Winsorized z-scores do not directly account for this skew, the methodology preserves information about hospitals' relative performance and reduces the likelihood of penalization for hospitals with zero adverse events. We note that Winsorization is not intended to produce a symmetric distribution; rather, it aims to reduce the impact of extreme values. We will continue to monitor the HAC Reduction Program and take the commenters' concerns under consideration as we strive to improve the Program.

Comment: Commenters expressed concern that the program's scoring methodology is extremely complex and requires a greater degree of transparency so hospitals can understand how this potential change could impact their Medicare payments as well as how they benchmark against peer hospitals. Commenters requested that CMS perform additional analysis on the proposed scoring methodology to determine whether certain types of hospitals are disproportionately impacted under the new approach. Commenters noted that grouping all hospitals into one population to be analyzed is not statistically sound. Commenters stated that there are simply too many differences between hospitals across the nation to perform accurate risk adjustments so that all hospitals are evaluated and scored fairly. Commenters recommend that CMS utilize peer cohorts, groupings, or stratification and compare only hospitals with similar volumes and demographics. One commenter

requested that CMS release a public use file showing the impact of the switch to the Winsorized z-score to allow hospitals to prepare for financial impacts.

Response: We understand commenters' concerns, however, we disagree with commenters' argument that the scoring methodology is extremely complex. We note that TEP members emphasized the proposed methodology offers ease of implementation, transparency, and familiarity to a wide range of stakeholders given their use in other quality measurement initiatives. We also note that the Five-Star Quality Rating System has already adopted Winsorization as part of its rating methodology. To address commenters' specific concerns about peer cohorts, groupings, or stratification, we remind readers that we discussed the ongoing work of NQF, ASPE, MedPAC and other stakeholders regarding risk adjustment in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49572). We will closely examine their findings and recommendations and consider how they apply to our quality programs.

Comment: Commenters expressed concern about the continuing shifts in all of the three performance-based programs due to measures moving in and out of the programs, changing domain weights, and performance and base years. Commenters noted that hospitals are overwhelmed with competing methodologies, varying target rates, and multiple confusing and mixed messages that these measures present when applied under different programs.

Response: We understand commenters' concerns and note that we work to provide education and outreach, as well as public materials, to assist stakeholders with understanding each program. We strive to make the HAC Reduction Program as transparent and straightforward as possible and note that the HAC Reduction Program, the Hospital VBP Program, and the Hospital Readmission Reduction Program have different policy goals. The measures and methodology selected for the HAC Reduction Program cover topics of critical importance to quality improvement in the inpatient hospital setting and to patient safety.

After consideration of the public comments we received, we are finalizing the changes to the scoring methodology discussed above as proposed.

4. Comments on Additional Measures for Potential Future Adoption

We view the addition of other quality measures as a critical component of value-based purchasing, and we are seeking public comments on what additional measures we should consider adopting in the future. We believe that our continued efforts to reduce HACs are vital to improving patients' quality of care and reducing complications and mortality, while simultaneously decreasing costs. The reduction of HACs is an important marker of quality of care and has a positive impact on both patient outcomes and cost of care. Our goal for the HAC Reduction Program is to heighten the awareness of HACs and reduce the number of incidences that occur. We seek to adopt measures for the HAC Reduction Program that promote better, safer, and more efficient care. Our overarching purpose is to support the NQS' three-part aim of better health care for individuals, better health for populations, and lower costs for health care.

To the extent practicable, all HAC Reduction Program measures should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. Measures should take into account widely accepted criteria established in medical literature. We note that all measures proposed for the HAC Reduction Program should follow the criteria established by the DRA of 2005 in that they consist of high-volume or high-cost conditions that could be prevented by the use of evidence-based guidelines.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25123), we welcomed public comment and suggestions for additional HAC Reduction Program measures that will help achieve the program goals in these or other measurement areas.

Comment: Commenters recommended that CMS not include measures based solely on current availability, but rather to include measures that: (1) Have standardized data collection processes; (2) external data validation programs to ensure the accuracy of the data; and (3) have support and endorsement of providers as valid measures to assess quality and cost of care. Commenters noted that by including measures that meet this criteria, CMS will ensure provider engagement and implement a process of assessing quality, cost, and value of care that is transparent. Commenters noted that quality measurement should become more focused on a small number of metrics that emphasize patient-reported and patient-generated data.

Commenters encouraged CMS to add additional measures that address adverse drug events, ventilator-associated events, diagnostic errors, and a broader scope of surgical site infections. One commenter believes that more can be done to improve the early detection and treatment of sepsis in the inpatient setting. One commenter recommended that CMS should add the Severe Sepsis and Septic Shock Management Bundle (NQF #0500) to the HAC Reduction Program. One commenter recommended CMS include measures that incorporate appropriate imaging technology. One commenter noted that there are numerous guidelines regarding the use of ultrasound and a reduction in HACs such as punctures, ruptures, pneumothorax, excessive bleeding, lacerations.

One commenter requested that CMS encourage quality-related activities around blood management and urged CMS to adopt a blood and blood products quality strategy that recognizes blood as a valuable resource that should be preserved through blood management and monitored via quality measures. One commenter requested that CMS adopt quality measures that pertain to wound care in general and continue to work with healthcare professionals and industry in the development of new wound care measures. One commenter stated that the U.S. Wound Registry would serve as an excellent resource in this regard, as it includes numerous wound care measures, some of which could be adopted for inpatient hospital quality programs with little or no modifications to the specifications. One commenter believed that the HAC Reduction Program should include an additional option for Domain 1 that would provide hospitals the ability to report an electronic measure of patient harm derived from electronic health records (EHRs). Finally, one commenter recommended that CMS create a quality measure on Surgical Site Infection (SSI) rates following C-section because it would further drive hospitals to boost their quality of care initiatives around this high-volume surgery.

Response: We thank the public for these views and we will consider them as we develop future policy.

5. Maintenance of Technical Specifications for Quality Measures

Technical specifications for AHRQ's PSI 90 measure in Domain 1 can be found at AHRQ's Web site at: *http://qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx.* Technical specifications for the CDC NHSN HAI measures in Domain 2 can be found at CDC's NHSN Web site at: *http://www.cdc.gov/nhsn/acute-care-hospital/*

index.html. Both Web sites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100), we described a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the HAC Reduction Program. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25123), we did not propose any changes to this policy at this time.

6. Extraordinary Circumstance Exception Policy for the HAC Reduction Program Beginning in FY 2016 and for Subsequent Years

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581) for a detailed discussion of the exception policy for hospitals located in areas that experience disasters or other extraordinary circumstances for the HAC Reduction Program. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25123 through 25124), we did not propose any changes to this policy for FY 2017.

J. Payment for Graduate Medical Education (GME) and Indirect Medical Education (IME) Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

The Affordable Care Act made a number of statutory changes relating to the determination of a hospital's FTE resident limit for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances.

Section 5503(a)(4) of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals training fewer residents than their caps, and to authorize the redistribution of the estimated number of excess FTE resident slots to other qualified hospitals. In addition, section 5503(b) amended section 1886(d)(5)(B)(v) of the Act to require the application of the section 1886(h)(8) of the Act provisions in the same manner to the IME FTE resident caps. The policy implementing section 5503 of the Affordable Care Act was included in the November 24, 2010 CY 2011 OPPS/ASC final rule with comment period (75 FR 72147 through 72212) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53424 through 53434). Section 5506(a) of the Affordable Care Act amended section 1886(h)(4)(H) of the Act to add a new clause (vi) that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The policy implementing section 5506 of the Affordable Care Act was included in the November 24, 2010 CY 2011 OPPS/ASC final rule with comment period (75 FR 72212 through 72238), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434 through 53448), and the FY 2015 IPPS/LTCH final rule (79 FR 50122–50140).

2. Change in New Program Growth From 3 Years to 5 Years

a. Urban and Rural Hospitals

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25124), section 1886(h)(4)(H)(i) of the Act requires CMS to establish rules for calculating the direct GME caps of teaching hospitals training residents in new programs established on or after January 1, 1995. Under section 1886(d)(5)(B)(viii) of the Act, these rules also apply to the establishment of a hospital's IME cap. CMS implemented these statutory requirements in the August 29, 1997 **Federal Register** (62 FR 46005) and in the May 12, 1998 **Federal Register** (63 FR 26333). Generally, when CMS (then HCFA) implemented the regulations at 42 CFR 413.79(e)(1) and 42 CFR 412.105(f)(1)(vii), these regulations provided that if a hospital did not train any allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it begins to participate in training residents in a new residency program (allopathic or osteopathic) on or after January 1, 1995, the hospital's unweighted FTE resident cap (which would otherwise be zero) may be adjusted based on the sum of the product of the highest number of FTE residents in any program year during

the third year of the first new program, for each new residency training program established during that 3-year period, and the minimum accredited length for each type of program. This 3-year period, which we refer to as the ''3-year window'' for ease of reference in the proposed rule and this final rule, started when a new program began, and the teaching hospital first began to train residents for the first time in that new program, typically on July 1, and ending when the third program year of that first new program ends.

Prior to development of the FY 2013 IPPS/LTCH PPS proposed rule, the teaching hospital community expressed concerns that 3 years do not provide for a sufficient amount of time for a hospital to ''grow'' its new residency programs and to establish FTE resident caps that are properly reflective of the number of FTE residents that it will actually train, once the programs are fully grown. Hospitals explained that 3 years is an insufficient amount of time primarily because a period of 3 years is not compatible with program accreditation requirements, particularly in instances where the qualifying teaching hospital wishes to start more than one new program. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule and final rule, we proposed and finalized changes to the regulations at 42 CFR 413.79(e) for direct GME and at 42 CFR 412.105(f)(1)(vii) for IME that revised the ''3-year window'' to a ''5-year window,'' for a new teaching hospital to establish and grow a new program, and thus begin training residents for the first time in new programs that are started on or after October 1, 2012. Thus, for urban hospitals that begin to train residents in a new medical residency training program for the first time on or after October 1, 2012, the cap will not be adjusted for new programs established more than 5 years after residents begin training in the first new program. However, rural hospitals are permitted to receive new cap adjustments for participating in training residents in new medical residency training programs at any time, and therefore, under § 413.79(e)(3), if a rural hospital participates in new medical residency training programs on or after October 1, 2012, the hospital's cap is adjusted for each new program based on a 5-year growth window. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for more details on this change in the regulations regarding the 5-year window for urban hospitals training residents in new medical residency training programs for the first time and for rural hospitals participating in new medical residency training programs (77 FR 53416 through 53424).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50111), we changed our policy regarding implementation of the FTE resident caps for new programs to be effective with the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(1), and beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each individual new program started for rural hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(3). In the same final rule, we also made the effective dates of the 3-year rolling average and IME IRB ratio cap consistent with the effective date of the new program FTE resident caps. That is, beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(1), and beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each individual new program started for rural hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(3), FTE residents participating in new medical residency training programs are included in the hospital's IRB ratio cap and the 3-year rolling average.

b. Policy Changes Relating to Rural Training Tracks at Urban Hospitals

To encourage the training of residents in rural areas, section 407(c) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) amended section 1886(h)(4)(H) of the Act to add a provision (subsection (iv)) that, in the case of a hospital that is not located in a rural area (an urban hospital) that establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area or has an accredited training program with an integrated rural track, the Secretary shall adjust the urban hospital's cap on the number of FTE residents under subsection (F), in an appropriate manner in order to encourage training of physicians in rural areas. Section 407(c) of Pub. L. 106–113 was made effective for direct GME payments to hospitals for cost reporting periods beginning on or after April 1, 2000, and for IME payments applicable to discharges occurring on or after April 1, 2000. We refer readers to the August 1, 2000 interim final rule with comment period (65 FR 47033 through 47037) and the FY 2002 IPPS final rule (66 FR 39902 through 39909) where we implemented section 407(c) of Pub. L. 106–113. The regulations for establishing rural track FTE limitations are located at 42 CFR 413.79(k) for direct GME and at 42 CFR 412.105(f)(1)(x) for IME.

In the August 1, 2003 IPPS final rule (68 FR 45456 through 45457), we clarified our existing policy that although the rural track provision allows an increase to the urban hospital's FTE cap, sections 1886(h)(4)(H)(iv) and 1886(d)(5)(B) of the Act do not provide for an exclusion from the rolling average for the urban hospital for those FTE residents training in a rural track. These provisions are interpreted to mean that, except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, when an urban hospital with an FTE resident cap establishes a new rural track program or expands an existing rural track program, FTE residents in the rural track that are counted by the urban hospital are included in the hospital's rolling average calculation immediately. This policy is reflected in the regulation at § 412.105(f)(1)(v)(F) for IME and § 413.79(d)(7) for direct GME, and applies for IME and direct GME to cost reporting periods beginning on or after April 1, 2000.

We received questions asking whether the change in the 3-year window to the 5-year window for new programs also applies to the establishment of rural training tracks. In the FY 2013 IPPS/LTCH PPS final rule, when we amended the regulations to provide for a 5-year new program growth window at § 413.79(e) for direct GME and at § 412.105(f)(1)(vii) for IME, and in the FY 2015 IPPS/LTCH PPS final rule when we made the FTE resident caps of new programs to be effective with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year, we inadvertently did not also change the growth window and effective date of FTE limitations for rural training tracks, which, under existing § 413.79(k) for direct GME and § 412.105(f)(1)(x) for IME, is 3 program years, and is effective after 3 program years, respectively.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25125), we proposed to revise the regulations at § 413.79(k) (and which, in turn, would

affect IME adjustments under § 412.105(f)(1)(x)) to permit that, in the first 5 program years (rather than the first 3 program years) of the rural track's existence, the rural track FTE limitation for each urban hospital would be the actual number of FTE residents training in the rural training track at the urban hospital, and beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural training track's existence, the rural track FTE limitation would take effect. This proposed change addresses concerns expressed by the hospital community that rural training tracks, like any program, should have a sufficient amount of time for a hospital to ''grow'' and to establish a rural track FTE limitation that reflects the number of FTE residents that it will actually train, once the program is fully grown.

However, as stated above, due to the statutory language at sections 1886(d)(5)(B) and 1886(h)(4)(H)(iv) of the Act as implemented in our regulations at §§ 412.105(f)(1)(v)(F) and 413.79(d)(7), except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, FTE residents in a rural track training program at the urban hospital are subject immediately to the 3-year rolling average for direct GME and IME. In addition, under the regulations at § 412.105(a)(1)(i), no exception to the IME intern- and resident-to-bed (IRB) ratio cap is provided for residents in a rural track training program (except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time). Accordingly, while we proposed that the urban hospital's rural track FTE limitation would first be effective beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence, the rural track training program's FTEs are included in the 3-year rolling average and are subject to the IME IRB ratio cap for hospitals with established FTE caps, even within the first 5 program years prior to the beginning of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence.

We note that, for programs with cost reporting periods beginning on or after October 1, 2003, our regulations at §§ 413.79(k)(1) through (k)(4) are divided between rural track FTE limitation adjustments for urban hospitals where the residents rotate to a rural area for more than one half of the duration of the program (§§ 413.79(k)(1) and (k)(2)), and where the residents rotate to a rural area for less than one-half of the duration of the program (§§ 413.79(k)(3) and (k)(4)). As we explained in the August 1, 2003 IPPS final rule (68 FR 45456 through 45458), ''duration of the program'' refers to the minimum accredited length of the particular specialty of the rural track training program. We clarified under the proposal that, although the urban hospital's rural track FTE limitation would not be effective until the beginning of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence, the rural track FTE limitation that would be provided, if any, is still subject to whether or not the urban hospital rotates the residents in the rural track training program to a rural area(s) for more than one-half of the ''duration of the program,'' and whether or not the urban hospital complies with existing §§ 413.79(k)(5) and (k)(6), and the proposed revised § 413.79(k)(7). In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25126), we proposed to revise § 413.79(k)(7), which specifies the effect on rural track FTE limitations when previously rural areas become urban areas due to updates in the OMB standards for delineating urban and rural areas, because the existing paragraphs under § 413.79(k)(7) discuss the ''3-year'' growth period. Consequently, we stated in the proposed rule that we need to make conforming changes by revising paragraphs (k)(7)(ii) and (iii) to account for rural track training programs started prior to October 1, 2012. (For more information regarding the effect on rural track FTE limitations when OMB makes changes to its standards for delineating statistical areas, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50113 through 50117).)

c. Effective Date

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50111), when we provided that the policy regarding the effective dates of the FTE residency caps, the 3-year rolling average, and the IRB ratio cap for FTE residents in new medical residency training programs would be effective with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started, we stated that this policy would be effective for urban hospitals that first begin to participate in training residents in their first new medical residency training program, and for rural hospitals, on or after October 1, 2012. We finalized this as the effective date because the policy providing a 5-year growth period for establishing the FTE resident caps (§§ 413.79(e)(1) and (e)(3)) was also effective for new programs started on or after October 1, 2012. Because we inadvertently did not also amend the separate regulations at § 412.105(f)(1)(x) and § 413.79(k) regarding the growth window and effective date of FTE limitations for rural track training programs when we amended the regulations regarding the 5-year growth window in the FY 2013 IPPS/LTCH PPS final rule and regarding the additional changes we made in the FY 2015 IPPS/LTCH PPS final rule, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25126), we proposed that the effective date regarding the change in the growth window for rural track training programs from 3 years to 5 years also be effective for rural track training programs started on or after October 1, 2012. We acknowledged that there could be urban hospitals that started a rural track training program after October 1, 2012 (likely on July 1, 2013) for which rural track FTE limitations would become effective under current policy after 3 years (likely on July 1, 2016). We proposed that, if our proposal is finalized, we would not actually apply the rural track FTE limitations that would have become effective for these hospitals after 3 program years. Instead, the rural track FTE limitations for these hospitals would be the actual number of FTE residents training in the rural track (subject to the rolling average at § 413.79(d)(7) and the IME IRB ratio cap at § 412.105(a)(1)(i), if applicable) for an additional 2 years (from July 1, 2016 through June 30, 2018), and the rural track FTE limitations would become effective with the cost reporting period that coincides with or follows the start of the sixth program year, which in this example would be July 1, 2018.

In summary, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25126), we proposed to revise the direct GME regulations at § 413.79(k) (and which, in turn, would affect IME adjustments under § 412.105(f)(1)(x)) to permit that, effective with rural track training programs started on or after October 1, 2012, in the first 5 program years of the rural track's existence, the rural track FTE limitation for each urban hospital would be the actual number of FTE residents (subject to the rolling average at § 413.79(d)(7) and the IME IRB ratio cap at § 412.105(a)(1)(i), if applicable), training in the rural track training program at the urban hospital, and the rural track FTE limitation would take

effect beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence.

We invited public comment on this proposal.

Comment: Commenters supported the policy changes as proposed.

Response: We appreciate the commenters' support.

Comment: Some commenters objected to the fact that CMS did not exempt rural training track programs from the 3-year rolling average and the IME IRB ratio cap in the proposal. These commenters claimed that immediate implementation of the rolling average and the IME IRB ratio cap are ''extremely detrimental'' to hospitals' ability to establish new rural tracks, as the training costs would not be fully paid in the initial years of the program's establishment.

Response: We understand the payment concerns resulting from immediate application of the rolling average and IRB cap to rural track programs. However, we note that we did not propose any changes with regard to these policies. Rather, we reiterated our current policy, as reflected in the regulations at § 412.105(f)(1)(v)(F) for IME and § 413.79(d)(7) for direct GME, effective for cost reporting periods beginning on or after April 1, 2000. In the FY 2017 IPPS/LTCH proposed rule (81 FR 25125), we referred to the August 1, 2003 IPPS final rule (68 FR 45456 through 45457), where we clarified our existing policy that sections 1886(h)(4)(H)(iv) and 1886(d)(5)(B) of the Act do not provide for an exclusion from the rolling average for the urban hospital for those FTE residents training in a rural track. These provisions are interpreted to mean that, except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, when an urban hospital with an FTE resident cap establishes a new rural track program or expands an existing rural track program, FTE residents in the rural track that are counted by the urban hospital are included in the hospital's rolling average calculation immediately.

Comment: One commenter requested that CMS confirm that a FTE resident cap adjustment for a rural teaching hospital participating in the rural track is only permitted in those cases where the approved residency program meets the CMS criteria for being a newly established program.

Response: We confirm the commenter's statement. Section 1886(h)(4)(H)(iv) of the Act provides for a FTE resident cap adjustment for an urban hospital that establishes separately accredited rural tracks; the statute does not provide for a similar adjustment to rural hospitals participating in rural tracks. Accordingly, only if the program is considered new for Medicare payment purposes can the rural teaching hospital also receive a resident cap adjustment for the program. Under § 413.79(e)(3), any time that a rural hospital participates in training residents in a new program, the rural hospital may receive an increase to its FTE resident caps. We refer readers to the FY 2010 IPPS/LTCH PPS final rule for the criteria identifying a new program for Medicare payment purposes (74 FR 43908 through 43917).

Comment: Many commenters expressed concern about the future of primary care and family practice in rural areas of the country. The commenters requested that CMS make additional policy changes that result in greater numbers of primary care physicians. One commenter specifically requested changes that would facilitate increased training of residents in emergency medicine. The commenters also requested that CMS allow additional opportunities through which rural hospitals, as well as urban hospitals that form rural training track programs, can increase their FTE resident caps and direct GME PRAs. Along those lines, some commenters requested that CMS revise its definition of a teaching hospital so that hospitals can choose to train residents but remain exempt from limits like FTE resident caps and PRAs. A number of commenters suggested that CMS relax its definition of ''newly established program'' to allow urban hospitals to establish new rural tracks that can establish their own cap limits. Another commenter requested that CMS allow any approved residency program in any specialty that meets the definition of ''rural track or integrated rural track'' at § 413.75 to be treated as such, even if it does not have approval as a rural track from the relevant accrediting body.

Response: We believe that these comments are outside of the scope of our proposal. The proposal was limited to conforming the window in which rural training track programs can establish their rural track FTE limitation to the 5-year window in which a new teaching hospital can establish new FTE resident caps, as described in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53416 through 53424). Therefore, we are not addressing these comments in this final rule.

Comment: Commenters asked CMS to clarify the circumstances under which rural hospitals can increase their FTE resident caps.

Response: Rural hospitals are permitted to receive cap adjustments for participating in training residents in new medical residency training programs at any time. Therefore, under § 413.79(e)(3), if a rural hospital participates in new medical residency training programs on or after October 1, 2012, the hospital's cap is adjusted for each new program based on a 5-year growth window. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53416 through 53424) for more details on this change in the regulations regarding the 5-year window for urban hospitals training residents in new medical residency training programs for the first time and for rural hospitals participating in new medical residency training programs. In addition, to determine if a program is a new medical residency training program for which a rural hospital could receive cap adjustments, as opposed to an expansion of an existing program, we refer readers to the discussion and criteria in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43908 through 43917). In that final rule, we explained that in order to determine whether a program is new and whether, as a result, a hospital qualifies for an FTE cap adjustment, the supporting factors that a hospital should consider are (but not limited to) as follows:

- Is the program director new?
- Is the teaching staff new?
- Are there new residents?

In determining whether a particular program is a newly established one, it may also be necessary to consider factors such as the relationship between hospitals (for example, common ownership or a shared medical school or teaching relationship) and the degree to which the hospital with the original program continues to operate its own program in the same specialty. In addition, the following factors could also be considered:

- Has this program been relocated from a hospital that closed?
- If so, was this program part of the closed hospital's FTE cap determination?
- More generally, is this program part of any existing hospital's FTE cap determination?

We would not consider a transferred program to be new in the case where the program director, teaching staff, and residents are the same as another program that closed in another hospital and the first hospital remains open, or when an FTE cap that was associated with the first program is still available for use by an existing provider.

Comment: One commenter requested that CMS provide a detailed example of how the urban cap adjustment and (if applicable) the rural cap adjustment are calculated at the start of the sixth year of the rural training track. The commenter requested that the example specify how the cap calculation is impacted by time spent by residents in the urban training site versus the rural training site.

Response: We appreciate the commenter's request for a detailed example of the calculation of the urban (and rural, if applicable) FTE resident caps adjustments after the close of the fifth program year of the rural track, as it provides the opportunity to clarify this calculation in the context of rural tracks, which we did not do in the proposed rule. The rural track FTE limitation for the urban hospital, and the FTE resident cap adjustment for the rural hospital (if the rural track is a new program), would be calculated in the same manner as the FTE resident caps are calculated for urban hospitals first participating in training residents in new programs and rural hospitals participating in new programs at §§ 413.79(e)(1) and (e)(3). Because the goal of our proposal was to conform the policies for calculating the rural track FTE limitation and FTE resident cap adjustment to those adopted in FYs 2013 and 2015, effective for rural track training programs started on or after October 1, 2012, we are conforming the methodology for calculating the rural track FTE limitations at § 413.79(k) to the methodology that is already at §§ 413.79(e)(1) and (c)(3) for calculating the FTE resident caps of new teaching hospitals. The regulations at §§ 413.79(e)(1) and (e)(3) state that the FTE resident cap adjustment is the sum of the product of 3 factors: (1) The highest total number of FTE residents trained in any program year, during the fifth year of the first new program's existence at all of the hospitals to which the residents in that program rotate; (2) the number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program; and (3) the ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period. This methodology accounts for the common scenario where residents spend time training at more than one hospital (and also nonprovider settings) during the 5-year growth window, and apportions the total FTE resident caps between or among the participating hospitals. The FY 2015 IPPS/LTCH PPS final rule (79 FR 50106 through 50107) contains an example of how the FTE resident caps are calculated after 5 years, and are apportioned between participating hospitals, one hospital being a new teaching hospital that qualifies for FTE resident cap adjustments, and one being an existing teaching hospital with an already established FTE resident caps. The formula requires determining the share of the overall FTE resident caps at both hospitals to ensure proper apportionment. Therefore, this methodology is used to determine and apportion the FTE resident caps of the urban hospital, when the rural track is not a new program, or the urban and rural hospitals, when the rural track program is a new program. Although the example in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50106 through 50107) illustrates the methodology, we are providing an additional example where residents train at an urban hospital, a rural hospital, and at a rural nonprovider site. Under § 413.78(g), if a hospital (or hospitals, urban or rural) incurs the cost of the resident's salary and fringe benefits while training at the nonprovider site and meets the other conditions set forth in the regulations, the hospital may count that FTE training time for IME and direct GME purposes, on the hospital's cost report in the current training year, but also when determining the hospital's share of the new program FTE resident cap adjustments. Following is the example:

Urban Hospital and Rural Hospital jointly sponsor a separately accredited rural track program. The program is in family medicine (3 years minimum accredited length), and is accredited for a total of 6 residents, 2 in each program year (PGY). The Urban Hospital and Rural Hospital do have previously existing FTE resident caps; however, neither trains residents in an existing family medicine program. The family medicine rural track is newly created, and meets the newness criteria as described in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43908 through 43917) and other applicable requirements at § 413.78(g). Therefore, Rural Hospital may receive an increase to its FTE resident caps for the rural track program. In addition, Urban Hospital complies with the criteria at § 413.79(k)(5). The residents spend PGY1 at Urban Hospital, and then the PGY2s and PGY3s rotate to a rural area, to train at both Rural Hospital and Rural Clinic (a nonprovider site). The PGY2 and PGY3 residents, while mostly assigned to the rural area, do come back to the Urban Hospital for some required training. However, the residents spend more than 50 percent of the duration of the 3 year program in the rural area. Therefore, Urban Hospital qualifies to receive a rural track FTE limitation. Rural Hospital incurs the cost of the salaries and fringe benefits of the residents for the time spent training at Rural Clinic and meets other applicable requirements at § 413.78(g) to be able to count the time residents spend training at the Rural Clinic. The rotations and the cap calculation are as follows:

Year 1	Year 2	Year 3	Year 4	Year 5
PGY1 2.0 Urban Hospital ..	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital.
PGY2 0	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @.10 Urban Hospital (.20).	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @.10 Urban Hospital (.20).	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @.10 Urban Hospital (.20).	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @.10 Urban Hospital (.20).
PGY3 0	PGY3 0	PGY3 2 @.95 Rural Hospital and Rural Clinic (1.9), 2 @.05 Urban Hospital (.10).	PGY3 2 @.95 Rural Hospital and Rural Clinic (1.9), 2 @.05 Urban Hospital (.10).	PGY3 2 @.95 Rural Hospital and Rural Clinic (1.9), 2 @.05 Urban Hospital (.10).
TOTAL 2.0	TOTAL 4.0	TOTAL 6.0	TOTAL 6.0	TOTAL 6.0 5 Year Total = 24.

Urban Hospital's 5 YEAR FTE TOTAL = 11.1.

Rural Hospital's 5 YEAR FTE TOTAL (includes time at Rural Clinic) = 12.9.

5 Year FTE Total = 24.

Step 1: Highest number of FTE residents training in any program year

during fifth year across all participating hospitals is 2.0:

PGY 1s = 2.0.
PGY 2s = 2.0.
PGY 3s = 2.0.

Step 2: 2.0 × 3 (minimum accredited length) = 6.

Step 3: Urban Hospital's cap adjustment is based on the ratio of training at Urban Hospital over all 5 years to the total training that is occurring at all sites over all 5 years: 6 × [11.1/(24)] = 2.76.

Step 4: Rural Hospital's cap adjustment is based on the ratio of training at Rural Hospital and Rural Clinic over all 5 years to the total training that is occurring at all sites over all 5 years: 6 × [12.9/(24)] = 3.24.

2.76 + 3.24 = 6.0, the total cap assignment does not exceed the total number of accredited slots. Urban Hospital's rural track FTE limitation is 2.76. Rural Hospital's FTE cap adjustment is 3.24. (We note that this calculation is done separately for IME and direct GME caps respectively.)

We also proposed to amend the regulations at § 413.79(k) (and which, in turn, would affect IME adjustments under § 412.105(f)(1)(x)) to reflect that, effective with rural track programs started on or after October 1, 2012, the rural track FTE limitation is calculated consistent with the methodology for new programs at § 413.79(e)(1) for urban hospitals and (e)(3) for rural hospitals.

After consideration of the public comments we received, we are finalizing our proposed revision of the regulations at § 413.79(k) (and which, in turn, will affect IME adjustments under § 412.105(f)(1)(x)), with the technical corrections described below, to permit that, in the first 5 program years (rather than the first 3 program years) of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents training in the rural training track at the urban hospital (subject to the rolling average at § 413.79(d)(7) and the IME ratio cap at § 412.105(a)(1)(i), if, applicable), and beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural training track's existence, the rural track FTE limitation will take effect.

In finalizing the proposed revisions to § 413.79, we reviewed the regulatory text as a whole and are making some technical corrections to the regulations text throughout § 413.79(k) as follows:

- At § 413.79(k)(1)(ii), we are removing the phrase ''or the rural hospital(s)'' from this paragraph because it is technically inaccurate; § 413.79(k)(1) specifies what the urban hospital may include in its FTE count and the regulation text at § 413.79(k)(1)(ii) inadvertently references training at the rural hospital, which cannot be included. Therefore, we are revising the regulation text by removing the phrase ''or the rural hospital(s)''. The provision now specifies that, for rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the third year of the rural track's existence are training in the rural track at the urban hospital and are designated at the beginning of their training to be rotated to the rural hospital(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2002, or for more than one-half of the duration of the program effective for cost reporting periods beginning on or after October 1, 2003, and the number of years those residents are training at the urban hospital.
- Throughout § 413.79(k), we are replacing the term ''nonhospital'' site with ''nonprovider'' site, consistent with section 5504 of the Affordable Care Act, titled ''Counting Resident Time in Non-Provider Settings,'' which refers to ''nonprovider setting[s]'' instead of ''nonhospital setting.''
- At § 413.79(k)(4), we are updating and correcting the reference to counting time in nonprovider settings from ''§ 413.78(d)'' to ''§ 413.78(d) through (g)''.
- At § 413.79(k)(4)(ii)(B)(*2*), we are inserting the italicized language to clarify the mathematical calculation, as follows: The *ratio of the* length of time in which the residents are training at the rural nonprovider site(s) only *to the total duration of the program.* The inserted italized language clarifies the precise ratio by which to apportion the urban hospital's rural track FTE limitation to reflect the amount of time the FTE residents spend at the rural nonprovider site. (We note that we had proposed to revise § 413.79(k)(4)(ii) as part of our proposal that, effective with rural track training programs started on or after October 1, 2012, the rural track FTE limitation would take effect beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence. In addition to this proposed change to the regulations text that we are finalizing, we are finalizing, with modification, § 413.79(k)(4)(ii)(B)(*2*) to insert the italicized language above to clarify the mathematical calculation.)

3. Notice of Closure of Teaching Hospital and Opportunity To Apply for Available Slots

a. Background

Section 5506 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the ''Affordable Care Act''), ''Preservation of Resident Cap Positions from Closed Hospitals,'' authorizes the Secretary to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Specifically, section 5506 of the Affordable Care Act amended the Act by adding subsection (vi) to section 1886(h)(4)(H) of the Act and modifying language at section 1886(d)(5)(B)(v) of the Act, to instruct the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the FTE resident caps in teaching hospitals that closed ''on or after a date that is 2 years before the date of enactment'' (that is, March 23, 2008). In the November 24, 2010 CY 2011 Outpatient Prospective Payment System (OPPS) final rule (75 FR 72212), we established regulations and an application process for qualifying hospitals to apply to CMS to receive direct graduate medical education (GME) and indirect medical education (IME) FTE resident cap slots from the hospital that closed. We made certain modifications to those regulations in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the Section 5506 application process in the FY 2015 IPPS/LTCH final rule (79 FR 50122 through 50134). The procedures we established apply both to teaching hospitals that closed on or after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that closed after August 3, 2010.

b. Notice of Closure of the Pacific Hospital of Long Beach, CA and Application Process—Round 8

CMS has learned of the closure of Pacific Hospital of Long Beach, Long Beach, CA (CCN 050277). The purpose of this notice is to notify the public of the closure of this teaching hospital, and to initiate another round of the application and selection process described in section 5506 of the Affordable Care Act. This round will be the eighth round (''Round 8'') of the application and selection process. The table below contains the identifying information and IME and direct GME

caps for the closed teaching hospital, which is part of the Round 8 application process under section 5506 of the Affordable Care Act.

CCN	Provider name	City and state	CBSA code	Terminating date	IME cap (including +/− MMA Sec. 422 [1] adjustments)	Direct GME cap (including +/− MMA Sec. 422 [1] adjustments)
050277	Pacific Hospital of Long Beach.	Long Beach, CA ..	31084	August 1, 2013	14.47 + 6.00 section 422 increase = 20.47 [2].	19.92 + 6.00 section 422 increase = 25.92.[3]

[1] Section 422 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.

[2] Pacific Hospital's 1996 IME FTE cap is 14.47. Under section 422 of the MMA, the hospital received an increase of 6 to its IME FTE cap: 14.47 + 6.00 =20.47. We note that, under 42 CFR 412.105(d)(4), IME cap slots associated with an increase received under section 422 of the MMA are to be paid with a multiplier of 0.66.

[3] Pacific Hospital's 1996 direct GME FTE cap is 19.92. Under section 422 of the MMA, the hospital received an increase of 6 to its direct GME FTE cap: 19.92 + 6.00 =25.92. We note that under 42 CFR 413.77(g), direct GME FTE cap slots associated with an increase received under section 422 of the MMA are to be paid using the appropriate locality-adjusted national average PRA.

c. Notice of Closure of the Huey P. Long Medical Center, Pineville, LA and Application Process—Round 9

CMS has learned of the closure of Huey P. Long Medical Center, Pineville, LA (CCN 190009). The purpose of this notice is to notify the public of the closure of this teaching hospital, and to initiate another round of the application and selection process described in section 5506 of the Affordable Care Act. This round will be the ninth round (''Round 9'') of the application and selection process. The table below contains the identifying information and the IME and direct GME caps for the closed teaching hospital, which is part of the Round 9 application process under section 5506 of the Affordable Care Act:

CCN	Provider name	City and state	CBSA code	Terminating date	IME Cap (including +/− ACA Sec. 5503 [1] adjustments)	Direct GME Cap (including +/− ACA Sec. 5503 [1] adjustments)
190009	Huey P. Long Medical Center.	Pineville, LA	10780	June 30, 2014	13.00 − 1.96 section 5503 reduction = 11.04 [2].	13.00 − 1.96 section 5503 reduction = 11.04.[3]

[1] Section 5503 of the Affordable Care Act of 2010 (ACA), Public Laws 111–148 and 111–152, redistributed unused IME and direct GME residency slots effective July 1, 2011.

[2] Huey P. Long Medical Center's 1996 IME FTE cap is 13.00. Under section 5503 of the ACA, the hospital received a reduction of 1.96 to its IME FTE cap: 13.00 − 1.96 = 11.04.

[3] Huey P. Long Medical Center's 1996 direct GME FTE cap is 13.00. Under section 5503 of the ACA, the hospital received a reduction of 1.96 to its direct GME FTE cap: 13.00 − 1.96 = 11.04.

d. Notice of Closure of St. Joseph's Hospital, Philadelphia, PA and Application Process—Round 10

CMS has learned of the closure of St. Joseph's Hospital, Philadelphia, PA (CCN 390132). The purpose of this notice is to notify the public of the closure of this teaching hospital, and to initiate another round of the application and selection process described in section 5506 of the Affordable Care Act. This round will be the 10th round (''Round 10'') of the application and selection process. The table below contains the identifying information and the IME and direct GME caps for the closed teaching hospital, which is part of the Round 10 application process under section 5506 of the Affordable Care Act:

CCN	Provider name	City and state	CBSA code	Terminating date	IME Cap (including +/− MMA Sec. 422 [1] and ACA Sec. 5503 [2] adjustments)	Direct GME Cap (including +/− MMA Sec. 422 [1] and ACA Sec. 5503 [2] adjustments)
390132	St. Joseph's Hospital.	Philadelphia, PA ...	37964	March 13, 2016 ...	9.51 − 0.43 section 422 reduction − 0.73 section 5503 reduction = 8.35 [3].	9.51 − 0.43 section 422 reduction − 0.73 section 5503 reduction = 8.35.[4]

[1] Section 422 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.

[2] Section 5503 of the Affordable Care Act of 2010 (ACA), Public Laws 111–148 and 111–152, redistributed unused IME and direct GME residency slots effective July 1, 2011.

[3] St. Joseph's Hospital's 1996 IME FTE cap is 9.51. Under section 422 of the MMA, the hospital received a reduction of 0.43 to its IME FTE cap, and under section 5503 of the ACA, the hospital received a reduction of 0.73 to its IME FTE cap: 9.51 − 0.43 − 0.73 = 8.35.

[4] St. Joseph's Hospital's 1996 direct GME FTE cap is 9.51. Under section 422 of the MMA, the hospital received a reduction of 0.43 to its direct GME FTE cap, and under section 5503 of the ACA, the hospital received a reduction of 0.73 to its direct GME FTE cap: 9.51 − 0.43 − 0.73 = 8.35.

e. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 is 90 days following notification to the public of a hospital closure. Therefore, hospitals wishing to apply for and receive slots from the above hospitals' FTE resident caps must submit applications directly to the CMS Central Office no later than October 31, 2016. The mailing address for the CMS Central Office is included on the application form. Applications must be received by the October 31, 2016 deadline date. It is *not* sufficient for applications to be postmarked by this date.

We note that an applying hospital may apply for any or all of the three rounds of section 5506 applications that were announced in this final rule. However, a separate application must be submitted for each round for which a hospital wishes to apply.

After an applying hospital sends a hard copy of a section 5506 application to the CMS Central Office mailing address, it must also send an email to: *ACA5506application@cms.hhs.gov.* In the email, the hospital should state: ''On behalf of [insert hospital name and Medicare CCN#], I, [insert your name], am sending this email to notify CMS that I have mailed to CMS a hard copy of a section 5506 application under Round [8, or 9, or 10] due to the closure of [Pacific Hospital of Long Beach, or Huey P. Long Medical Center, or St. Joseph's Hospital]. If you have any questions, please contact me at [insert phone number] or [insert your email address].'' An applying hospital should not attach an electronic copy of the application to the email. The email will only serve to notify the CMS Central Office to expect a hard copy application, which should be mailed to the CMS Central Office.

In the CY 2011 OPPS/ASC final rule with comment period, we did not establish a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received by the deadline, and notify applicants of our determinations as soon as possible.

We refer readers to the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/dgme.html* to download a copy of the application form (Section 5506 CMS Application Form) that hospitals are to use to apply for slots under section 5506. We also refer readers to this same Web site to access a copy of the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50140) and a list of additional section 5506 guidelines for an explanation of the policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

K. Rural Community Hospital Demonstration Program

1. Background

Section 410A(a) of Pub. L. 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing ''rural community'' hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A(a)(4) of Pub. L. 108–173 specified that the Secretary was to select for participation no more than 15 rural community hospitals in rural areas of States that the Secretary identified as having low population densities. Using 2002 data from the U.S Census Bureau, we identified the 10 States with the lowest population density in which rural community hospitals were to be located in order to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003).

CMS originally solicited applicants for the demonstration in May 2004; 13 hospitals began participation with cost reporting periods beginning on or after October 1, 2004. In 2005, 4 of these 13 hospitals withdrew from the program and converted to CAH status. This left 9 hospitals participating at that time. In 2008, we announced a solicitation for up to 6 additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These 4 additional hospitals began under the demonstration payment methodology with the hospital's first cost reporting period starting on or after July 1, 2008. At that time, 13 hospitals were participating in the demonstration.

Five hospitals (3 of the hospitals were among the 13 hospitals that were original participants in the demonstration program and 2 of the hospitals were among the 4 hospitals that began the demonstration program in 2008) withdrew from the demonstration program during CYs 2009 and 2010. (Three of these hospitals indicated that they would be paid more for Medicare inpatient hospital services under the rebasing option allowed under the SCH methodology provided for under section 122 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). One hospital restructured to become a CAH, and one hospital closed.) In CY 2011, one hospital that was among the original set of hospitals that participated in the demonstration withdrew from the demonstration. These actions left seven of the originally participating hospitals (that is, hospitals that were selected to participate in either 2004 or 2008) participating in the demonstration program as of June 1, 2011.

Sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) amended section 410A of Pub. L. 108–173, changing the rural community hospital demonstration program in several ways. First, the Secretary is required to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. Further, the Affordable Care Act requires, in the case of a rural community hospital that is participating in the demonstration program as of the last day of the initial 5-year period, the Secretary to provide for the continued participation of such rural hospital in the demonstration program during the 5-year extension period, unless the hospital makes an election to discontinue participation.

In addition, the Affordable Care Act provides that, during the 5-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary to 20. Further, the Secretary is required to use the same criteria and data that the Secretary used to determine the States for purposes of the initial 5-year period. The Affordable Care Act also allows not more than 30

rural community hospitals in such States to participate in the demonstration program during the 5-year extension period.

We published a solicitation for applications for additional participants in the rural community hospital demonstration program in the **Federal Register** on August 30, 2010 (75 FR 52960). Applications were due on October 14, 2010. The 20 States with the lowest population density that were eligible for the demonstration program are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). We approved 19 new hospitals for participation in the demonstration program. We determined that each of these new hospitals would begin participating in the demonstration with its first cost reporting period beginning on or after April 1, 2011.

Three of these 19 hospitals declined participation prior to the start of the cost reporting periods for which they would have begun the demonstration. In addition to the 7 hospitals that were selected in either 2004 or 2008, the new selection led to a total of 23 hospitals in the demonstration. During CY 2013, one additional hospital among the set selected in 2011 withdrew from the demonstration, similarly citing a relative financial advantage to returning to the customary SCH payment methodology, which left 22 hospitals participating in the demonstration, effective July 1, 2013. In October 2015, another hospital among those selected in 2011 closed, leaving 14 among this cohort still participating. (By this date, as described below, the 7 hospitals that were selected in either 2004 or 2008 had completed the 5-year extension period mandated by the Affordable Care Act.)

Section 410A(c)(2) of Public Law 108–173 required that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral in its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. Typically, this form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration program may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration program's participants. These reduced expenditures offset increased payments elsewhere under the demonstration program, thus ensuring that the demonstration program as a whole is budget neutral or yields savings. However, the small scale of this demonstration program, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration program could be viable under the usual form of budget neutrality.

Specifically, cost-based payments to participating small rural hospitals are likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration program is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these same hospitals. In the past 12 IPPS final rules, spanning the period for which the demonstration program has been implemented, we have adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. As we discussed in the FYs 2005 through 2016 IPPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145, and 80 FR 49585, respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

2. Budget Neutrality Offset Adjustments: Fiscal Years 2005 Through 2016

a. Fiscal Years 2005 Through 2013

In general terms, in each of these previous years from FYs 2005 through 2016, we used available cost reports for the participating hospitals to derive an estimate of the additional costs attributable for the demonstration. For FYs 2005 through 2012, we used finalized, or settled, cost reports, as available, and ''as submitted'' cost reports for hospitals for which finalized cost reports were not available to derive this estimate of the additional costs attributable to the demonstration. Annual market basket percentage increase amounts provided by the CMS Office of the Actuary reflecting the growth in the prices of inputs for inpatient hospitals were applied to cost amounts obtained from these cost reports. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53452), we initiated two general changes to the methodology for estimating the costs of the demonstration (which we have continued to apply through FY 2016). First, we used ''as submitted'' cost reports for each hospital participating in the demonstration in estimating the costs of the demonstration (for FY 2013, we used cost reports for cost reporting periods ending in CY 2010). Second, in FY 2013, we incorporated different update factors (the market basket percentage increase and the applicable percentage increase, as applicable, to several years of data as opposed to solely using the market basket percentage increase) for the calculation of the budget neutrality offset amount. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453) for a detailed discussion of the methodology initiated in FY 2013.

In each of these fiscal years, an annual update factor provided by the CMS Office of the Actuary reflecting growth in the volume of inpatient operating services was also applied to update the estimated costs. For the budget neutrality calculations in the IPPS final rules for FYs 2005 through 2011, the annual volume adjustment applied was 2 percent; for the IPPS final rules for FYs 2012 through 2016, it was 3 percent. For a detailed discussion of our budget neutrality offset calculations, we refer readers to the IPPS final rule applicable to the fiscal year involved.

In general, for FYs 2005 through 2013, we based the budget neutrality offset estimate on the estimated cost of the demonstration in an earlier given year. For these periods, we derived that estimated cost by subtracting the estimated amount that would otherwise be paid without the demonstration in an earlier given year from the estimated amount for the same year that would be paid under the demonstration under the reasonable cost-based methodology authorized by section 410A of Public Law 108–173. (We ascertained the estimated amount that would be paid in an earlier given year under the reasonable cost methodology and the estimated amount that would otherwise be paid without the demonstration in an

earlier given year from finalized or ''as submitted'' cost reports as discussed earlier.) For FYs 2005 through 2012, we then updated the estimated costs described earlier to the upcoming year by multiplying them by the market basket percentage increases applicable to the years involved and the applicable annual volume adjustment. Beginning in FY 2013, as discussed earlier, we began incorporating different update factors—we used the IPPS market basket percentage increases applicable to the years involved to update the estimated amount that would be paid under the demonstration under the reasonable cost-based methodology, and the applicable percentage increases applicable to the years involved to update the amounts that would otherwise be paid without the demonstration. We continued to apply the annual volume adjustment as discussed earlier.

For the FY 2010 IPPS/RY 2010 LTCH PPS final rule, data from finalized cost reports reflecting the participating hospitals' experience under the demonstration were available. Specifically, the finalized cost reports for the first 2 years of the demonstration, that is, cost reports for cost reporting years beginning in FYs 2005 and 2006 (CYs 2004, 2005, and 2006) were available. These data showed that the actual costs of the demonstration for these years exceeded the amounts originally estimated in the respective final rules for the budget neutrality adjustment. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we included an additional amount in the budget neutrality offset amount in that fiscal year. This additional amount was based on the amount that the costs of the demonstration for FYs 2005 and 2006 exceeded the budget neutrality offset amounts finalized in the IPPS rules applicable for those years.

In the final rules for FYs 2011 through 2013, we continued to use a methodology for calculating the budget neutrality offset amount consisting of two components: (1) The estimated demonstration costs in the upcoming fiscal year; and (2) the amount by which the actual demonstration costs corresponding to an earlier, given year (which would be known once finalized cost reports became available for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. However, we noted in the FYs 2011, 2012, and 2013 IPPS final rules that, because of a delay affecting the settlement process for cost reports for IPPS hospitals occurring on a larger scale than merely for the demonstration, we were unable to finalize this component of the budget neutrality offset amount accounting for the amount by which the actual demonstration costs in an earlier given year exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule for cost reports of demonstration hospitals dating to those beginning in FY 2007.

b. Fiscal Years 2014 and 2015

In the final rules for FYs 2014 and 2015, we continued to apply the general methodology discussed earlier (with the modifications initiated in FY 2013) in estimating the costs of the demonstration for the specific fiscal year, using the set of ''as submitted'' cost reports from the most recent calendar year for which they are available (cost reporting periods ending in 2011 and 2012, respectively), and updating the cost amounts according to the factors discussed earlier. In addition, in these final rules, because finalized cost reports for FYs 2007 and 2008 had become available, we were able to include in the budget neutrality offset adjustment the amount by which the actual demonstration costs in each of those years exceeded the budget neutrality offset amounts finalized in the IPPS final rules for these years.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50742 through 50744), we determined the final budget neutrality offset amount to be applied to the FY 2014 IPPS rates to be $52,589,741. This amount was comprised of the two distinct components identified earlier: (1) The final resulting difference between the total estimated FY 2014 reasonable cost amount to be paid under the demonstration to the 22 participating hospitals for covered inpatient hospital services, and the total estimated amount that would otherwise be paid to such hospitals without the demonstration (this amount was $46,549,861); and (2) the amount by which the actual costs for the demonstration for FY 2007 (as shown in the finalized cost reports for cost reporting periods beginning in FY 2007 for the nine hospitals that participated in the demonstration during FY 2007) exceeded the budget neutrality offset amount that was finalized in the FY 2007 IPPS final rule (this amount was $6,039,880).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50141 through 50145), we determined the final budget neutrality offset amount to be applied to the FY 2015 IPPS rates to be $64,566,915. This amount was also comprised of the two earlier referenced components: (1) The final resulting difference between the total estimated FY 2015 reasonable cost amount to be paid under the demonstration to the 22 participating hospitals for covered inpatient hospital services, and the total estimated amount that would otherwise be paid to such hospitals in FY 2015 without the demonstration (this amount was $54,177,144); and (2) the amount by which the actual costs of the demonstration for FY 2008 (as shown in the finalized cost reports for the hospitals that participated in the demonstration during FY 2008) exceeded the budget neutrality offset amount that was finalized in the FY 2008 IPPS final rule (this amount was $10,389,771).

c. Fiscal Year 2016

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49586 through 49591), we continued to apply the general methodology discussed earlier for FYs 2014 and 2015 in estimating the costs of the demonstration for FY 2016, with some modifications. For FY 2016, we used the set of ''as submitted'' cost reports from the most recent calendar year for which they were available (cost reporting periods ending in CY 2013), and updated the cost amounts using the IPPS market basket percentage increase and applicable percentage increase applicable to the years involved as discussed earlier. Although the methodology for FY 2016 was similar to that for the previous several rules, because the demonstration began to phase out prior to the beginning of FY 2016, appropriate changes to the calculations were made. The 7 ''originally participating hospitals,'' that is, those hospitals that were selected for the demonstration in either 2005 or 2008, were scheduled to end their participation in the 5-year extension period authorized by the Affordable Care Act prior to the start of FY 2016. Therefore, we did not include the financial experience of these hospitals in the calculation of either the estimated reasonable cost amount or the estimated amount that otherwise would be paid without the demonstration for FY 2016. In addition, 8 hospitals that entered the demonstration in 2011 and 2012 through the solicitation that followed the Affordable Care Act amendments expanding the demonstration, and that were still participating in the demonstration at the time of the FY 2016 IPPS/LTCH PPS final rule, were scheduled to end their participation on a rolling basis before September 30, 2016. As discussed in the FY 2016 IPPS/LTCH PPS final rule, for these 8 hospitals, the estimated reasonable cost amount and the estimated amount that

would otherwise be paid without the demonstration were prorated according to the ratio of the number of months between October 1, 2015, and the end of the hospital's cost reporting period in relation to the entire 12-month period. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49586 through 49588) for a discussion of these additional calculations.

The resulting estimate of costs of the demonstration for FY 2016 for the 15 hospitals participating in the demonstration for FY 2016 was $26,044,620.

In addition, in the FY 2016 IPPS/LTCH PPS final rule, we were able to finalize the amounts by which the actual demonstration costs for FYs 2009 and 2010 differed from the budget neutrality offset amount finalized in the corresponding final rules for these years using the approach described below.

We identified the difference between the actual cost of the demonstration for FY 2009 as indicated in the finalized cost reports for hospitals that participated in FY 2009 and that had cost reporting periods beginning in FY 2009 (this amount was $14,332,936), and the budget neutrality offset amount that was identified in the FY 2009 IPPS final rule (73 FR 48671) (this amount was $22,790,388). Analysis of this set of cost reports showed that the budget neutrality offset amount that was finalized to account for the demonstration costs in FY 2009 (as set forth in the FY 2009 IPPS final rule) exceeded the actual cost of the demonstration for FY 2009 by $8,457,452.

We included the amount by which the actual costs of the demonstration for FY 2010 (as shown in the finalized cost reports for the nine hospitals that completed a cost reporting period beginning in FY 2010) ($16,817,922) differed from the amount that was finalized as the costs of the demonstration for FY 2010 as set forth in the FY 2010 IPPS/RY 2010 LTCH PPS final rule and the FY 2011 IPPS/LTCH PPS final rule ($21,569,472). Analysis of this set of cost reports showed that the budget neutrality offset amount that was finalized to account for the demonstration costs in FY 2010 (as set forth in the FY 2010 IPPS/RY 2010 LTCH PPS final rule and the FY 2011 IPPS/LTCH PPS final rule) exceeded the actual cost of the demonstration for FY 2010 by $4,751,550.

Unlike in previous years, because the budget neutrality offset amount identified in the corresponding final rules for each of FYs 2009 and 2010 exceeded the actual costs of the demonstration, we subtracted the differences between these amounts for each fiscal year (that is, $8,457,452 applicable to FY 2009 and $4,751,550 applicable to FY 2010) from the estimated amount of the costs of the demonstration for FY 2016 (that is, $26,044,620). Thus, the final budget neutrality offset amount for which the adjustment to the national IPPS rates was calculated was $12,835,618.

3. Budget Neutrality Methodology for FY 2017 and Reconciliation for FYs 2011 Through 2016

As described earlier, we have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports have become available, we have determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. We note that we have calculated this difference between the actual costs of the demonstration for FYs 2005 through 2010, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

a. Budget Neutrality Methodology for FY 2017

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25130), we proposed a different methodology as compared to previous years for analyzing the costs attributable to the demonstration for FY 2017. We noted that the demonstration will have substantially phased out by the beginning of FY 2017. The 7 ''originally participating hospitals,'' that is, those that were selected for the demonstration in 2004 and 2008, ended their participation in the 5-year extension period authorized by the Affordable Care Act prior to the start of FY 2016. In addition, we stated in the proposed rule that the participation period for the 14 hospitals that entered the demonstration following the mandate of the Affordable Care Act and that were still participating was to end on a rolling basis according to the end dates of the hospitals' cost report periods, respectively, from April 30, 2016 through December 31, 2016. (As noted earlier, 1 hospital among this cohort closed in October 2015.) Of these 14 hospitals, 10 will end participation on or before September 30, 2016, leaving 4 hospitals participating for the last 3 months of CY 2016 (that is, the first 3 months of FY 2017). As discussed in the proposed rule, we believe that, given the small number of participating hospitals and the limited time of participation for such hospitals during FY 2017, a revised methodology is appropriate for determining the costs of the demonstration during this period as discussed below.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25130), we noted that estimating the costs of the demonstration for these 4 hospitals for their extent of participation in the demonstration in FY 2017 would entail a prorating calculation if we followed the methodology we used for FY 2016 as described earlier, as well as application of update factors to project increases in cost. We further noted that, for the 4 hospitals that will end their participation in the demonstration effective December 31, 2016, the financial experience of the last 3 months of the calendar year (that is, the first 3 months of FY 2017) will be included in the finalized cost reports for FY 2016. (Consistent with the methodology used for the final rules for previous years, a hospital's cost report is included in the analysis of a given fiscal year if the cost reporting period begins in that fiscal year.) We believe that examining the finalized cost reports for FY 2016 for these hospitals would lead to a more

accurate and administratively feasible calculation of budget neutrality for the demonstration in FY 2017 than conducting an estimate of the costs of the demonstration for this 3-month period based on ''as submitted cost reports'' (as would occur according to the budget neutrality methodology currently in effect).

In addition, as we stated in the proposed rule, given that the extent of covered services for FY 2017 subject to the payment methodology under the demonstration is a small fraction of that in previous fiscal years, we believe that it is appropriate to forego the process of estimating the costs attributable to the demonstration for FY 2017 and to instead analyze the set of finalized cost reports for cost reporting periods beginning in FY 2016, which will reflect the actual cost of the demonstration, when they become available. Such an approach also would eliminate the need to perform for FY 2017 the second component of the budget neutrality methodology discussed earlier (that is, determining the amount by which the actual costs of the demonstration for the fiscal year, as determined in finalized cost reports once available, differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year). Thus, for the reasons discussed earlier, we proposed to calculate the costs of the demonstration and the resulting budget neutrality adjustment factor for the demonstration for FY 2017 once the finalized cost reports for cost reporting periods beginning in FY 2016 become available. We invited public comments on this proposal.

We did not receive any public comments on this proposal. Therefore, in this final rule, we are finalizing, without modification, our proposal as described above to forego the process of estimating the costs attributable to the demonstration for FY 2017, and to instead calculate the actual costs of the demonstration and any resulting budget neutrality adjustment factor for FY 2017 once the finalized cost reports for cost reporting periods beginning in FY 2016 become available.

b. Budget Neutrality Offset Reconciliation for FYs 2011 Through 2016

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49591), we stated that we intended to discuss in the FY 2017 IPPS/LTCH PPS proposed rule how we would reconcile the budget neutrality offset amounts identified in the IPPS final rules for FYs 2011 through 2016 with the actual costs of the demonstration for those years, considering the fact that the demonstration will end December 31, 2016. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25130), we stated that we believe it would be appropriate to conduct this analysis for FYs 2011 through 2016 at one time, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available. Such an aggregate analysis encompassing the cost experience through the end of the period of performance of the demonstration represents an administratively streamlined method, allowing for the determination of any appropriate adjustment to the IPPS rates and obviating the need for multiple fiscal-year-specific calculations and regulatory actions. Given the general lag of 3 years in finalizing cost reports, we expect any such analysis to be conducted in FY 2020.

We did not receive any public comments on this proposal. Therefore, in this final rule, we are finalizing our proposal, without modification, to reconcile, at one time, the budget neutrality offset amounts identified in the IPPS final rules for FYs 2011 through 2016 with the actual costs of the demonstration for those years, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available.

As discussed in the proposed rule, we also note that, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49591), we indicated that we were considering whether to propose in future rulemaking that the calculation of the final costs of the demonstration for a fiscal year reflect that some of the participating hospitals would otherwise have been eligible for the payment adjustment for low-volume hospitals in that fiscal year if they had not participated in the demonstration. Our policy under the demonstration is that hospitals participating in the demonstration are not able to receive the low-volume adjustment in addition to the reasonable cost-based payment authorized by section 410A of Public Law 108–173. We refer readers to Change Request 7505 dated July 22, 2011, available on the CMS Web site at: *http://www.cms.gov*. Section 1886(d)(12) of the Act provides for a payment adjustment to account for the higher costs per discharge for low-volume hospitals under the IPPS, effective FY 2005 (69 FR 49099 through 49102). We note that sections 3125 and 10314 of the Affordable Care Act provided for temporary changes in the qualifying criteria and payment adjustment for low-volume hospitals for FYs 2011 and 2012, which have been extended through subsequent legislation: Through FY 2013, by the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) (78 FR 50610 through 50613), through March 31, 2014, by the Pathway for SGR Reform Act (Pub. L. 113–67) (79 FR 15022 through 15025); through March 21, 2015, by the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) (79 FR 49998 through 50001); and most recently through September 30, 2017, by section 204 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–110). These temporary changes have increased the number of hospitals that are eligible to receive the low-volume hospital payment adjustment.

We further stated in the FY 2016 IPPS/LTCH PPS final rule that taking the low-volume hospital payment adjustment into account in determining the costs of the demonstration would require detailed consideration of the data sources and methodology that would be used to determine which among the demonstration hospitals would have otherwise been eligible for the low-volume payment adjustment and to estimate the amount of the adjustment. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 24521), we invited public comments on this issue.

We stated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25131) that we are continuing to examine this issue and are considering whether to incorporate the low-volume payment adjustment amounts that would have otherwise been made into the calculation of the difference between the actual costs of the demonstration and budget neutrality offset amounts for FYs 2011 through 2016. We note that applying such a methodology may lower the calculated amounts of the actual costs of the demonstration compared to not applying such a methodology, making it more likely that the actual costs of the demonstration for a year will not exceed the estimated costs of the demonstration identified in the final rule for that year. We again invited public comments on this issue.

We did not receive any public comments on this issue. We will continue to examine this issue.

L. Hospital and CAH Notification Procedures for Outpatients Receiving Observation Services

1. Background

a. Statutory Authority

On August 6, 2015, the Notice of Observation Treatment and Implication for Care Eligibility Act (the NOTICE Act), Public Law 114–42 was enacted. Section 2 of the NOTICE Act amended

section 1866(a)(1) of the Act by adding new subparagraph (Y) that requires hospitals and critical access hospitals (CAHs) to provide written notification and an oral explanation of such notification to individuals receiving observation services as outpatients for more than 24 hours at such hospitals or CAHs. Section 1866(a)(1) of the Act lists requirements for providers of services to participate in the Medicare program and be eligible for payments under Medicare pursuant to provider agreements.

Section 1866(a)(1)(Y) of the Act, as added by section 2 of the NOTICE Act, specifies that the notification process must consist of a written notification as specified by the Secretary through rulemaking and containing such language as the Secretary prescribes consistent with the statutory provision, and an oral explanation of the written notification and documentation of the provision of the explanation, as the Secretary determines to be appropriate. Notification to each individual who receives observation services as an outpatient for more than 24 hours must be provided no later than 36 hours after observation services are initiated (or sooner, if upon release from the hospital or CAH). Section 1866(a)(1)(Y)(ii) of the Act provides that the written notice must explain that the individual is an outpatient receiving observation services, and is not an inpatient of a hospital or CAH. In addition, the written notice must include the reason(s) the individual is an outpatient receiving observation services and must explain the implications of being an outpatient receiving observation services, such as cost-sharing requirements and post-hospitalization eligibility for coverage of skilled nursing facility (SNF) services under Medicare. The written notification also must include any additional information as deemed appropriate by the Secretary. Moreover, the written notification must be signed by either the individual receiving observation services as an outpatient, or a person acting on the individual's behalf, to acknowledge receipt of the notification. In cases where a signature by the individual or the person acting on the individual's behalf is refused, section 1866(a)(1)(Y)(ii)(IV)(bb) of the Act stipulates that the notification be signed by the staff member of the hospital or CAH who presented the written notification and include the name and title of the staff member, a certification statement that the notification was presented, and the date and time that the notification was presented. Finally, section 1866(a)(1)(Y)(ii)(V) of the Act provides that the notification be written and formatted using plain language and is made available in appropriate languages as determined by the Secretary.

b. Effective Date

As discussed in the proposed rule (81 FR 25131), section 2 of the NOTICE ACT provides the effective date for this notification requirement as effective beginning 12 months after the date of enactment of the NOTICE Act; that is, effective on August 6, 2016. Since the date the NOTICE Act was enacted, CMS has been working to implement the statutory requirement in a timely manner. On December 14, 2015, CMS released an electronic mailbox address for individuals who wished to submit email comments on the provisions of the NOTICE Act. In addition, CMS held a listening session on December 21, 2015, to provide stakeholders further opportunity to provide comment on the NOTICE Act. We thank those individuals who shared their input. The agency reviewed all comments submitted, as well as those comments provided during the public listening session in developing the provisions of the proposed rule. This final rule is effective as specified in the ''Effective Date'' section of this final rule. The standardized notice, the MOON, is going through the PRA approval process and is subject to a 30-day public comment period that begins on the date of publication of this final rule. Following review of comments and final approval of the MOON under the PRA process, hospitals and CAHs must fully implement use of the MOON no later than 90 calendar days from the date of PRA approval of the MOON.

2. Implementation of the NOTICE Act Provisions

a. Notice Process

We proposed to implement section 1866(a)(1)(Y) of the Act by revising the requirements that providers agree to as part of participating in Medicare under a provider agreement, by establishing regulations (at proposed 42 CFR 489.20(y)) that would specify a process for hospitals and CAHs to notify an individual, orally and in writing, of the individual's receipt of observation services as an outpatient and the implications of receiving such services as set forth below. Under this proposed process, hospitals and CAHs would be required to furnish notice to such an individual entitled to Medicare benefits if the individual receives observation services as an outpatient for more than 24 hours. We proposed the use of a standardized notice, referred to as the Medicare Outpatient Observation Notice (MOON), to be used by all applicable hospitals and CAHs. The MOON would include all of the informational elements required by section 1866(a)(1)(Y)(ii) of the Act to fulfill the written notice requirement of the NOTICE Act.

Comment: One commenter stated the NOTICE Act and MOON will continue to increase the cost of care and suggested that CMS require hospitals and CAHs to provide the information required by the NOTICE Act to patients in a lower cost environment. The commenter recommended that patients receive the NOTICE Act required information when signing up for Medicare, or as part of an annual visit.

Response: We appreciate the commenter's recommendation and interest in providing the notice required by the NOTICE Act in a less costly setting. The NOTICE Act specifically requires hospitals and CAHs to deliver both a written notice and an oral explanation of the notice to individuals who receive observation services as an outpatient for more than 24 hours. The statute does not afford an alternative method of delivering the required notice, for example, during an annual wellness or other visit to a doctor, or to beneficiaries when signing up for Medicare. Consistent with the NOTICE Act, we believe that furnishing information related to being an outpatient receiving observation services when those services are furnished will have the most impact.

After consideration of the public comments we received, we are finalizing the notification process provisions of the proposed rule with respect to the method of delivery without modification.

b. Notification Recipients

Section 1866(a)(1)(Y) of the Act requires hospitals and CAHs to furnish notice to each individual who receives observation services as an outpatient at such hospital or CAH for more than 24 hours. Throughout section 1866 of the Act, ''individual'' generally refers to a person entitled to have payment made for services under Title XVIII of the Act, or a person not entitled to have payment made for services under Title XVIII if certain conditions are met. The provisions of the NOTICE Act specify that notice must be provided to individuals receiving observation services as an outpatient for more than 24 hours; the provisions do not specify qualifications related to payment for such services as a condition of notice. Accordingly, we proposed under the

new § 489.20(y) that the notification required by section 1866(a)(1)(Y) of the Act must be provided to individuals entitled to benefits under Title XVIII of the Act, whether or not the services furnished are payable under Title XVIII, when individuals receive observation services as an outpatient for more than 24 hours. For example, an individual receiving Medicare Part A benefits who has not enrolled in Medicare Part B would still receive notice even though the observation services received as an outpatient fall under the Part B benefit and would not be covered or payable by Medicare for that person.

A beneficiary enrolled in a Medicare Advantage (MA) or other Medicare health plan would receive the required notice under the existing rules that apply to hospitals and CAHs under a provider agreement governed by the provisions of section 1866(a)(1)(Y) of the Act. MA regulations related to selection and credentialing of contract providers at § 422.204(b)(3) require that, with respect to providers that meet the definition of ''provider of services'' as defined in section 1861(u) of the Act, basic benefits may only be provided by these providers if they have a provider agreement with CMS permitting them to provide services under original Medicare. Under section 1861(u) of the Act, the term ''provider of services'' means a hospital, CAH, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1814(g) and section 1835(e) of the Act, a fund.

Observation services are required to be provided under a physician's order that specifies the initiation of observation services. As a general matter, hospital observation services are defined in the Medicare Benefits Policy Manual (Pub. 100–02), Chapter 6, Section 20.6, as services that are medically reasonable and necessary, specifically ordered by a physician or other nonphysician practitioner authorized by State licensure law and hospital staff bylaws to admit patients to the hospital or to order outpatient services, and meet other published Medicare criteria for payment. The term ''physician'' encompasses these authorized qualified nonphysician practitioners for the purposes of our proposed and final policy regarding implementation of the NOTICE Act provisions in the proposed and final rules. Individuals receiving observation services must be registered as outpatients; however, not all outpatients receive observation services. ''Outpatient,'' as defined in the Medicare Claims Processing Manual (Pub. 100–04), Chapter 1, Section 50.3.1, means ''a person who has not been admitted as an inpatient but who is registered in the hospital or critical access hospital (CAH) records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH.'' We proposed that the provisions in the proposed rule would apply to the subset of individuals entitled to benefits under Title XVIII of the Act who are receiving treatment as outpatients and are receiving observation services for more than 24 hours. For outpatients who are not receiving observation services, or who are receiving observation services but not for more than 24 hours, hospitals and CAHs would not be required to deliver notice.

Comment: Many commenters suggested that CMS expand delivery of the MOON beyond Medicare beneficiaries who receive observation services as an outpatient at hospitals or CAHs for more than 24 hours. A few commenters requested clarification of who was required to receive a notice. In terms of expanding the delivery requirements, some commenters suggested that CMS require hospitals and CAHs to provide the MOON to all Medicare beneficiaries in outpatient status. Other commenters suggested that CMS require delivery of the MOON to any outpatient who has spent a night in the hospital, is in the hospital over 24 hours, and has not been admitted or had a long stay.

One commenter requested clarification about whether the NOTICE Act requires delivery of the MOON to a patient in extended outpatient recovery requiring an overnight stay, which the commenter explained were not observation services. Similarly, another commenter requested that CMS clarify that the NOTICE Act provisions do not apply to outpatients without an order for observation services.

Response: We appreciate all of the recommendations submitted by the commenters. The NOTICE Act explicitly states that hospitals and CAHs are required to furnish notice to an individual who receives observation services as an outpatient at such hospital or CAH for more than 24 hours, and we proposed to implement this provision (delivery of the MOON) requiring hospitals and CAHs to provide the required notice to just that population of notification recipients. We do not believe it would be appropriate to expand the population of notification recipients, as the statute expressly provides the scope of that population. Therefore, we do not require hospitals and CAHs to furnish the MOON to outpatients other than those who have received observation services as outpatients for more than 24 hours, as set forth in the statute. However, as we explain below, hospitals and CAHs may deliver the MOON to individuals receiving observation services as an outpatient before such individuals have received more than 24 hours of observation services, and be in compliance with the written delivery requirements set forth in the NOTICE Act.

Comment: One commenter noted that several States require that a notice similar to the MOON be delivered to a different population than that specified under the NOTICE Act; for example, some States require notice be furnished to all outpatients, regardless of whether they received observation services. The commenter stated it would be beneficial to allow hospitals and CAHs flexibility to deliver the MOON to a broader population of Medicare beneficiaries to minimize confusion among beneficiaries, administrative complexity for providers, and in recognition that the financial implications for beneficiaries start once services begin. The commenter recommended that CMS allow broader distribution of the MOON to include outpatients in general to accommodate both State and Federal laws. Several other commenters made similar recommendations.

Response: We appreciate the recommendations and acknowledge that, in some States, notice of outpatient status is required for all outpatients, regardless of the payer and irrespective of whether the patient has received observation services. We understand the commenters' interest in minimizing duplication of effort and information provided to a Medicare beneficiary who requires care in a hospital or CAH. However, the NOTICE Act specifically requires hospitals and CAHs to deliver notice (written and oral), as prescribed by the Secretary, to Medicare beneficiaries who receive observation services as an outpatient for more than 24 hours. The MOON satisfies the written NOTICE Act requirement for a designated population of Medicare beneficiaries receiving a specific set of services, as provided for at section 1866(a)(1)(Y) of the Act. In some cases, delivering the MOON may also fulfill State notice requirements for the Medicare population. Hospitals and CAHs will need to make that determination on a State-by-State basis. Where State law, in pertinent part, requires notification to Medicare beneficiaries who receive observation services as an outpatient for more than 24 hours and requires such notice to

contain content that is not included in the MOON, hospitals may utilize the free text field in the MOON's ''Additional Information'' section for communicating such additional content. Hospitals and CAHs will need to determine whether providing such additional information in this field of the MOON will satisfy State law requirements. Hospitals and CAHs subject to State law notice requirements may also attach an additional page to the MOON to supplement the ''Additional Information'' section in order to communicate additional content required under State law, or may attach the notice required under State law to the MOON. Nevertheless, we do not believe it would be appropriate to require hospitals and CAHs to deliver the MOON, or an amended version of the MOON, to patients who have not received observation services and who are not entitled to benefits under the Medicare program because the NOTICE Act was not aimed at some other, larger patient population. The MOON contains information specific to individuals entitled to receive benefits through Medicare that receive observation services in the hospital outpatient setting. Therefore, we are not accepting the commenters' recommendation.

Comment: One commenter asserted that proposed § 489.20(y) requiring hospitals and CAHs to deliver notice (the MOON) to individuals receiving observation services as an outpatient for more than 24 hours, even if the individual is subsequently admitted as an inpatient, violates the intent of the NOTICE Act. The commenter stated that requiring hospitals and CAHs to provide the MOON to an individual subsequently admitted as an inpatient is unduly burdensome, serves no purpose, and provides no informational benefit to beneficiaries or their families. Another commenter agreed with CMS' proposal to require hospitals and CAHs to deliver notice to individuals receiving observation services as an outpatient for more than 24 hours, even if the individual is subsequently admitted as an inpatient, because the time as an outpatient receiving observation services does not count toward the 3 consecutive day inpatient hospital stay requirement for coverage of post-hospital SNF care. However, the commenter stated that the MOON did not adequately explain the implications on cost-sharing and coverage of post-hospital SNF care in such a situation.

Response: We appreciate these comments. However, we disagree with the suggestion that providing the MOON to an individual who is subsequently admitted as an inpatient serves no purpose and provides no informational benefit to beneficiaries or their families. We agree with the commenter who asserted that it is important to provide the MOON to individuals who are subsequently admitted as an inpatient because the time the individual spent as an outpatient receiving observation services does not count toward the 3 consecutive day inpatient hospital stay requirement for coverage of post-hospital SNF care. While not all patients who are admitted ultimately receive post-hospital SNF care following discharge, the implications of receiving observation services on an outpatient basis for individuals who eventually receive such care can be significant, which is why information is required to be included in the notice to beneficiaries (that is, written notification that explains the implications of such status on subsequent eligibility for coverage for services furnished by a SNF, as specified in section 1866(a)(1)(Y)(ii)(II) of the Act). Moreover, we believe the NOTICE Act requires hospitals and CAHs to deliver notice to individuals who receive more than 24 hours of observation services, and are subsequently admitted as an inpatient.

We acknowledge that cost-sharing for an individual receiving observation services as an outpatient will change if the individual is subsequently admitted as an inpatient. Related outpatient services directly preceding an inpatient admission may fall under the payment window for outpatient services for which the costs are treated as costs of inpatient services (also known as the 3-day payment window), as discussed in the Medicare Claims Processing Manual (Pub. 100–4), Chapter 3, Section 40.3 and Chapter 4, Section 10.12. Outpatient services that fall under the 3-day payment window prior to an inpatient admission will be subject to Part A cost-sharing rules. We expect that this information will be communicated by hospital staff to the individual during the oral explanation of the notification. In addition, if an individual who receives more than 24 hours of observation services as an outpatient is admitted as an inpatient prior to the delivery of the MOON, in the ''Additional Information'' section of the MOON the hospital should explain that, as an inpatient, the individual may have Part A cost-sharing responsibilities. Therefore, we are not accepting the recommendations of the commenters suggesting that the hospitals and CAHs be able to forego the delivery of the MOON in cases where individuals receiving observation services as outpatients are later admitted as inpatients.

Comment: Several commenters noted that it will be difficult and/or unnecessary to provide the MOON to MA enrollees and requested that CMS consider eliminating the proposed requirement that MOON delivery include MA enrollees. According to one commenter, MA plans often deny an inpatient admission after the patient is discharged from the hospital and will only approve the stay as outpatient observation following the individual's discharge from the inpatient hospital stay. Another commenter believed it was unnecessary to include the managed Medicare population in the proposed requirement because this population is not affected by the same coverage guidelines as original Medicare beneficiaries, such as the requirement for a 3-day qualifying inpatient hospital stay for coverage of post-hospitalization SNF care. Commenters believed that providing the MOON to enrollees in MA plans will result in confusion if the information related to coverage and cost sharing is not applicable to an MA enrollee and that it adds an unnecessary burden on the hospital staff.

Response: We recognize that MA plans may have certain rules that differ from original Medicare and that these variances may result in some of the information in the MOON being inapplicable to some MA enrollees. For example, under an MA plan's benefit structure, the enrollee may not need to have a 3-day qualifying inpatient hospital stay in order to qualify for coverage of post-hospital SNF care. However, we do not believe it would be appropriate to exclude MA enrollees from the requirement that a hospital or CAH deliver the MOON to any beneficiary who receives observation services as an outpatient for more than 24 hours. In developing the MOON, we have attempted to mitigate the potential variation between original Medicare and MA by directing MA enrollees who receive the MOON to contact their plans for specific information that may be relevant to the receipt of outpatient observation services. As described in the proposed rule, the MOON must be delivered while the individual is in the hospital receiving outpatient observation services. Specifically, section 1866(a)(1)(Y) of the Act and under proposed new § 489.20(y), hospitals and CAHs must provide notice to an individual who receives observation services as an outpatient for more than 24 hours, and such notice must be furnished no later than 36 hours after observation services are

initiated, or sooner if the individual is transferred, discharged, or admitted as an inpatient. If, as described in the commenter's example, the individual is initially admitted to a hospital or CAH as an inpatient, the requirement to deliver the MOON does not apply (in cases where the individual receives outpatient observation services for fewer than 24 hours prior to the inpatient admission), notwithstanding any later determination by the MA plan (following the individual's discharge) related to the inpatient hospital admission. It is our expectation that a contracted hospital and the MA plan coordinate and communicate regarding the appropriate level of care while the enrollee is receiving care in the contracted hospital in accordance with the requirements at § 422.112 related to continuity of care and integration of services.

As noted in the preamble to the proposed rule, a beneficiary enrolled in a MA or other Medicare health plan would receive the required notice under the existing rules that apply to hospitals and CAHs under a provider agreement governed by the provisions of section 1866(a)(1)(Y) of the Act. The MA regulations related to selection and credentialing of contract providers at § 422.204(b)(3) require that, with respect to providers that meet the definition of ''provider of services'' as defined in section 1861(u) of the Act, basic benefits may only be provided by these providers if they have a provider agreement with CMS permitting them to provide services under original Medicare. Under section 1861(u) of the Act, the term ''provider of services'' means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1814(g) and section 1835(e) of the Act, a fund. Given the statutory language in section 1866 of the Act and the regulatory requirements in 42 CFR part 422 related to provider agreements, we do not agree with commenters, and do not believe it would be appropriate to exclude hospitals and CAHs from the NOTICE Act requirements with respect to MA enrollees. Therefore, hospitals and CAHs must furnish the MOON to MA enrollees who receive observation services as an outpatient for more than 24 hours as set forth in this final rule.

Comment: One commenter requested that CMS remove the requirement that hospitals and CAHs deliver the MOON to Medicare beneficiaries who are not enrolled in Medicare Part B. The commenter believed it would be inappropriate to provide information on the rules for insurance coverage to individuals who do not have that coverage.

Response: We appreciate the commenter's suggestion. However, one intent of the NOTICE Act is to inform beneficiaries of costs they might not otherwise be aware of relating to their classification as either an outpatient receiving observation services or an inpatient. A beneficiary who receives observation services as an outpatient (which are covered under Medicare Part B), who is enrolled in Medicare Part A, but does not have Part B coverage, may be unaware that he or she may be financially responsible for the full cost of the services he or she is receiving, due to lack of Part B coverage. We believe providing the MOON to beneficiaries who do not have Part B coverage will serve to inform such beneficiaries of the financial consequences consistent with the NOTICE Act. Therefore, we are not adopting the commenter's recommendation.

Comment: One commenter requested that CMS explain whether hospitals and CAHs must deliver the MOON when the primary payer is a commercial plan and the secondary payer is Medicare or MA.

Response: The provisions of the NOTICE Act amended section 1866 of the Act and apply to hospitals and CAHs furnishing services to individuals entitled to benefits under Title XVIII of the Act, whether or not the services are payable under Title XVIII. If an individual is entitled to benefits under Title XVIII (and receives observation services as an outpatient for more than 24 hours), the notice requirement applies, regardless of whether Medicare is the secondary payer. The applicability of the notice requirement depends on whether the individual is entitled to benefits under Title XVIII, not on whether Medicare makes payment (primary or otherwise).

After consideration of the public comments we received, we are finalizing the notification recipients provisions of the proposed rule without modification.

c. Timing of Notice Delivery

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25132), and as provided at section 1866(a)(1)(Y) of the Act, we proposed under proposed new § 489.20(y) that hospitals and CAHs must provide notice to an individual who receives observation services as an outpatient for more than 24 hours and that such notice must be furnished no later than 36 hours after observation services are initiated, or sooner if the individual is transferred, discharged, or admitted as an inpatient.

For purposes of our proposed and final policy regarding implementation of the NOTICE Act provisions in the FY 2017 IPPS/LTCH PPS proposed and final rules, consistent with existing billing rules, observation services are initiated when a physician orders such services. According to the Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 290.2.2, hospital reporting for observation services ''begins at the clock time documented in the patient's medical record, which coincides with the time that observation services are initiated in accordance with a physician's order.'' Because valid medical documentation for observation services will always contain the time when observation services are initiated, we believe hospitals and CAHs will be able to readily determine the timeframe within which the notice must be delivered. We expect that there will be cases where an individual receives more than 24 hours of observation services and has not yet received the MOON, but there are imminent plans for discharge to home or another facility, transfer to another unit or facility to receive care that does not include observation services, or admission to the hospital or another facility as an inpatient. In these cases, pursuant to section 1866(a)(1)(Y) of the Act, which provides that notice be provided not later than 36 hours after the time such an individual begins receiving such services (or, if sooner, upon release), we proposed that the MOON must be given sooner than the 36-hour time limit for delivery because the MOON must be delivered before the individual is discharged, transferred, or admitted. When there are no plans to transfer, discharge, or admit an individual who receives observation services for more than 24 hours, we proposed that the MOON must be provided within 36 hours of the initiation of observation services.

In rare circumstances where a physician initially orders inpatient services, but following internal utilization review (UR) performed while the patient is hospitalized, the hospital determines that the services do not meet its inpatient criteria and the physician concurs with UR and orders the discontinuation of inpatient services and initiation of outpatient observation services (that is, a Condition Code 44 situation), we stated in the proposed rule that the MOON would be delivered as required by the NOTICE Act (when outpatient observation services have been ordered and furnished for more than 24 hours). If observation services are ordered when Condition Code 44

applies, the 24-hour time period for observation notification commences at the same time that observation services are initiated under a physician's order, consistent with existing policy for observation services furnished to outpatients. (We refer readers to the Medicare Claims Processing Manual (Pub. 100–04), Chapter 1, Section 50.3.)

As discussed in the proposed rule and as stated in the notice announcing CMS Ruling CMS–1455–R (78 FR 16614), the Part B Inpatient Billing Ruling, in cases where reviewers find that an inpatient admission was not medically reasonable and necessary after the beneficiary is discharged, and thus, not appropriate for payment under Medicare Part A, the beneficiary's patient status remains ''inpatient'' as of the time of the inpatient admission. The patient's status is not changed to outpatient because the beneficiary was formally admitted as an inpatient, and there is no provision to change a beneficiary's status after he or she is discharged from the hospital. Where CMS denies a claim after the beneficiary has been discharged because the inpatient admission was not medically reasonable and necessary, there would be no need to issue the MOON because the individual's status remains inpatient, despite the fact that the inpatient admission was improper. Similarly, where a hospital determines through UR after a beneficiary is discharged that his or her inpatient admission was not reasonable and necessary and the hospital bills the services that were provided on a Medicare Part B claim, the NOTICE Act notification requirements would not apply for these individuals because their status would also remain inpatient.

Comment: Several commenters indicated that it would be difficult from an operational perspective to deliver the MOON within a narrow window of 12 hours following the beneficiary's receipt of more than 24 hours of observation services and the requirement that the notice be furnished within 36 hours of the initiation of observation services. Some commenters recommended the notice be furnished within 24 hours or 48 hours following the initiation of observation services as an outpatient. Other commenters indicated that if State regulations require notice of observation services as an outpatient be furnished to patients within 24 hours of the initiation of observation services as an outpatient, the State policy should be followed in order to provide the most protection possible to the consumer. Another commenter requested that CMS clarify whether there are consequences for having the MOON delivered and signed before 24 hours of observation services are furnished. The commenters urged CMS to use its regulatory discretion and create flexibility on the timing of delivery of the notice and to establish clear standards for consistent implementation across State lines.

One commenter opined that the statute provides latitude for CMS to permit an earlier delivery of the MOON to the Medicare beneficiary. The commenter explained that the NOTICE Act requires delivery of notice to outpatients who receive observation services for more than 24 hours, but does not preclude a hospital or CAH from voluntary delivery of the notice prior to an individual's receipt of 24 hours of observation services. The commenter further explained, given that some of the implications to be explained in the notice are present from the initiation of observation services, it may be beneficial for beneficiaries to receive the notice earlier. Earlier delivery of the notice, in the commenter's opinion, would provide flexibility for hospitals and CAHs in States with conflicting laws to satisfy both Federal and State requirements, while minimizing provider burden. The commenter recommended that CMS allow hospitals and CAHs to provide the MOON to a patient prior to furnishing 24 hours of observation services, but no later than 36 hours following the initiation of observation services. Several other commenters made a similar recommendation.

Response: We appreciate the many comments submitted on the issue of the timing of delivery of notice under the NOTICE Act. Section 1866(a)(1) of the Act, as amended by the NOTICE Act, requires hospitals and CAHs to deliver notice, consisting of a written notice (as specified by the Secretary of HHS following promulgation of rules) and an oral explanation of the notice, to each individual who receives observation services as an outpatient for more than 24 hours. Under the statute, the notice and explanation must be delivered no later than 36 hours after the time such individual begins receiving observation services (or, if sooner, upon release). We specified in proposed § 489.20(y) that the notification required by section 1866(a)(1)(Y) of the Act must be provided to individuals entitled to benefits under Title XVIII of the Act, whether or not the services furnished are payable under Title XVIII, when individuals receive observation services as an outpatient for more than 24 hours. As we stated in the proposed rule, for outpatients who are receiving observation services but not for more than 24 hours, hospitals and CAHs would not be required to deliver notice (81 FR 25132).

We agree with the commenter who suggested that the statute provides latitude to permit a hospital or CAH to voluntarily deliver notice prior to an individual's receipt of more than 24 hours of observation services as an outpatient. The NOTICE Act requires notice to individuals receiving more than 24 hours of observation services as an outpatient. While hospitals are not required to deliver notice to an individual who has not received more than 24 hours of observation services as an outpatient, nothing in the statute precludes hospitals and CAHs from delivering notice before an individual has received more than 24 hours of observation services as an outpatient, provided the information contained in the notice is accurate. Hospitals and CAHs that are subject to State laws requiring written notice to outpatients receiving observation services within 24 hours of the initiation of services, for example, may deliver the MOON to those individuals it believes will trigger the required notice under the NOTICE Act during the State-mandated timeframes and still be in compliance with the timing of notice delivery requirement of the NOTICE Act (provided the MOON is delivered not later than 36 hours after the time such individual begins receiving outpatient observation services, or, if sooner, upon release (that is, sooner, if transferred, discharged, or admitted as an inpatient)). Accordingly, we are revising proposed § 489.20(y) to clarify that hospitals and CAHs may deliver the MOON before an individual has received more than 24 hours of observation services as an outpatient.

However, we reiterate that the notice required by the NOTICE Act must be delivered within the timeframe established in statute; that is, no later than 36 hours after the time an individual begins receiving observation services as an outpatient, or if sooner, upon release. As specified in proposed § 489.20(y), the notice must be provided to the individual not later than 36 hours after observation services are initiated or sooner if the individual is transferred, discharged, or admitted. Delivering notice after this timeframe (for example, within 48 hours of the initiation of observation services, as suggested by one commenter) would not comply with the NOTICE Act requirement for timing of notice delivery. Therefore, we are not accepting the commenters' recommendations to allow hospitals and CAHs to deliver the notice as required by the NOTICE Act later than 36 hours after the individual entitled to notice

begins receiving observation services as an outpatient.

While, as previously stated, nothing in the statute precludes hospitals and CAHs from delivering notice before an individual has received more than 24 hours of observation services as an outpatient, provided the information contained in the notice is accurate, we note that we do not encourage hospitals and CAHs to deliver the MOON at the initiation of outpatient observation services. Routine and systematic delivery of the MOON by a hospital or CAH at the initiation of observation services would, in effect, render the MOON a notice of receiving outpatient observation services, as all patients receiving observation services would be given the MOON independent of the length of time they received observation services. In addition, at the initiation of outpatient observation services, patients may be completely preoccupied with concern for their safety and well-being, as they may be unsure of their diagnosis at a time when the signs and symptoms of their presenting condition(s) may be at the height of their clinical acuity. At the initiation of outpatient observation services, patients also may be overwhelmed and confused by notices and hospital paperwork that are presented at the time, often simultaneously. For these reasons, we reiterate that the NOTICE Act requires notice be provided to individuals who receive observations services as an outpatient for more than 24 hours, not later than 36 hours after the time the individual begins receiving such services, or, if sooner, upon release, but that the statute does not preclude earlier delivery, and that we encourage hospitals and CAHs to not deliver the MOON at the initiation of outpatient observation services.

Comment: Several commenters requested that CMS clarify when the 24 hour timeframe for receiving observation services as an outpatient begins. The commenters requested clarification as to whether the timeframe starts: (1) After services begin following the written order for observation services; (2) when related services commence if such services commence before the written order was executed and the patient occupies an outpatient bed count; or (3) based on the documentation of when nursing care began. Several commenters requested that CMS clarify, in situations where a resident orders observation services, whether the commencement of the 24-hour period for determining eligibility for the MOON begins when the resident writes the order or when the attending physician ''confirms'' that order.

Response: We appreciate the commenters' request for clarification regarding the time at which outpatient observation services are initiated for the purpose of determining when more than 24 hours of outpatient observation services have been received. In the proposed rule, we stated, ''For purposes of this proposed rule, consistent with existing billing rules, observation services are initiated when a physician orders such services'' (81 FR 25132). We then explained our existing billing rules contained in the CMS Internet Only Manual (IOM). ''According to the Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 290.2.2, hospital reporting for observation services 'begins at the clock time documented in the patient's medical record, which coincides with the time that observation services are initiated in accordance with a physician's order.' ''

As the commenters noted, there may be times when an individual is subject to an order for observation services, but is not actually receiving observation services. For example, following an order for observation services in an emergency department, a hospital may need to wait to begin furnishing observation services until a bed is available for the patient. In this situation, services are considered initiated when observation services commence.

In this final rule, we are clarifying our explanation in the preamble of the proposed rule that the start of observation services, for the purposes of determining when more than 24 hours of observation services have been received, is the clock time as documented in the patient's medical record at which observation services are initiated (furnished to the patient) in accordance with a physician's order.

With respect to the request for clarification of the effect of a resident's order for services on the counting of hours of observation care, we stated the following in our proposed rule that ''hospital observation services are defined in the Medicare Benefits Policy Manual (Pub. 100–02), Chapter 6, Section 20.6, as services that are medically reasonable and necessary, specifically ordered by a physician or other nonphysician practitioner authorized by State licensure law and hospital staff bylaws to admit patients to the hospital or to order outpatient services, and meet other published Medicare criteria for payment. The term 'physician' will encompass these authorized qualified nonphysician practitioners for the purposes of this proposed rule'' (81 FR 25132). Therefore, to the extent that a resident is authorized by State licensure law and hospital staff bylaws to order outpatient services, once observation services are initiated in accordance with the resident's order, the 24 hour time period will commence.

Comment: One commenter stated that, for the purpose of determining when a hospital or CAH must notify a patient under the NOTICE Act, that is, when an individual receives observation services as an outpatient for more than 24 hours, the counting of hours to trigger the notification requirement could be interpreted as elapsed or clock time (meaning starting the 24-hour clock at the time of the physician's order for observation services as an outpatient and ending with the discharge order from observation), or billable time (meaning tracking and counting only those hours which would be billable as outpatient observation services upon claim submission). The commenter recommended that CMS require hospitals and CAHs to use billable time when counting the hours of observation services received for the purpose of triggering the notification requirement. Another commenter recommended that CMS use elapsed time and not billable observation hours to determine when an individual has received 24 hours of observation services.

Response: We appreciate the comments and recommendations submitted on this issue. The NOTICE Act requires hospitals and CAHs to deliver notice to an individual who receives observation services as an outpatient for more than 24 hours, and requires delivery of the notice no later than 36 hours after the time such individual begins receiving observation services (or, if sooner, upon release). We believe using elapsed time rather than billed time is more consistent with the plain language of the statute for the purpose of determining when an individual is required to receive notice and when such notice must be delivered. Therefore, for purposes of identifying the 24-hour timeframe for which an individual has received observation services, and thus is required by the NOTICE Act to receive notice by the hospital or CAH, observation time will be measured as the elapsed time in hours beginning at the clock time documented in the patient's medical record, which coincides with the time that observation care is initiated in accordance with a physician's order. For example, an individual for whom observation services are initiated, in accordance with a physician order at 3:19 p.m. on Monday would meet the more than 24-

hour threshold to require delivery of notice, after 3:19 p.m. the following day (Tuesday), and delivery of the notice would be required by 3:19 a.m. on the subsequent day (Wednesday), or sooner, if the individual is discharged, transferred, or admitted.

Comment: One commenter requested that CMS clarify when the 24-hour time period ends for the purposes of determining whether a patient has received more than 24 hours of observation services as an outpatient, when the physician orders the discharge of the patient or when the patient leaves the building.

Response: Observation time ends when all medically necessary observation services are completed. To be clear, this could be before discharge when the need for observation services has ended, but other medically necessary services not meeting the definition of hospital observation services are provided (in which case, the additional medically necessary services received after the completion of observation services would be billed separately or be included as part of the emergency department or clinic visit). Alternatively, the end time of observation services may coincide with the time the patient is actually discharged from the hospital or admitted as an inpatient.

Comment: One commenter requested CMS to clarify how the MOON will work with the 2-midnight policy.

Response: The NOTICE Act requirements regarding delivery of notice to an individual who receives observation services as an outpatient for more than 24 hours, and no later than 36 hours after the time such individual begins receiving observation services (or, if sooner, upon release), do not impact or change the current requirements and guidance related to the 2-midnight policy previously issued by CMS. Hospitals will be required to adhere to all existing requirements of the 2-midnight policy, as well as adhere to the requirements set forth by the NOTICE Act. We remind commenters that the 2-midnight policy has been put forth by CMS to give hospitals and physicians guidance as to when an inpatient admission is eligible for Part A payment. The NOTICE Act requires hospitals to inform patients who have remained outpatients of the hospital and received observation services for more than 24 hours that they are not hospital inpatients and are subject to potentially different cost-sharing requirements and postacute care benefits than someone who has been admitted as an inpatient. We note that a scenario could arise whereby a patient is admitted to the hospital immediately after being a hospital outpatient receiving observation services for greater than 24 hours. In such a scenario, the inpatient admission may be payable under Medicare Part A under the 2-midnight policy and, as stated earlier, the hospital or CAH would still be required to furnish the MOON to the patient within 36 hours after the time the individual begins receiving observation services.

Comment: One commenter recommended that CMS require delivery of notice before the initiation of observation services, similar to the Advance Beneficiary Notice of Noncoverage (ABN), so that a patient can decide prior to incurring financial liability whether to receive the services or leave the hospital. The commenter believed that if the hospital does not notify the patient in advance of the initiation of observation services, the patient should be relieved of financial liability.

Response: We appreciate the recommendations of the commenter. However, the NOTICE Act established a requirement for notice specifically to an individual who receives observation services as an outpatient for more than 24 hours. We are not adopting the commenter's recommendation.

Comment: One commenter indicated that CMS significantly misstated when and how observation status is used. The commenter stated that use of Condition Code 44 is not rare and despite the 2-midnight policy, patients who remain in the hospital for multiple days often are coded as outpatients.

Response: As we have previously stated in Chapter 1, Section 50.3 of the Medicare Claims Processing Manual, CMS set the policy for the use of Condition Code 44 to address those relatively infrequent occasions, such as a late-night weekend admission when no case manager is on duty to offer guidance, when internal review subsequently determines that an inpatient admission does not meet hospital criteria and that the patient would have been registered as an outpatient under ordinary circumstances. Use of Condition Code 44 is not intended to serve as a substitute for adequate staffing of utilization management personnel or for continued education of physicians and hospital staff about each hospital's existing policies and admission protocols. As education and staffing efforts continue to progress, the need for hospitals to correct inappropriate admissions and to report Condition Code 44 should become increasingly rare.

After consideration of the public comments we received, we are finalizing the provisions of the proposed rule for timing of notice delivery with modifications as noted above.

d. Requirements for Written Notice

In the proposed rule (81 FR 25133), we proposed to implement section 1866(a)(1)(Y)(ii) of the Act, the requirement for written notification, under proposed new § 489.20(y)(1) by proposing the basic requirements for the written notice that hospitals and CAHs must use to notify individuals receiving outpatient observation services. Specifically, we proposed that hospitals and CAHs would be required to use a proposed standardized notice (the MOON) for written notification to an individual who receives observation services as an outpatient under the appropriate circumstances. By requiring use of a standardized notice, hospitals and CAHs would be assured that they are providing all of the statutorily required elements in a manner that is understandable to individuals receiving the notice. As provided at section 1866(a)(1)(Y)(ii)(I) of the Act, we proposed at § 489.20(y)(1)(i) that the MOON would explain to individuals that they are outpatients receiving observation services and not inpatients of the hospital or CAH, and the reason(s) for such status as an outpatient receiving observation services. By definition (as specified in the Medicare Benefits Policy Manual (Pub. 100–02), Chapter 6, Section 20.6), the reason for ordering observation services will always be the result of a physician's decision that the individual does not currently require inpatient services and observation services are needed for the physician to make a decision regarding whether the individual needs further treatment as a hospital inpatient or if the individual is able to be discharged from the hospital. We proposed at § 489.20(y)(1)(ii) that the proposed MOON also would provide an explanation of the implications of receiving observation services furnished by a hospital or CAH as an outpatient, including services furnished on an inpatient basis, such as those related to cost-sharing requirements for the patient under Medicare, and post-hospitalization eligibility for Medicare-covered SNF care, in standardized language to ensure that all Medicare eligible individuals receive accurate information. We proposed the inclusion of a blank ''Additional Information'' section on the MOON so that hospitals and CAHs may include additional information. Finally, as required by section 1866(a)(1)(Y)(ii)(V) of the Act,

the proposed MOON would include this information in plain language written for beneficiary comprehension.

Comment: Numerous commenters submitted comments regarding the general formatting and readability of the MOON. Several commenters expressed concern that the MOON was too complex for patients to have a full understanding of the issues included in the notice and the implications of being an outpatient receiving observation services. Some commenters did not consider the MOON to be written in ''plain language.'' Some commenters suggested the reading level of the MOON was too advanced for the typical beneficiary. Another commenter noted that the MOON is written at a 12.1 grade level and cited a study that claims that the average American's reading level proficiency is generally to be considered to be 5th to 7th grade level. Some commenters made suggestions on how the MOON could be reordered and simplified to improve understandability and effectiveness. Commenters also believed there were duplicative time and date fields as well as unnecessary fields for physician and hospital names when that information can be found in the beneficiary's medical record, or can be otherwise printed on the top of the notice, in the case of the hospital name. One commenter requested that the MOON have more room for the beneficiary's name and date of birth, while another commenter requested that the MOON be limited to one page. Another commenter provided copies of State-issued observation notices as examples that CMS may wish to consider during this notice development process. Other commenters suggested specific language for revising the notice. One commenter proposed incorporating a question and answer format on the MOON. Some commenters were concerned with which physician (admitting or attending) name should be included on the MOON. Other commenters did not want a requirement to include a physician name on the notice, as many physicians at a hospital can be involved with a beneficiary's outpatient care.

Response: We agree with the commenters that some fields are unnecessary when the information is contained in the patient's medical record. To that end, we have reduced the number of fillable fields on the MOON. Specifically, the fields for physician name and the date and time observation services began are no longer on the notice. In addition, we removed the field for the hospital name. Consistent with requirements for current beneficiary notices, and as will be detailed in future guidance, hospitals will be permitted to preprint the MOON to include their hospital name and logo at the top of the notice.

In response to the suggestion to condense the MOON into a single page, we are unable to do so, as condensing the notice, as suggested, would negatively affect its readability; for example, reducing the notice to one page would require use of an extremely small font size. However, we note that hospitals may print the MOON as two sides of a single page. Finally, we have drafted the MOON to contain all of the elements of notice we believe are required under the NOTICE Act. We have taken commenters' suggestions for specific wording changes under advisement and note that CMS' Office of Communications has performed a plain language review, and we have incorporated appropriate changes, wherever possible. The MOON has been revised and the updated draft is subject to a 30-day comment period in accordance with the requirements of the Paperwork Reduction Act (PRA). This revised MOON will not be final until any public comments have been received and considered. We do not routinely use specific readability tests on beneficiary publications. We appreciate the commenters' concerns and have made changes to the MOON, as discussed above, in order to help ensure maximum readability and comprehension. We believe the notice is now more streamlined and easier to comprehend. In addition to these revisions, as with most beneficiary notices, we expect that the MOON will be updated periodically based on our continued experience with the notice, through the PRA renewal process, which requires reapproval every 3 years.

Comment: Numerous commenters submitted comments related to the notice section containing contact information to express quality of care concerns to QIOs. Some commenters suggested moving this section further down or to the end of the notice. Other commenters suggested removing this information entirely. Some commenters explained that inclusion of this contact information would be confusing to beneficiaries and could mislead them as to the purpose of this notice. One commenter recommended revising the language to specifically state that QIOs do not have the authority to change a patient's status from outpatient to inpatient. Some commenters believed that the inclusion of QIO contact information may encourage calls to the QIO expressing that the beneficiary should be an inpatient, rather than outpatient, and regard the outpatient status as a quality of care issue, rather than a level of service issue. Another commenter suggested that CMS amend the QIO scope of work to account for additional inquiries that may result when required MOON delivery begins. One commenter believed the information about filing complaints about quality of care with MA plans is unnecessary. That commenter expressed concern that because outpatient status is not appealable, this contact information may cause unnecessary confusion.

Response: We agree with the commenters' suggestion to keep the focus of the MOON on status as an outpatient and related coverage and cost-sharing implications. Therefore, we have removed the QIO contact section from the MOON.

Comment: One commenter suggested that CMS remove the requirement directing a patient to contact 1–800–MEDICARE with questions, and replace that entire paragraph with hospital contact information. The commenter reasoned that because hospitals provide robust financial counseling services, physician advisors, care management teams, among others, they can better answer beneficiary questions in a friendly, in-person manner. Conversely, another commenter recommended removing the language referring beneficiaries with questions to hospital staff and physicians. This commenter believed that beneficiary questions regarding coverage and financial responsibility for receiving observation services as an outpatient are more appropriately directed to 1–800–MEDICARE. Another commenter suggested that CMS establish a point of contact in addition to 1–800–MEDICARE for questions related to the MOON.

Response: We disagree with the comments summarized above. The inclusion on the MOON of 1–800–Medicare contact information is consistent with other beneficiary notices. In addition to observation stay questions, beneficiaries may have other concerns related to Medicare billing, coverage, and associated issues.

We are maintaining the MOON's direction of patients to hospital personnel, in general, rather than to specific hospital contacts, to afford hospitals flexibility in the contact information they provide. However, hospitals may use the ''Additional Information'' section to specify particular hospital staff members and their contact information.

Finally, we believe that beneficiary information needs are satisfied by the existing options of using 1–800–Medicare as well as using hospital staff.

Beneficiaries have access to broad benefit and coverage information through 1–800–Medicare, and case-specific information from their hospitals. Therefore, we do not believe an additional point of contact is not necessary.

Comment: Several commenters explained that the MOON does not clearly state that the patient is not an inpatient for the purposes of meeting the 3 consecutive day inpatient hospital qualifying stay for coverage of post-hospital SNF care. One commenter suggested that the MOON explain the potential financial implications of being classified as an outpatient, rather than an inpatient, in simple, easy to understand terms. Another commenter noted that the MOON includes complex phrases such as ''observation stay'' and ''prior qualifying inpatient hospital stay'' without explanation. The commenter stated if these specific terms must be used, they should be defined in the notice. Many commenters suggested clarifying Part B coverage information and moving that language up in the ordering of the notice. One commenter suggested specific language to more clearly convey the information contained in this section.

Response: We agree with the commenters that this important information regarding coverage of post-hospital SNF care and Part B coverage should be more clearly stated and prominently displayed on the notice. To that end, we have simplified this language as part of the MOON's plain language changes and moved it near the top of the MOON.

Comment: Several commenters indicated that the NOTICE Act requires hospitals to explain the reason patients are classified as outpatients rather than inpatients. The commenters recommended that the MOON include a section for physicians to indicate the reason for outpatient status. Another commenter suggested that the MOON contain standard language explaining that the decision to classify a beneficiary as an outpatient, rather than admit as an inpatient, is based on Medicare regulations, without regard to cost-sharing responsibilities or skilled nursing facility eligibility. One commenter requested that CMS provide standard narratives to be used by hospitals when explaining the possible reasons for outpatient classification. Conversely, another commenter was satisfied with the MOON's standard language regarding the ''reason'' for observation services. However, this commenter believed this language was not clearly and prominently communicated on the notice.

Response: We agree with the commenters who suggested that the MOON should contain a field where a hospital will be required to state the specific reason a beneficiary is an outpatient, rather than inpatient. We believe this recommendation is consistent with the statute, specifically section 1866(a)(1)(Y)(ii)(I) of the Act. The MOON now contains a free text field where the specific reason for receiving observation services as an outpatient shall be completed by the hospital or CAH. We may consider, in the future, the other suggestions commenters made to improve the MOON, such as checkboxes with common reasons for the patient's outpatient status or suggested narratives for insertion in this section.

Comment: Several commenters asked that CMS clarify what additional information is expected to be included in the ''Additional Information'' section on the MOON.

Response: We generally do not specify expected language for the additional information sections of beneficiary notices. However, we believe hospitals and CAHs may use this section to include information such as unique circumstances regarding the particular patient (such as Medicare Accountable Care Organization (ACO) information), notation that a beneficiary refused to sign the MOON, hospital waivers of the beneficiary's responsibility for the cost of self-administered drugs, Part A cost sharing responsibilities if the beneficiary is subsequently admitted as an inpatient, or specific information for contacting hospital staff.

Comment: Several commenters urged CMS to clarify whether hospitals and CAHs will be required to provide the MOON to Medicare beneficiaries in States that already have a requirement to notify all patients of their status as an outpatient receiving observation services. The commenters expressed concern that furnishing two separate notices to beneficiaries would be counterproductive, burdensome on providers, and potentially confusing for patients. Some commenters requested CMS provide flexibility to hospitals to create their own notice that would comply with the requirements of the NOTICE Act. Some commenters requested CMS to address whether a hospital that complies with substantially equivalent requirements imposed under State law could be considered to be in compliance with the requirements of the NOTICE Act when furnishing a State-mandated notice. Some commenters recommended that where a hospital meets applicable State requirements related to observation notification, CMS deem the hospital to have met the NOTICE Act requirements. One commenter requested that where there is an existing State law that overlaps the requirements of the NOTICE Act, CMS clarify which requirements take precedence and expressly preempt the State law.

Response: The NOTICE Act requires hospitals and CAHs to furnish written notice specified by the Secretary pursuant to rulemaking, containing such language as the Secretary prescribes, consistent with the statute. Given the statutory language of the NOTICE Act, we believe the Federal standardized notice (the MOON) must be delivered to Medicare beneficiaries entitled to notice under the NOTICE Act, consistent with the provisions of this final rule, notwithstanding any similar notice that hospitals may previously had to deliver to such patients under State law or otherwise. In some cases, delivering the MOON may also fulfill State notice requirements for the Medicare population. Hospitals and CAHs will need to make that determination on a State-by-State basis. As we previously explained, where State law requires content that is not included in the MOON, hospitals may utilize the free text field in the MOON (''Additional Information'') for communicating such additional content. Hospitals and CAHs subject to State law notice requirements may also attach an additional page to the MOON to supplement the free text field in order to communicate additional content required under State law, or may attach the notice required under State law to the MOON. To the extent that there are requirements in a State law that directly conflict with or contradict requirements in the NOTICE Act, we will expect to address those issues of preemption as they are brought to our attention. However, at this time, we are not aware of any such State laws that contradict or conflict with the provisions of the NOTICE Act.

We believe the delivery of the MOON, an OMB standardized notice with consistent language, to all Medicare beneficiaries entitled to notice under the NOTICE Act best fulfills the requirements of the statute. Requiring the use of an OMB standardized notice ensures that all required statutory language is included, that the notice is written and formatted to be easily understandable to beneficiaries, and that the specific notice has been subject to public comment and input through the PRA process. Therefore, we are not adopting the commenters' recommendations.

Comment: One commenter asked whether hospitals that provide their

own notice to all patients receiving observation services as outpatients would still need to provide the MOON to Medicare beneficiaries who have received 24 hours of observation services as an outpatient.

Response: We recognize that some hospitals may voluntarily issue a notice to outpatients, or in some cases to outpatients who have received observation services, informing patients of the implications of being an outpatient on cost-sharing and benefits. However, the NOTICE Act requires hospitals and CAHs to furnish written notice specified by the Secretary through rulemaking, containing such language as the Secretary prescribes consistent with the statute. Given the statutory language and intent of the NOTICE Act, we believe the Federal standardized notice (the MOON) must be delivered to Medicare beneficiaries entitled to notice under the NOTICE Act, consistent with the provisions of this final rule, notwithstanding any similar notice that hospitals may previously have had to deliver to such patients pursuant to State law or otherwise.

Comment: One commenter recommended that, if an inpatient admission occurs prior to delivery of the MOON, the MOON be annotated with date and time of the inpatient admission so the patient is aware that outpatient status has ended and inpatient status has begun.

Response: We agree with the commenter that, if an inpatient admission occurs prior to delivery of the MOON, the MOON should be annotated with date and time of the inpatient admission. Therefore, we are requiring that, in the event that a patient is subsequently admitted as a hospital inpatient directly after receiving observation services for more than 24 hours, and the inpatient admission occurs prior to delivery of the MOON, the MOON be annotated with the date and time of the inpatient admission. Additional guidance regarding elements for the free text field of the MOON will be provided in the CMS Internet Only Manual.

Comment: One commenter indicated that the MOON does not include language specific to beneficiaries aligned with certain Medicare Accountable Care Organizations (ACO), such as Pioneer and Next Generation, where certain eligibility requirements for post-hospital SNF care may have been waived. The commenter recommended that CMS clarify that, in these situations, it is not necessary to include information related to post-hospital SNF care coverage implications of outpatient status where the 3 consecutive day inpatient hospital stay requirement has been waived.

Response: We appreciate the information from the commenter. As required by the NOTICE Act, we have created a notice that includes statutorily required information and other information needed for patients to understand their status as an outpatient, the distinction between being an outpatient and an inpatient, and the implications for being an outpatient receiving observation services. In addition, the NOTICE Act requires hospital and CAH staff to provide an oral explanation of the information contained in the written notice. We expect that, as part of the oral explanation, hospital staff will be available to answer questions that patients may have to assist them in understanding these concepts and the effects on their financial responsibility. Where there are exceptions to general rules for a very limited beneficiary population, such as waivers of the 3 consecutive day inpatient hospital stay requirement for beneficiaries aligned with particular ACOs, we would expect this information to be conveyed as part of the oral explanation or included in the ''Additional Information'' section of the MOON if the hospital or CAH is aware of the applicable exception. Because the MOON is a standard form approved by OMB, hospitals and CAHs will not be permitted to alter the included language, only the information to be included in the free text fields. To the extent that waivers of the post-hospital SNF coverage requirements become more prevalent and apply to a broader segment of the Medicare population, we will reconsider including such information in the MOON.

Comment: Several commenters suggested that the MOON be revised to reflect a recent policy statement issued by the HHS Office of Inspector General (OIG) regarding hospitals that discount or waive amounts owed by Medicare beneficiaries for self-administered drugs dispensed in outpatient settings. Other commenters suggested any language related to costs owed by beneficiaries for self-administered drugs dispensed in an outpatient setting be removed in light of the OIG policy statement. The OIG policy statement is located at: *http://oig.hhs.gov/compliance/alerts/guidance/policy-10302015.pdf*. The OIG policy statement assures hospitals that they will not be subject to OIG administrative sanctions if they discount or waive amounts that Medicare beneficiaries owe for self-administered drugs they receive in outpatient settings when those drugs are not covered by Part B, subject to certain specified conditions.

Response: We appreciate the commenters' recommendation. While we disagree that the language in the MOON should be omitted based on the referenced OIG policy permitting hospitals to discount or waive amounts owed by Medicare beneficiaries for self-administered drugs dispensed in outpatient settings, we agree that revisions to the MOON instructions are needed. Hospitals have discretion to take such actions based on the OIG policy statement, and the information on self-administered drugs that we proposed to be included in the MOON will be relevant for beneficiaries receiving care in hospitals that have not elected to waive or discount such amounts. In circumstances where the hospital does waive or discount costs for self-administered drugs, the hospital can include an explanation in the free-text field of the MOON (''Additional Information'') and/or provide an oral explanation to the individual. However, this is not required by the NOTICE Act. We have added language to the MOON instructions indicating that the hospital waiving or discounting the beneficiary's responsibility for the cost of self-administered drugs is an appropriate use of the ''Additional Information'' free text field of the MOON.

Comment: Several commenters requested specification on whether it was necessary for hospitals to retain a signed copy of the completed MOON in the patient's medical record and the requirements for doing so. One commenter asked whether hospitals could document in the medical record that the MOON was provided to the patient and an oral explanation was furnished without retaining a copy of the notice. Another commenter requested that CMS clarify hospitals can obtain an electronic signature and retain the MOON only in electronic form. One commenter requested CMS to clarify if there is a mechanism for hospitals to provide, when necessary, evidence the notice was delivered to the patient.

Response: Consistent with longstanding practice in implementing beneficiary notices, we will require that hospitals and CAHs retain a signed copy of the MOON. Such a practice assures both hospitals and CAHs and surveyors that the appropriate notices have been delivered as required. However, in the past, we have permitted providers to determine the method of storage. This same flexibility will be afforded to hospitals and CAHs delivering the MOON. Hospitals and CAHs may

choose to retain a signed notice as a hard copy or electronically.

After consideration of the public comments we received, we are finalizing the proposed requirements for written notice without modification.

e. Outpatient Observation Services and Beneficiary Financial Liability

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25133 through 25134), Section 20.6, Chapter 6, of the Medicare Benefit Policy Manual (Pub. 100–2) specifies that observation services furnished by hospitals and CAHs are ''a well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital.'' Typically, observation services are ordered for individuals who present to the emergency department (ED) and who then require a significant period of treatment and monitoring to determine whether or not their condition warrants inpatient admission or discharge. Individuals also may receive outpatient observation services in other areas of a hospital or CAH when necessary. For example, a patient who receives a drug infusion in a hospital's outpatient infusion center and then experiences post-infusion hypertension may require observation services. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, and usually in less than 24 hours. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. All hospital observation services, regardless of duration of care, that are medically reasonable and necessary are covered by Medicare.

In some cases, Medicare beneficiaries receiving observation services while in a hospital or CAH may not be aware of their status as an inpatient or an outpatient, and thus may not be aware that there are significant differences in financial liability between inpatient status and outpatient status. CMS has published educational materials for Medicare beneficiaries to help inform them of financial and coverage liabilities associated with inpatient and outpatient services.[90] As an outpatient receiving observation services, a beneficiary may incur financial liability for Medicare Part B copayments,[91] the cost of self-administered drugs that are not covered under Part B, and the cost of post-hospital SNF care because section 1861(i) of the Act requires a prior 3-day hospital inpatient consecutive stay to be eligible for coverage of post-hospital SNF care under Medicare Part A. In contrast, as a hospital inpatient under Medicare Part A, a beneficiary pays an annual deductible ($1,288 in CY 2016) for all inpatient services provided during the first 60 days in the hospital of each benefit period for the year. Cost-sharing requirements for individuals enrolled in Medicare Part C, known as MA health plans, are dependent on the particular plan's policies. In addition, Medicare beneficiaries qualified through their State Medicaid program (QMBs) have different cost-sharing rules. For example, QMBs cannot be billed for Medicare Part A or Part B deductibles, coinsurance, or copayments and may have different rules regarding qualifying for SNF services. CMS has produced informational publications for beneficiaries that advise Medicare Advantage enrollees to check with their plans for information on coverage of observation services furnished to an outpatient.

As mentioned earlier, a beneficiary's liability for medication costs also is likely affected by whether the individual is hospitalized as an inpatient or receiving care as an outpatient. When an individual is hospitalized under a covered Medicare Part A inpatient stay, payment for medically reasonable and necessary medications that are provided by the hospital are covered under Medicare Part A. Generally, Medicare Part B covers drugs that are usually not self-administered. Based on the statutory prohibition at section 1861(s)(2) of the Act and its implementing regulation at § 410.29(a), Medicare Part B generally does not cover or pay for any drug or biological that can be self-administered. ''Self-administered drugs'' are considered prescription and over-the-counter medications that beneficiaries routinely take on their own. For safety reasons, many hospitals do not allow patients to take medications brought from home. Medicare prescription drug plans (Part D) may help pay for drugs provided by the hospital. Individuals with Medicare Part D will likely need to pay out-of-pocket costs to the hospital for these drugs and request reimbursement from their Part D plan.

In addition, whether an individual is receiving treatment or care as an inpatient admitted to the hospital or is receiving observation services as an outpatient pursuant to a doctor's orders may impact Medicare coverage for post-hospital SNF services. Section 1861(i) of the Act requires a beneficiary to be an inpatient of a hospital for not less than 3 consecutive days before discharge from the hospital in order to be eligible for coverage of post-hospital extended care services in a SNF under Medicare. For purposes of Medicare SNF coverage, the time spent receiving observation services as an outpatient does not count towards the requirement of a 3-day hospital inpatient stay because these services are outpatient.

Comment: Several commenters suggested that CMS revise language on the MOON regarding cost-sharing to reflect the fact that claims for most patients who receive observation services as an outpatient for 24 hours will be paid under a comprehensive APC (C–APC) under the OPPS that imposes a single copayment rather than a copayment for every service received. Other commenters also recommended that CMS remove or simplify the language included in the MOON regarding Part B cost-sharing for doctor services as the copayment requirement for doctor services are not affected by the decision to admit the patient as an inpatient or order observation services as an outpatient.

Response: The commenters are correct that, effective January 1, 2016, CMS established a C–APC for comprehensive observation services (C–APC 8011). To qualify for the C–APC payment, beneficiaries must have received 8 or more hours of hospital observation services in conjunction with a qualifying hospital visit, during a nonsurgical encounter. Under the C–APC payment policy, we note that, instead of paying copayments for a number of separate services that are generally individually subject to the copayment liability cap at section 1833(t)(8)(C)(i) of the Act, beneficiaries can expect to pay a single copayment for the comprehensive service that would be subject to the copayment liability cap. As a result, we expect that this

[90] ''Are You a Hospital Inpatient or Outpatient? If You Have Medicare—Ask!'' CMS Product No. 11435. May 2014.

[91] A beneficiary who receives hospital outpatient services typically pays 20 percent of the Medicare payment amount for outpatient items and services after paying the annual Part B deductible ($166 in CY 2016). The coinsurance amount for an outpatient CAH service is based on 20 percent of charges. In most cases, the cost-sharing for each individual outpatient service should not be more than the inpatient deductible. However, Medicare beneficiaries who receive several separately payable outpatient services, or are treated for extended periods of time as hospital outpatients, may have greater cost-sharing liabilities as an outpatient under observation than they may have if they were admitted as an inpatient to the hospital.

policy likely reduces the possibility that the overall beneficiary liability exceeds the copayment liability cap for most of these outpatient encounters involving observation services. Observation services that do not meet the criteria for payment under C–APC 8011 will not be paid under the C–APC and cost-sharing requirements for each individual separately payable service (up to the copayment liability cap at section 1833(t)(8)(C)(i) of the Act) will apply.

While Part B cost-sharing amounts for physician services do not differ based on the inpatient or outpatient status of the beneficiary, we still believe it is required to include information about the Part B cost-sharing for physician services as it is part of the total cost-sharing for which the beneficiary is responsible.

Comment: One commenter referenced the statement in the preamble of the proposed rule that CMS has produced informational publications for beneficiaries that advise MA enrollees to check with their plans for information on coverage of outpatient observation services. The commenter recommended that hospitals and CAHs be required to distribute copies of this publication to beneficiaries as part of the standard notice procedures.

Response: The MOON contains language advising MA enrollees to contact their plan for specific information on coverage for outpatient observation services. The language in the MOON was based on the language used in the referenced CMS publication on observation services (''*Are You a Hospital Inpatient or Outpatient*?''). As such, we do not believe there is value in requiring hospitals and CAHs to assume the burden of distributing a CMS publication that is readily available to Medicare beneficiaries and which includes the same instruction as the MOON regarding the importance of contacting the individual's plan for specific coverage information. Therefore, we are not accepting the commenter's suggestion.

f. Delivering the Medicare Outpatient Observation Notice

As discussed in the proposed rule (81 FR 25134), an English language version of the proposed MOON was submitted to OMB for approval. We stated in the proposed rule that once we receive OMB approval, a Spanish language version of the MOON will be made available. If the individual receiving the notice is unable to read its written contents and/or comprehend the required oral explanation, we expect hospitals and CAHs to employ their usual procedures to ensure notice comprehension. (We refer readers, for example, to the Medicare Claims Processing Manual (Pub. 100–4), Chapter 30, Section 40.3.4.3., for similar existing procedures related to notice comprehension for the Advance Beneficiary Notice of Noncoverage (ABN).) Usual procedures may include, but are not limited to, the use of translators, interpreters, and assistive technologies. Hospitals and CAHs are reminded that recipients of Federal financial assistance have an independent obligation to provide language assistance services to individuals with limited English proficiency (LEP) consistent with section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964. In addition, recipients of Federal financial assistance have an independent obligation to provide auxiliary aids and services to individuals with disabilities free of charge, consistent with section 1557 of the Affordable Care Act and section 504 of the Rehabilitation Act of 1973

Comment: A number of commenters recommended that CMS provide the MOON in additional languages other than English and Spanish. Some commenters specifically requested that the MOON be provided in languages spoken by the lower of 5 percent or 1,000 Medicare beneficiaries. Other commenters recommended that CMS provide translation of the document into at least the top 15 languages nationally. Some commenters more generally requested that CMS make the notice available in additional languages over time.

Response: We appreciate commenters' concerns that beneficiaries have access to the MOON in a language they understand. As stated above and in the proposed rule, we will provide the MOON in both English and Spanish. We believe hospitals and CAHs already have in place various procedures to ensure that beneficiaries are able to understand notices and information delivered to them, and we expect they can further utilize those procedures to deliver the MOON. In addition, we believe that the requirements under section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964, as listed above, mandate that hospitals and CAHs have the responsibility to provide language assistance to LEP individuals, and that these requirements apply to delivery of the MOON. Therefore, we are not accepting the commenters' recommendations.

Comment: Some commenters recommended that CMS allow hospitals and CAHs to provide solely oral interpretation of the English-based version of the MOON for at least 6 months after the MOON is finalized for more common languages (except Spanish once the Spanish-based version is finalized) and permanently for less common languages.

Response: As noted above and in the proposed rule, we expect hospitals and CAHs to employ their usual procedures to ensure beneficiaries are able to comprehend language included in the MOON. We understand that these procedures may include use of oral interpretation using translators. We believe it is the responsibility of hospitals and CAHs to ensure they are fulfilling statutory requirements regarding the provision of the notice.

Comment: Numerous commenters expressed concern that hospitals and CAHs will not have sufficient time to prepare for MOON implementation. The commenters recommended that CMS provide transition time for hospitals to implement the provisions of this final rule; recommended implementation periods ranged from at least 3 to more than 6 months. Several commenters requested that CMS delay monitoring and enforcement until the MOON is translated into the requisite number of foreign languages to meet anti-discrimination requirements for individuals with limited English proficiency. One commenter requested that CMS specify the date when MOON delivery must begin. In addition, the commenter requested clarification of whether a hospital would be required to deliver the notice only to outpatients whose observation services begin on or after the implementation date, or if hospitals must also include patients already receiving outpatient services as of the implementation date.

Response: We are clarifying that the MOON is on a separate approval track from this implementing regulation, as discussed above. The MOON is following the established OMB notice approval process under the PRA and is being published for the 30-day comment period along with this final rule as part of the PRA process.

We expect final PRA approval of the MOON around the time the implementing regulations are effective. Therefore, the implementation period for hospitals and CAHs will begin sometime after the effective date of this final rule and will be announced on the CMS Beneficiary Notices Initiative Web site at: *https://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html* and in an HPMS memorandum to MA plans. During this implementation period, hospitals and CAHs will have time to prepare for

implementation, consistent with past implementation practices for beneficiary notices. Hospitals and CAHs will be required to deliver the MOON to applicable patients who begin receiving observation services as outpatients on or after the notice implementation date. As we stated in the proposed rule, we have been working toward implementation since the NOTICE Act was passed. We recognize that the effective date of this final rule will be at some date after the statutory implementation date of August 6, 2016, has passed. We are striving to balance the statutory requirements to provide notice to the specified population with the desire to provide the affected industry sufficient time to put systems and business processes in place to implement the NOTICE Act requirements. Under the PRA approval process, the public will have 30 days to comment on the revised MOON following publication of this final rule and, OMB will review the MOON after the comment period. Once the MOON has been approved, hospitals and CAHs must fully implement use of the MOON and comply with all of the NOTICE Act requirements no later than 90 calendar days from the date of PRA approval of the MOON. This implementation schedule takes into consideration the statutory requirements of the NOTICE Act, as well as our longstanding experience in developing implementation schedules for new beneficiary notices.

Comment: Many commenters requested a delay in monitoring and enforcement of MOON delivery. Several commenters recommended graduated enforcement. One commenter requested that CMS explain the repercussions for a hospital failing to provide proper notice to Medicare beneficiaries, and whether failure to provide this notification would result in termination of the hospital from participation in the Medicare program. The commenter recommended that CMS only sanction hospitals for a pattern of notice delivery failure, and follow the same process currently in place for conditions of participation enforcement regarding substantial condition level violations. One commenter requested clarification of the consequences for failure to obtain or retain a signed notification prior to the patient being discharged. Several commenters suggested that CMS impose a graduated enforcement scheme beginning with notice and education of regulatory requirements and potential noncompliance so the hospital or CAH may develop and carry out a corrective action plan. Another commenter recommended that CMS establish a clear standard—developing consistent implementation across State lines and providing necessary audit protocols to surveyors. One commenter recommended that in cases where the MOON was not delivered to an individual as required, the beneficiary receive covered inpatient care paid under Medicare Part A. Finally, one commenter requested auditing guidelines published before the end of a ''grace period'' prior to the implementation date.

Response: We appreciate the commenters' interest in the oversight of MOON delivery. All monitoring and enforcement of the MOON will be consistent with our oversight procedures for other hospital delivered notices. We are reviewing our surveying protocols to identify changes that may be needed to facilitate effective monitoring and enforcement of these requirements. These revised procedures will be developed and implemented in the normal course of business.

Comment: One commenter noted that CMS did not provide guidance in the proposed rule specifying the hospital or CAH staff responsible for MOON delivery. The commenter believed that hospitals and CAHs should be responsible for this determination. Another commenter requested that CMS clarify what staff would be appropriate for delivering the MOON. One commenter believed that any trained member of the hospital staff should be permitted to deliver the MOON, but stated that the CMS burden estimate in the proposed rule appears to anticipate that it will be a nurse. The commenter explained that, in its experience, hospitals are more likely to use social workers, discharge planners, or administrative staff.

Response: We generally do not prescribe what staff must deliver a notice to a beneficiary. We agree with the commenter that the hospital or CAH is in the best position to determine the appropriate staff member to deliver the MOON. We clarify that inclusion of a particular occupation in a burden estimate reflects our attempts to best approximate, while not underestimating, the anticipated costs of notice delivery. This occupation choice does not serve as a notice delivery staff requirement.

After consideration of the public comments we received, we are finalizing the proposed provisions for delivering the MOON without modification.

g. Oral Notice

In the proposed rule (81 FR 25134), pursuant to the statutory requirement at section 1866(a)(1)(Y)(i) of the Act, we proposed under proposed new regulation at § 489.20(y)(2) that hospitals and CAHs provide an oral explanation of the written notice furnished to individuals who receive observation services as outpatients. We stated in the proposed rule that we will provide guidance for oral notification in our forthcoming Medicare manual provisions. Hospitals and CAHs are familiar with providing oral explanations of written notices (for example, surgical and procedural consent notices and the Important Message from Medicare), and we expect that oral notification will occur in conjunction with delivery of the MOON. Again, hospitals and CAHs are reminded that recipients of Federal financial assistance have an independent obligation to provide language assistance services to individuals with LEP consistent with section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964. In addition, recipients of Federal financial assistance have an independent obligation to provide auxiliary aids and services to individuals with disabilities free of charge, subject to section 1557 of the Affordable Care Act and section 504 of the Rehabilitation Act of 1973.

Comment: Some commenters questioned how hospitals should handle and document the oral explanation required by the NOTICE Act. One commenter requested that CMS allow public comment on any guidance issued on the oral explanation in CMS operating manuals. This commenter questioned if the oral component is required, and whether the patient's signature on the MOON would be considered sufficient documentation that the oral notice was given and understood by the patient or the patient's representative. Another commenter stated that delivery of the MOON is unnecessary and suggested that the intent of the notice requirement should be satisfied by the oral explanation by the hospital staff followed by documentation and confirmation of the explanation in the patient's electronic medical record. One commenter recommended that CMS allow hospitals to deliver the oral explanation with a video presentation. The commenter indicated that staff would be present to answer questions and provide additional explanation where necessary, in addition to the video explanation.

Response: The statute requires that there be an oral explanation of the written notification, or MOON. We believe it is essential that hospital staff

are available to provide a verbal explanation and answer questions in the interest of beneficiaries fully understanding the MOON. A video presentation of the MOON is acceptable if an individual is available to answer questions. Finally, the NOTICE Act requires hospitals and CAHs to deliver both a written notice and an oral explanation of the notice when notice delivery is required. Therefore, we do not believe providing only an oral notice is permissible under the statute.

Comment: One commenter expressed concern that hospitals [and CAHs] would be required to maintain around the clock staff who are trained to deliver the MOON. The commenter stated that it would place an enormous burden on hospitals [and CAHs] and would be costly to implement.

Response: We believe that hospitals and CAHs furnishing observation services are sufficiently staffed to furnish such observation services and that hospitals and CAHs would appropriately train the staff that furnishes observation services to deliver the MOON, as required, in the applicable cases.

After consideration of the public comments we received, we are finalizing the proposed provisions for oral notice without modification.

h. Signature Requirements

As specified in the proposed rule (81 FR 25134), as set forth at section 1866(a)(1)(Y)(ii)(IV) of the Act, the written notification must be either signed by the individual receiving observation services as an outpatient or a person acting on such individual's behalf to acknowledge receipt of notification. Moreover, the statute provides that if such individual or person refuses to provide a signature, the written notification is to be signed by the staff member of the hospital or CAH who presented the written notification and certain information needs to be included with such signature. Accordingly, we proposed under proposed new § 489.20(y)(3), that the written notice be signed, as described above, in order to acknowledge receipt and understanding of the notice. The MOON would include a dedicated signature area for this purpose. In cases where the individual receiving the MOON refuses to sign the notice, we proposed that the MOON must be signed by the staff member who presents the notice to the individual. The staff signature would include the staff member's name and title, a certification statement that the notice was presented, and the date and time that the notice was presented.

Comment: Several commenters requested that CMS clarify procedures for obtaining a signature when a patient is unable to sign the MOON due to a medical or mental condition or when someone is under duress and no representative is available. One commenter found the MOON to be unclear with respect to how providers can determine when it is appropriate to seek alternative signatures and who (patient family member or other caregiver) should be engaged to sign the MOON. Some commenters recommended that CMS allow a hospital representative to annotate the notice to indicate the patient was unable to sign and that no patient representative was available, in the same manner CMS proposed to permit staff to sign and date the MOON when a beneficiary refuses to sign. Other commenters believed that a notice that is not understandable is defective. Several commenters recommended that CMS require that a hospital or CAH deliver the MOON only to a patient able to comprehend it, and, if not, provide the notice to a representative able to do so. The commenters suggested that failure to do so will result in a defective notice. Another commenter recommended that hospitals be required to provide written and oral notification to the patient's family member, caregiver, or power of attorney, similar to existing procedures related to notice delivery and comprehension for the ABN. One commenter expressed concern that the proposed rule did not set standards for assuring competency of the patient who is given the notice and ''acknowledges receipt.'' The commenter explained that patients who have diminished capacity due to pain or medication or other conditions may not understand either the notice or its implications, and recommended that CMS address competency and assuring that the patient understands the notice in the final rule.

Response: The NOTICE Act requires hospitals and CAHs to deliver written notice to an individual who has received more than 24 hours of observation services as an outpatient, and requires hospitals and CAHs to document acknowledgment of receipt of the notice by obtaining a signature of the individual or the person acting on the individual's behalf. The NOTICE Act also provides a mechanism for hospitals and CAHs to comply with the acknowledgment requirement if the individual or person acting on behalf of the individual refuses to sign the written notice. To the extent that additional guidance related to delivery of notice is necessary, we will issue instructions in the CMS Internet Only Manual.

Comment: One commenter stated that requiring a signature of the hospital staff when a patient refuses to sign the MOON raises ethical concerns for physicians and other hospital providers who may believe they do not have the right to sign a document when they are not financially responsible for, or legally acting on the patient's behalf. The commenter recommended that CMS instead include a check or initial box to indicate that a patient or caregiver refused to sign.

Response: We appreciate the concerns raised by the commenter. However, the NOTICE Act expressly requires that if such individual entitled to notice or person acting on such individual's behalf refuses to provide signature, the MOON be signed by the staff member of the hospital or CAH who presented the written notification and includes the name and title of such staff member, a certification that the notification was presented, and the date and time the notification was presented (in accordance with section 1866(a)(1)(Y)(ii)(IV)(bb) of the Act). We believe accepting something in lieu of signature of the individual, person acting on individual's behalf, or relevant staff member would not be appropriate. Therefore, we are maintaining this proposed signature requirement in this final rule.

Comment: Several commenters suggested that the signature of a beneficiary reflect notice comprehension as well as receipt of the notice.

Response: We clarify that a notice signature will reflect notice receipt as well as comprehension, consistent with statutory requirements that the notice be written and formatted using plain language, be made available in appropriate languages, and be accompanied by an oral explanation. The MOON makes clear that the signature attests to both receipt and understanding of the notice. We will be publishing guidance, pursuant to our usual approval process, to further guide hospitals and CAHs in delivery of the MOON. We plan for this guidance to be available to hospitals and CAHs before notice delivery is required, which will be at the end of the implementation period after the MOON receives final approval.

After consideration of the public comments we received, we are finalizing the proposed signature requirements without modification.

i. No Appeal Rights Under the NOTICE Act

As indicated in the proposed rule (81 FR 25134), section 1866(a)(1)(Y) of the Act, as added by the NOTICE Act, does not afford appeal rights to beneficiaries regarding the notice provided pursuant to that statutory provision. To provide clarity to this point, we proposed to amend the regulations at § 405.926 relating to actions that are not initial determinations, by adding new paragraph (u) to explain that issuance of the MOON by a hospital or CAH does not constitute an initial determination and therefore does not trigger appeal rights under 42 CFR part 405, subpart I.

Comment: Several commenters submitted comments regarding appeal rights and the MOON. One commenter expressed concern that the proposed rule explicitly prevents Medicare beneficiaries from appealing their ''observation status determination.'' The commenter stated that the proposed MOON is the only instance in which Medicare beneficiaries receiving a notice of denial of coverage are not given a process to appeal the determination, and further stated that delivery of the MOON corresponds with noncoverage of post-hospital SNF care upon hospital discharge and impacts coverage of care while in the hospital. The commenter recommended CMS remove proposed regulatory language in § 405.926(u) that states Medicare beneficiaries receiving the MOON do not have appeal rights. Another commenter believed that the MOON should inform beneficiaries of their right to appeal observation services received as an outpatient. Another commenter believed that the MOON should explain that a patient does not have an immediate right to appeal their status as an outpatient receiving observation services as well as the fact that their physician does not have the authority to change their status. One commenter recommended that CMS clarify why beneficiaries may not challenge their status as an outpatient and the provision of observation services.

Response: We thank the commenters for the recommendations. However, we believe that the comments reflect concerns outside the scope of the NOTICE Act or a misunderstanding of the nature of the notice required under the legislation. We disagree with the commenter's assertion that delivery of the MOON constitutes a determination of noncoverage of post-hospital SNF care. We also disagree with the commenter's characterization of the proposed MOON constituting a notice of denial of coverage in general. Finally, we do not believe the MOON is the appropriate document to communicate appeal rights; the Medicare Summary Notice (MSN) fulfills that purpose. Therefore, we are not accepting the commenters' recommendations.

The MOON is a required informational/educational notice regarding patient status provided by a hospital or CAH when the beneficiary is still in the hospital or CAH and receives observation services as an outpatient for more than 24 hours. The MOON explains the current status of the patient as an outpatient and not an inpatient, in addition to the implications of being an outpatient receiving observation services. As we explained in the proposed rule, delivery of the MOON does not constitute an initial determination issued in response to a claim for benefits, and the MOON itself is not a notice of an initial determination (81 FR 25134). Furthermore, delivery of the MOON by a hospital or CAH does not constitute a denial of coverage of any services, and does not constitute a noncoverage decision with respect to post-hospital SNF care as asserted by the commenter. In fact, generally beneficiaries will still be receiving care when the MOON is delivered and will sometimes be formally admitted as inpatients after delivery of the MOON.

The NOTICE Act does not provide for appeal rights regarding the notice itself, which makes sense given the nature of the document, as explained above. The NOTICE Act also does not afford any new appeal rights beyond those already available (under section 1869 of the Social Security Act), nor does the NOTICE Act limit or restrict currently available appeal rights. Consistent with the legislation, the proposed rule did not propose to expand or limit appeal rights. For the reasons discussed above, we are not adopting the various recommendations with respect to amending the MOON to include appeal rights or an explanation of the lack of appeal rights.

As we have stated repeatedly, the decision to admit a beneficiary as an inpatient is a complex medical decision made by the physician in consideration of various factors, including the beneficiary's age, disease processes, comorbidities, and the potential impact of sending the beneficiary home. It is the responsibility of the physician to make the complex medical determination of whether the beneficiary's risk of morbidity or mortality dictates the need to remain at the hospital because the risk of an adverse event would otherwise be unacceptable under reasonable standards of care, or whether the beneficiary may be discharged. We expect that the NOTICE Act and implementing policies will result in beneficiaries having a better understanding of the care they are receiving.

After consideration of the public comments we received, we are finalizing the proposed revision to § 405.926(u) without modification.

j. Out of Scope Public Comments

We received several comments that were outside the scope of the provisions of the proposed rule, and we are not responding to them in this final rule. These comments were related to (1) defining inpatient care; (2) alternate notification for transition to inpatient status; (3) increased protection for inappropriate placement; (4) beneficiary education and outreach; (5) standardized language for hospitals to use when a beneficiary does not meet inpatient criteria after internal utilization review; (6) requirement for hospital pharmacies to work with MA and Part D plans on an in-network basis; (7) waiver of therapy cap; (8) waiver of functional limitation reporting; and (9) physician education and outreach in regards to handling beneficiary concerns and complaints.

k. Provisions of the Final Regulations

After consideration of the public comments we received, we are finalizing the addition of paragraph (u) to § 405.926 as proposed. The proposed addition of paragraph (y) to § 489.20 is being revised to clarify that hospitals and CAHs may deliver the MOON before an individual has received more than 24 hours of observation services as an outpatient.

M. Technical Changes and Correction of Typographical Errors in Certain Regulations Under 42 CFR Part 413 Relating to Costs to Related Organizations and Medicare Cost Reports

1. General Background

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25134 through 25135), as part of our ongoing review of the Medicare regulations, we have identified a number of technical changes or corrections of typographical errors in 42 CFR part 413 relating to costs to related organizations and Medicare cost reports that need to be made. Below we are summarizing these proposed changes or corrections, with our corresponding final policy decisions.

2. Technical Change to Regulations at 42 CFR 413.17(d)(1) on Cost to Related Organizations

Prior to the enactment of section 911(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), a provider had the right to nominate a fiscal intermediary (currently known as a Medicare Administrative Contractor (MAC) and referred to in this section as a ''contractor'') of its choice. Public Law 108–173 repealed the nomination provisions formerly found in section 1816 of the Act and added section 1874A (Contracts with Medicare Administrative Contractors). Currently, a provider will be assigned to the contractor that covers the geographic locale where the provider is located, as specified in the regulations at 42 CFR 421.404(b).

Because a provider is no longer permitted to select a contractor of its choice, and a contractor is now assigned to a provider, the parenthetical language of the regulation text at 42 CFR 413.17(d)(1) referring to a provider's nomination of a contractor is obsolete. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25134), we proposed to revise § 413.17(d)(1) to remove the parenthetical reference to a provider's nomination of a contractor.

We did not receive any public comments regarding this proposal. Therefore, we are finalizing our proposal to revise § 413.17(d)(1) to remove the parenthetical reference to a provider's nomination of a contractor.

3. Changes to 42 CFR 413.24(f)(4)(i) Relating to Electronic Submission of Cost Reports

In § 413.24(f)(4)(i), we incorrectly refer to a ''Federally qualified health clinic.'' The correct entity title under section 1861(aa) of the Act is ''Federally qualified health center.'' In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25135), we proposed to correct this error.

In addition, § 413.200(c)(1)(i) requires a histocompatibility laboratory to file a Medicare cost report in accordance with the regulations at § 413.24(f). For cost reporting periods ending on or after March 31, 2005, organ procurement organizations (OPOs) and histocompatibility laboratories are required to submit Medicare cost reports in a standardized electronic format, but histocompatibility laboratories were inadvertently omitted from the list of providers in the regulations text at § 413.24(f). As evidenced by the reference in the August 22, 2003 **Federal Register** document (68 FR 50720) to the Office of Management and Budget (OMB) approval number 0938–0102 of the Paperwork Reduction Act request for the cost reporting form entitled ''Organ Procurement Agency/Laboratory Statement of Reimbursable Costs,'' histocompatibility laboratories were intended to be included in the regulation text. Both OPOs and histocompatibility laboratories have used that Medicare cost report form to report their statements of reimbursable costs since its approval by OMB for use for cost reporting periods ending on or after March 31, 2005. To correct this omission, we proposed a technical change to § 413.24(f)(4)(i) to add ''histocompatibility laboratories'' to the list of providers required to submit cost reports in a standardized electronic format.

We did not receive any public comments regarding these proposals. Therefore, we are finalizing our proposal to correct the entity title of a ''Federally qualified health center'' in § 413.24(f)(4)(i). We are also finalizing our proposal to add ''histocompatibility laboratories'' to the list of providers required to submit cost reports in a standardized electronic format in § 413.24(f)(4)(i).

4. Technical Changes to 42 CFR 413.24(f)(4)(ii) Relating to Electronic Submission of Cost Reports and Due Dates

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25135), we proposed a technical correction in § 413.24(f)(4)(ii) to the effective date for the submission of Medicare cost reports in a standardized electronic format for skilled nursing facilities (SNFs) and home health agencies (HHAs) from cost reporting periods ending on or after December 31, 1996 to cost reporting periods ending on or after February 1, 1997 to accurately reflect the regulation text finalized in the January 2, 1997 final rule, ''Medicare Program: Electronic Cost Reporting for Skilled Nursing Facilities and Home Health Agencies,'' published in the **Federal Register** at 62 FR 26 through 31.

For the same reasons articulated in section IV.M.3. of the preamble of the proposed rule (81 FR 25135), we also proposed to revise § 413.24(f)(4)(ii) by adding histocompatibility laboratories to the list of providers required to file electronic cost reports. To correct a typographic error, we proposed to remove the duplicate word ''contractor'' from the second sentence of this paragraph.

We did not receive any public comments regarding these proposals. Therefore, we are finalizing our proposal to make a technical correction in § 413.24(f)(4)(ii) to the effective date for the submission of Medicare cost reports in a standardized electronic format for SNFs and HHAs from cost reporting periods ending on or after December 31, 1996 to cost reporting periods ending on or after February 1, 1997, to accurately reflect the regulation text finalized in the January 2, 1997 final rule published in the **Federal Register** at 62 FR 26 through 31. We also are finalizing our proposal to revise § 413.24(f)(4)(ii) by adding histocompatibility laboratories to the list of providers required to file electronic cost reports for the same reasons provided in section IV.M.3. of the preamble of this final rule. In addition, we are correcting a typographic error to § 413.24(f)(4)(ii) by removing the duplicate word ''contractor'' from the second sentence of this paragraph.

5. Technical Changes to 42 CFR 413.24(f)(4)(iv) Relating To Reporting Entities, Cost Report Certification Statement, Electronic Submission and Cost Reports Due Dates

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25135), we proposed to revise § 413.24(f)(4)(iv) to make a technical correction to the effective date for SNFs and HHAs to submit hard copies of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a certifying statement signed by its administrator or chief financial officer, from cost reporting periods ending on or after December 31, 1996, to cost reporting periods ending on or after February 1, 1997, to accurately reflect the regulation text finalized in the January 2, 1997 final rule (62 FR 26 through 31).

We proposed to revise § 413.24(f)(4)(iv) by adding histocompatibility laboratories to the list of providers required to file electronic cost reports for the same reasons provided in section IV.M.3. of the preamble of the proposed rule (81 FR 25135). In addition, we proposed to add histocompatibility laboratories to the list of providers required to submit hard copies of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a certifying statement signed by its administrator or chief financial officer, for cost reporting periods ending on or after March 31, 2005, for the same reasons.

We also proposed to correct a typographical error that occurred in the Medicare cost report certification statement set forth in § 413.24(f)(4)(iv)

by adding the word ''and'' between the words ''Sheet'' and ''Statement'' to denote the two separate financial documents required to be submitted with the cost report; that is, the Balance Sheet and the Statement of Revenue and Expenses. The cost report certification statement historically correctly denoted the two separate and distinct financial forms, the Balance Sheet and the Statement of Revenue and Expenses on Worksheet S (Form CMS–2552–92) of the Medicare cost report since the Worksheet S was first used in 1993. The Medicare cost report certification statement was later incorporated into § 413.24(f)(4)(iv) in a final rule with comment period (59 FR 26964 through 26965) issued in response to public comments received following the Uniform Electronic Cost Reporting System for Hospitals proposed rule (56 FR 41110). A typographical error excluding the word ''and'' occurred during the incorporation of the certification statement into the regulations text at § 413.24(f)(4)(iv).

We did not receive any public comments regarding these proposals. Therefore, we are finalizing our proposals without modification to revise § 413.24(f)(4)(iv) to make a technical correction to the effective date for SNFs and HHAs to submit hard copies of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a certifying statement signed by its administrator or chief financial officer, from cost reporting periods ending on or after December 31, 1996, to cost reporting periods ending on or after February 1, 1997, to accurately reflect the regulation text finalized in the January 2, 1997 final rule (62 FR 26 through 31). We also are finalizing our proposal to revise § 413.24(f)(4)(iv) by adding histocompatibility laboratories to the list of providers required to file electronic cost reports for the same reasons provided in section IV.M.3. of the preamble of this final rule. In addition, we are finalizing our proposal to add histocompatibility laboratories to the list of providers required to submit hard copies of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a certifying statement signed by its administrator or chief financial officer, for cost reporting periods ending on or after March 31, 2005, for the same reasons.

Furthermore, we are finalizing our proposal to correct a typographical error that occurred in the Medicare cost report certification statement set forth in the regulations text at § 413.24(f)(4)(iv) by inserting the word ''and'' between the words ''Sheet'' and ''Statement'' to denote the two separate financial documents required to be submitted with the cost report; that is, the Balance Sheet and the Statement of Revenue and Expenses.

6. Technical Correction to 42 CFR 413.200(c)(1)(i) Relating to Medicare Cost Report Due Dates for Organ Procurement Organizations and Histocompatibility Laboratories

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25135), we proposed to make a technical correction to the reference in § 413.200(c)(1)(i) to the due date for the Medicare cost report for organ procurement organizations (OPOs) and histocompatibility laboratories from ''three months'' to ''5 months'' after the end of the fiscal year. Section 413.200(c)(1)(i) requires independent OPOs and histocompatibility laboratories to file a cost report in accordance with § 413.24(f). In the 1995 final rule (60 FR 33137), we revised § 413.24(f) to extend the Medicare cost report due date for all providers required to file a cost report from 3 months to 5 months after the end of a provider's fiscal year end, but inadvertently neglected to make a conforming change to § 413.200(c)(1)(i), which we proposed to correct in the proposed rule.

We did not receive any public comments regarding these proposals. Therefore, we are finalizing our proposal to make a technical correction to the reference in § 413.200(c)(1)(i) to the due date for the Medicare cost report for organ procurement organizations (OPOs) and histocompatibility laboratories from ''three months'' to ''5 months'' after the end of the fiscal year.

N. Finalization of Interim Final Rule With Comment Period Implementing Legislative Extensions Relating to the Payment Adjustments for Low-Volume Hospitals and the Medicare-Dependent, Small Rural Hospital (MDH) Program

In the interim final rule with comment period (IFC) that appeared in the **Federal Register** on August 17, 2015 (80 FR 49594 through 49597), we addressed the legislative extension of the MDH program as well as certain provisions relating to payment to low-volume hospitals under the IPPS made by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Public Law 114–10. (For the remainder of this section, we will refer to this IFC as the ''August 2015 IFC''.) Section 204 of the MACRA extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment under the IPPS, originally provided for by the Affordable Care Act, for discharges occurring on or after April 1, 2015 through FY 2017 (September 30, 2017). Section 205 of the MACRA extended the MDH program for hospital discharges occurring on or after April 1, 2015 through FY 2017 (September 30, 2017).

In this final rule, we discuss the provisions of the August 2015 IFC, acknowledge the public comments received (which we determined were all outside the scope of the provisions of the IFC), and state the final policy (which we are not modifying from the IFC).

1. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

a. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital that is paid under IPPS beginning in FY 2005, and the low-volume hospital payment policy is set forth in the regulations at 42 CFR 412.101. Sections 3125 and 10314 of the Affordable Care Act provided for a temporary change in the low-volume hospital payment policy for FYs 2011 and 2012. Specifically, the provisions of the Affordable Care Act amended the qualifying criteria for low-volume hospitals to specify, for FYs 2011 and 2012, that a hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A during the fiscal year. In addition, the statute as amended by the Affordable Care Act, provides that the low-volume hospital payment adjustment (that is, the percentage increase) is to be determined using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year. We revised the regulations governing the low-volume hospital policy at § 412.101 to reflect the changes to the qualifying criteria and the payment adjustment for low-volume hospitals according to the provisions of the Affordable Care Act in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414).

The temporary changes to the low-volume hospital qualifying criteria and payment adjustment originally provided for by the Affordable Care Act have been extended by subsequent legislation as

follows: Through FY 2013 by the American Taxpayer Relief Act of 2012 (ATRA), Public Law 112–240; through March 31, 2014, by the Pathway for SGR Reform Act of 2013, Public Law 113–167; through March 31, 2015, by the Protecting Access to Medicare Act of 2014 (PAMA), Public Law 113–93; and most recently through FY 2017 by section 204 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10. The extension provided by section 204 of the MACRA is discussed in greater detail in section IV.L.2.b. of the preamble of the August 2015 IFC and this final rule. For additional details on the implementation of the previous extensions, through March 31, 2015, of the temporary changes to the low-volume hospital qualifying criteria and payment adjustment originally provided for by the Affordable Care Act, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS notice (78 FR 14689 through 14691); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50611 through 50612); the FY 2014 IPPS interim final rule with comment period (79 FR 15022 through 15025); the FY 2014 IPPS notice (79 FR 34444 through 34446); and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49998 through 50001).

b. Implementation of Provisions of the MACRA for FY 2015

Section 204 of the MACRA provided for an extension of the temporary changes to the low-volume hospital qualifying criteria and payment adjustment for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017). As discussed in the August 2015 IFC (80 FR 49594), we addressed the extension of the temporary changes to the low-volume hospital payment policy for the last half of FY 2015, that is, for discharges occurring on or after April 1, 2015, through September 30, 2015, in instructions issued in Change Request 9197, Transmittals 3263 and 3281. Generally, hospitals that were receiving the low-volume hospital payment adjustment for FY 2015 as of March 31, 2015 continued to receive the adjustment for the second half of FY 2015, as long as the hospital continued to meet the applicable qualifying low-volume hospital criteria.

In the instructions issued in Change Request 9197, for discharges occurring on or after April 1, 2015, through September 30, 2015, consistent with the existing regulations at § 412.101(b)(2)(ii), we stated that the same discharge data used for the low-volume adjustment for discharges occurring during the first half of FY 2015 will continue to be used for discharges occurring during the last half of FY 2015, as these data were the most recent available data at the time of the development of the FY 2015 payment rates. Specifically, for FY 2015 discharges occurring on or after April 1, 2015, through September 30, 2015, the low-volume hospital qualifying criteria and payment adjustment (percentage increase) is determined using FY 2013 Medicare discharge data from the March 2014 update of the MedPAR files. These discharge data can be found in Table 14 of the Addendum to the FY 2015 IPPS/LTCH PPS final rule, which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2015-IPPS-Final-Rule-Home-Page-Items/FY2015-Final-Rule-Tables.html*. We note that, consistent with past practice, Table 14 is a list of IPPS hospitals with fewer than 1,600 Medicare discharges and is not a listing of the hospitals that qualify for the low-volume adjustment for FY 2015; it does not reflect whether or not the hospital meets the mileage criterion (that is, the hospital must also be located more than 15 road miles from any other IPPS hospital). In order to receive the applicable low-volume hospital payment adjustment (percentage increase) for FY 2015 discharges, a hospital must meet both the discharge and mileage criteria. We discussed the conforming changes to the regulations at § 412.101 consistent with the extension of the temporary changes to the low-volume hospital definition and payment adjustment provided by section 204 of the MACRA in section IV.L.2.c. of the preamble of the August 2015 IFC.

c. Low-Volume Hospital Definition and Payment Adjustment for FY 2016

As discussed in the August 2015 IFC (80 FR 49595) and above, under section 1886(d)(12) of the Act, as amended by section 204 of the MACRA, the temporary changes in the low-volume hospital payment policy originally provided by the Affordable Care Act and extended through subsequent legislation, are effective through FY 2017. Under the prior extension, in accordance with section 105 of PAMA, those temporary changes in the low-volume hospital payment policy were to be in effect for discharges on or before March 31, 2015 only. We stated in the August 2015 IFC that, due to the timing of the development of the FY 2016 IPPS/LTCH PPS proposed rule and the enactment of the MACRA, we were unable to address the extension of the changes in the low-volume hospital payment policy for FY 2016 (or the last half of FY 2015, as discussed in section IV.L.2.b. of the preamble of the August 2015 IFC) in that proposed rule. In the August 2015 IFC, we revised the regulations at § 412.101 to conform to the provisions of section 204 of the MACRA.

To implement the low-volume hospital payment adjustment for FY 2016 consistent with provisions of the MACRA, in accordance with existing § 412.101(b)(2)(ii) and consistent with our historical approach, we updated the discharge data source used to identify qualifying low-volume hospitals and calculate the payment adjustment (percentage increase). Under existing § 412.101(b)(2)(ii), for the applicable fiscal years, a hospital's Medicare discharges from the most recently available MedPAR data, as determined by CMS, are used to determine if the hospital meets the discharge criteria to receive the low-volume payment adjustment in the current year. The applicable low-volume percentage increase, as originally provided for by the Affordable Care Act, is determined using a continuous linear sliding scale equation that results in a low-volume hospital payment adjustment ranging from an additional 25 percent for hospitals with 200 or fewer Medicare discharges to a zero percent additional payment adjustment for hospitals with 1,600 or more Medicare discharges. For FY 2016, consistent with our historical policy, qualifying low-volume hospitals and their payment adjustment are determined using the most recently available Medicare discharge data from the March 2015 update of the FY 2014 MedPAR file, as these data are the most recent data available at the time of the development of the FY 2016 IPPS/LTCH PPS final rule and the August 2015 IFC. Table 14 listed in the Addendum of the FY 2016 IPPS/LTCH PPS final rule (which is available via the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp*) listed the ''subsection (d)'' hospitals with fewer than 1,600 Medicare discharges based on the claims data from this FY 2014 MedPAR file and their potential low-volume payment adjustment for FY 2016. Consistent with past practice, we noted that this list of hospitals with fewer than 1,600 Medicare discharges in Table 14 did not reflect whether or not the hospital meets the mileage criterion. Eligibility for the low-volume hospital payment adjustment for FY 2016 also is dependent upon meeting the mileage

criterion specified at § 412.101(b)(2)(ii); that is, the hospital must be located more than 15 road miles from any other IPPS hospital. In other words, eligibility for the low-volume hospital payment adjustment for FY 2016 also is dependent upon meeting (in the case of a hospital that did not qualify for the low-volume hospital payment adjustment in FY 2015) or continuing to meet (in the case of a hospital that did qualify for the low-volume hospital payment adjustment in FY 2015) the mileage criterion specified at revised § 412.101(b)(2)(ii) (that is, the hospital is located more than 15 road miles from any other subsection (d) hospital).

In order to receive a low-volume hospital payment adjustment under § 412.101 for FY 2016, consistent with our previously established procedure, a hospital must notify and provide documentation to its MAC that it meets the discharge and distance requirements under § 412.101(b)(2)(ii), as revised. Specifically, for FY 2016, a hospital must have made a written request for low-volume hospital status that was received by its MAC no later than September 1, 2015, in order for the applicable low-volume hospital payment adjustment to be applied to payments for its FY 2016 discharges occurring on or after October 1, 2015. Under this procedure, a hospital that qualified for the low-volume payment adjustment in FY 2015 may continue to receive a low-volume payment adjustment for FY 2016 without reapplying if it continues to meet the Medicare discharge criterion established for FY 2016 and the mileage criterion. However, the hospital had to send written verification that was received by its MAC no later than September 1, 2015, stating that it continues to be more than 15 miles from any other ''subsection (d)'' hospital. This written verification could be a brief letter to the MAC stating that the hospital continues to meet the low-volume hospital distance criterion as documented in a prior low-volume hospital status request. We stated that if a hospital's written request for low-volume hospital status for FY 2016 was received after September 1, 2015, and if the MAC determines that the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine the payment for the hospital's FY 2016 discharges, effective prospectively within 30 days of the date of its low-volume hospital status determination, consistent with past practice. (For additional details on our established process for the low-volume hospital payment adjustment, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53408) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50000 through 50001).)

In the August 2015 IFC, we made conforming changes to the existing regulations text at § 412.101 to reflect the extension of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals through FY 2017 (that is, through September 30, 2017) in accordance with section 204 of the MACRA. In general, these conforming changes consisted of replacing the phrase ''through FY 2014, and the portion of FY 2015 before April 1, 2015'' with ''through FY 2017'' each place it appears, and replacing the phrase ''the portion of FY 2015 beginning on April 1, 2015, and subsequent fiscal years'' with the phrase ''FY 2018 and subsequent fiscal years'' each place it appears. Specifically, we revised paragraphs (b)(2)(i), (b)(2)(ii), (c)(1), (c)(2), and (d) of § 412.101. Under these revisions to § 412.101, beginning with FY 2018, consistent with section 1886(d)(12) of the Act, as amended, the low-volume hospital qualifying criteria and payment adjustment methodology will revert to that which was in effect prior to the amendments made by the Affordable Care Act and subsequent legislation (that is, the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010).

2. Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

a. Background for MDH Program

Section 1886(d)(5)(G) of the Act provides special payment protections, under the IPPS, to a Medicare-dependent, small rural hospital (MDH). (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).)

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program has been extended by subsequent legislation as follows: First, section 606 of the ATRA (Pub. L. 112–240) extended the MDH program through FY 2013 (that is, for discharges occurring before October 1, 2013). Second, section 1106 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) extended the MDH program through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Third, section 106 of the PAMA (Pub. L. 113–93) extended the MDH program through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015). Most recently, section 205 of the MACRA (Pub. L. 114–10) extended the MDH program though FY 2017 (that is, for discharges occurring before October 1, 2017). For additional information on the extensions of the MDH program after FY 2012, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53413 through 53414); the FY 2013 IPPS notice (78 FR 14689); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50647 through 50649); the FY 2014 interim final rule with comment period (79 FR 15025 through 15027); the FY 2014 notice (79 FR 34446 through 34449); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50022 through 50024); and the August 2015 IFC (80 FR 49596).

b. MACRA Provisions for Extension of the MDH Program

Section 205 of the MACRA provided for an extension of the MDH program for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Specifically, section 205 of the MACRA amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act by striking ''April 1, 2015'' and inserting ''October 1, 2017''. Section 205 of the MACRA also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act.

In the August 2015 IFC (80 FR 49596), we made conforming changes to the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the extension of the MDH program provided for by the MACRA. We stated in that IFC that, due to the timing of the development of the FY 2016 IPPS/LTCH PPS proposed rule and the enactment of the MACRA, we were unable to address the extension of the MDH program for FY 2016 (or the last half of FY 2015) in that proposed rule. After the MACRA was enacted, we addressed the extension of the MDH program for the last half of FY 2015 (that is, for discharges occurring on or after April 1, 2015, through September 30, 2015) in instructions issued in Change Request 9197, Transmittals 3263 and 3281.

As explained in Change Request 9197, consistent with the previous extensions of the MDH program and the regulations at § 412.108, generally, a provider that was classified as an MDH as of March 31, 2015, was reinstated as an MDH effective April 1, 2015, with no need to reapply for MDH classification. However, if the MDH had classified as

an SCH or cancelled its rural classification under § 412.103(g) effective on or after April 1, 2015, the effective date of MDH status may not be retroactive to April 1, 2015. For more details regarding MDH status for the second half of FY 2015, we refer the reader to Change Request 9197.

3. Statement of Final Policy

We received 14 timely pieces of correspondence in response to the August 2015 IFC. We have determined that all of this correspondence contains public comments on issues that were outside the scope of the provisions of the IFC. Therefore, we are finalizing the provisions of the August 2015 IFC without modification.

4. Collection of Information Requirements

The August 2015 IFC and this final rule do not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

5. Impact of Legislative Extensions

In the August 2015 IFC, we presented the estimated effects of the provisions. This impact has not changed. Therefore, below we are presenting the impact as set forth in that IFC.

a. Effects of the Payment Adjustment for Low-Volume Hospitals for FY 2016

Based on the latest available data at the time of the August 2015 IFC, we estimated that approximately 593 hospitals will qualify as a low-volume hospital in FY 2016. We projected that the extension for FY 2016 of the temporary changes to the low-volume hospital definition and the payment adjustment methodology provided for by the MACRA will result in an increase in payments of approximately $322 million in FY 2016 as compared to payments to qualifying hospitals without the extension of the temporary changes to the low-volume hospital definition and the payment adjustment methodology.

b. Effects of the Extension of the MDH Program for FY 2016

Hospitals that qualify as MDHs receive the higher of operating IPPS payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the amount by which the hospital-specific rate (a hospital-specific cost-based rate) exceeds the Federal standardized amount. Based on the latest available data we had for 163 MDHs at the time of the August 2015 IFC, we projected that 90 MDHs will receive the blended payment (that is, the Federal standardized amount plus 75 percent of the amount by which the hospital-specific rate exceeds the Federal standardized amount) for FY 2016. We estimated that those hospitals will experience an overall increase in payments of approximately $96 million as compared to payments they would have received had the MDH program not been extended for FY 2016.

O. Clarification Regarding the Medicare Utilization Requirement for Medicare-Dependent, Small Rural Hospitals (MDHs) (§ 412.108)

Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in FY 1987 or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report were attributable to inpatients entitled to benefits under Part A). The regulations at 42 CFR 412.108 set forth the criteria that a hospital must meet to be classified as an MDH.

The Medicare utilization requirement is set forth at section 1886(d)(5)(G)(iv)(IV) of the Act and implemented by regulation at 42 CFR 412.108(a)(1)(iii). Consistent with the policy noted in the FY 1991 IPPS final rule (55 FR 35995) and further discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287), in order to not disadvantage hospitals that receive payment from a Medicare Advantage (MA) organization under Medicare Part C for inpatient care provided to Medicare beneficiaries enrolled in Medicare Part C plans, we count the days and discharges for those stays toward the 60-percent Medicare utilization requirement for MDH classification.

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25135 through 25136), in accordance with the regulations at § 412.108(b)(5), MACs evaluate, on an ongoing basis, whether or not a hospital continues to qualify for MDH status. For hospitals that qualify for MDH status under § 412.108(a)(1)(iii)(C) and in accordance with the regulations at § 412.108(b)(5), at each cost report settlement, the MAC will determine whether the hospital has a Medicare utilization of at least 60 percent in at least two of the last three most recent audited cost reporting periods for which the Secretary has a settled cost report by including the newly settled cost report in the evaluation.

Medicare policy requires hospitals that receive certain additional payments such as IME, direct GME, and DSH, to submit claims for services furnished to individuals enrolled in a MA plan under Medicare Part C. Specifically, teaching hospitals that provide services to individuals enrolled in a MA plan under Medicare Part C must submit timely claims in order to receive the supplemental IME and direct GME payments for services provided to these individuals. Likewise, hospitals that operate nursing or allied health education programs and incur costs associated with individuals enrolled in a MA plan under Medicare Part C also must submit timely claims in order to receive the additional payment amount for those MA enrollees. In addition, hospitals that are eligible for DSH payments are required to submit claims in a timely manner for individuals enrolled in a MA plan under Medicare Part C in order for these days to be captured in the DSH calculation. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53409) for more information and background on the requirements for filing no pay bills for services furnished to individuals enrolled in a MA plan under Medicare Part C.

Consistent with this policy, for a hospital that is eligible for IME, direct GME, or DSH payments, CMS only includes MA days or discharges as reported on the cost report and verified by the properly and timely submitted claims for the services furnished to individuals enrolled in a MA plan under Medicare Part C associated with those days or discharges in calculating Medicare utilization for MDH purposes. CMS verifies the accuracy of the MA days and discharges reported on the cost report using claims data; once verified, the cost report data can then be properly applied in the Medicare utilization calculation.

For a hospital that is not eligible for IME, direct GME, or DSH payments and is not required to submit bills for services furnished to individuals enrolled in a MA plan under Medicare Part C, we clarified in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25136) that CMS will include the MA days or discharges associated with those services in the Medicare utilization calculation, regardless of whether the hospital submitted claims for services associated with those days or discharges

provided that the hospital submits proper documentation, such as provider logs, that allow the MAC to verify the MA days or discharges as reported on the hospital's cost report. However, as we noted in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25136), while not required, timely submission of claims for the services furnished to individuals enrolled in a MA plan under Medicare Part C allows CMS to establish whether the hospital meets the MDH classification criteria in an expeditious and timely manner. We note that we did not receive any public comments on this clarification.

P. Adjustment to IPPS Rates Resulting From 2-Midnight Policy

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50906 through 50954), we adopted the 2-midnight policy, effective for dates of admission on or after October 1, 2013. As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25136 through 25138), under the 2-midnight policy, an inpatient admission is generally appropriate for Medicare Part A payment if the physician (or other qualified practitioner) admits the patient as an inpatient based upon the reasonable expectation that the patient will need hospital care that crosses at least 2 midnights. In assessing the expected duration of necessary care, the physician (or other qualified practitioner) may take into account outpatient hospital care received prior to inpatient admission. If the patient is expected to need less than 2 midnights of care in the hospital, the services furnished should generally be billed as outpatient services. We note that revisions were made to this policy in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70545). Our actuaries estimated that the 2-midnight policy would increase expenditures by approximately $220 million in FY 2014 due to an expected net increase in inpatient encounters. We used our authority under section 1886(d)(5)(I)(i) of the Act to make a reduction of 0.2 percent to the standardized amount, the Puerto Rico standardized amount, and the hospital-specific payment rates, and we used our authority under section 1886(g) of the Act to make a reduction of 0.2 percent to the national capital Federal rate and the Puerto Rico-specific capital rate, in order to offset this estimated $220 million in additional IPPS expenditures in FY 2014. We indicated that although our exceptions and adjustments authority should not be routinely used in the IPPS system, we believed that the systemic and widespread nature of this issue justified an overall adjustment to the IPPS rates and such an adjustment is authorized under section 1886(d)(5)(I)(i) of the Act.

In *Shands Jacksonville Medical Center, Inc.* v. *Burwell,* No. 14–263 (D.D.C.) and related cases, hospitals challenged the 0.2 percent reduction in IPPS rates to account for the estimated $220 million in additional FY 2014 expenditures resulting from the 2-midnight policy. In its Memorandum Opinion, issued September 21, 2015, the Court found that the ''Secretary's interpretation of the exceptions and adjustments provision is a reasonable one'' for this purpose. However, the Court also ordered the 0.2 percent reduction remanded back to the Secretary, without vacating the rule, to correct certain procedural deficiencies in the promulgation of the 0.2 percent reduction and reconsider the adjustment. The Court did not believe it would be appropriate to vacate the rule because such action would, in effect, dictate a substantive outcome based on a procedural error and concluded that the disruptive consequences would be considerable.

In accordance with the Court's order, we published a notice with comment period that appeared in the December 1, 2015 **Federal Register** (80 FR 75107), which discussed the basis for the 0.2 percent reduction and its underlying assumptions and invited comments on the same in order to facilitate our further consideration of the FY 2014 reduction. We received numerous public comments on the notice with comment period.

In considering these public comments, and those on the same topic received in response to the CY 2016 OPPS/ASC proposed rule, we continued to recognize that the 0.2 percent reduction issue is unique in many ways. The underlying question of patient status, which resulted in the creation of the 2-midnight policy, is a complex one with a long history, including large improper payment rates in short-stay hospital inpatient claims, requests to provide additional guidance regarding the proper billing of those services, and concerns about increasingly long stays of Medicare beneficiaries as outpatients due to hospital uncertainties about payment. (For further discussion of this history, we refer readers to the FY 2014 IPPS/LTCH PPS proposed and final rules (78 FR 27644 through 27649 and 78 FR 50906 through 50954, respectively).)

The 2-midnight policy itself and our implementation and enforcement of it have also evolved over time as a result of a combination of statutory, regulatory, and operational changes. For example, as part of our efforts to provide education to stakeholders on the new 2-midnight policy, CMS hosted numerous ''Open Door Forums,'' conducted national provider calls, and shared information and answers to frequently asked questions on the CMS Web site. In addition, we instructed MACs to conduct a ''Probe and Educate'' process for inpatient claims with dates of admission on or after October 1, 2013 through September 30, 2014, to assess provider understanding and compliance with the new 2-midnight policy. We also prohibited Recovery Auditor's post-payment medical reviews of inpatient hospital patient status for claims with dates of admission between October 1, 2013 and September 30, 2014.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) was enacted. Section 111 of Public Law 113–93 permitted CMS to continue medical review activities under the Inpatient Probe and Educate process through March 31, 2015. The same law also extended the prohibition on Recovery Auditor reviews of inpatient hospital patient status for claims with dates of admission through March 31, 2015, absent evidence of systematic gaming, fraud, abuse, or delays in the provision of care by a provider of services. On April 16, 2015, the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) was enacted. Section 521 of Public Law 114–10 permitted CMS to further extend the medical review activities under the Inpatient Probe and Educate process for inpatient claims through September 30, 2015, and extended the prohibition of Recovery Auditor reviews of inpatient hospital patient status for claims with dates of admission through September 30, 2015. CMS then announced in August 2015 that it would not approve Recovery Auditors to conduct patient status reviews for dates of admission of October 1, 2015 through December 31, 2015.

As we indicated in the CY 2016 OPPS/ASC final rule with comment period, throughout the Probe and Educate process, we saw positive effects and improved provider understanding of the 2-midnight policy. We also discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70545 through 70549) a number of additional changes we had made and were continuing to make to the Recovery Audit Program and changes to the medical review responsibilities for Quality Improvement Organizations (QIOs) in regard to short hospital stay claims.

With respect to the 2-midnight policy itself, in light of stakeholder concerns

and in our continued effort to develop the most appropriate and applicable framework for determining when payment under Medicare Part A is appropriate for inpatient admissions, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70545), we modified the original ''rare and unusual'' exceptions policy under the 2-midnight policy to allow for Medicare Part A payment on a case-by-case basis for inpatient admissions that do not satisfy the 2-midnight benchmark, if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than 2 midnights.

We also recognized in reviewing the public comments we received on the 0.2 percent reduction in response to the December 1, 2015 notice with comment period and the CY 2016 OPPS/ASC proposed rule that, in addition to the long history of the question of patient status underlying the 2-midnight policy and the statutory, regulatory, and operational changes that have occurred since its initial implementation, the original estimate for the 0.2 percent reduction had a much greater degree of uncertainty than usual. As indicated in the Office of the Actuary's August 19, 2013 memorandum (which was included as Appendix A of the December 1, 2015 notice with comment period (80 FR 75112 through 75114)), the estimate depended critically on the assumed utilization changes in the inpatient and outpatient hospital settings, relatively small changes would have a disproportionate effect on the estimated net costs, the estimate was subject to a much greater degree of uncertainty than usual, and the actual results could differ significantly from the estimate.

Lastly, in reviewing the public comments we received on the December 1, 2015 notice with comment period, we also considered the fact that our actuaries' most recent estimate of the impact of the 2-midnight policy varies between a savings and a cost over the FY 2014 to FY 2015 time period. The memorandum describing this new analysis is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

We still believe the assumptions underlying the 0.2 percent reduction to the rates put in place beginning in FY 2014 were reasonable at the time we made them in 2013. Nevertheless, taking all the foregoing factors into account, we stated in the FY 2017 IPPS/LTCH PPS proposed rule that we believe it would be appropriate to use our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to prospectively remove, beginning in FY 2017, the 0.2 percent reduction to the rates put in place beginning in FY 2014. The 0.2 percent reduction was implemented by including a factor of 0.998 in the calculation of the FY 2014 standardized amount, the hospital-specific payment rates, and the national capital Federal rate, permanently reducing the rates for FY 2014 and future years until the 0.998 is removed. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25138), we proposed to permanently remove the 0.998 reduction beginning in FY 2017 by including a factor of (1/0.998) in the calculation of the FY 2017 standardized amount, the hospital-specific payment rates, and the national capital Federal rate.

In addition, taking all the foregoing factors into account, and given the unique nature of this situation, we stated in the proposed rule that we believe it would be appropriate to use our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to temporarily increase the rates, only for FY 2017, to address the effect of the 0.2 percent reduction to the rates in effect for FY 2014, the 0.2 percent reduction to the rates in effect for FY 2015 (recall the 0.998 factor included in the calculation of the FY 2014 rates permanently reduced the rates for FY 2014 and future years until it is removed), and the 0.2 percent reduction to the rates in effect for FY 2016. We believe that the most transparent, expedient, and administratively feasible method to accomplish this is a temporary one-time prospective increase to the FY 2017 rates of 0.6 percent (= 0.2 percent + 0.2 percent + 0.2 percent). Specifically, we proposed to include a factor of 1.006 in the calculation of the standardized amount, the hospital-specific payment rates, and the national capital Federal rate in FY 2017 and then remove this temporary one-time prospective increase by including a factor of (1/1.006) in the calculation of the rates for FY 2018. While we generally do not believe it is appropriate in a prospective system to retrospectively adjust rates, we take this action in the specific context of this unique situation.

In summary, for the reasons described above, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25138), we proposed to include a permanent factor of (1/0.998) and a temporary one-time factor of (1.006) in the calculation of the FY 2017 standardized amount, the hospital-specific payment rates, and the national capital Federal rate. We also proposed to include a factor of (1/1.006) in the calculation of the FY 2018 standardized amount, the hospital-specific payment rates, and the national capital Federal rate to remove the temporary one-time factor of 1.006.

We invited public comments on all aspects of these proposals. As we stated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25138), the foregoing discussion and proposals constituted the final notice required by the Court in the *Shands Jacksonville Medical Center, Inc.* v. *Burwell,* No. 14–263 (D.D.C.) and related cases.

Comment: The vast majority of commenters recognized the unique nature of this situation and supported prospectively removing the 0.2 percent reduction to the rates and making a temporary one-time prospective increase to the FY 2017 rates to address the effect of the 0.2 percent reduction to the rates for FYs 2014 through 2016. One commenter suggested that, instead of a temporary one-time prospective increase to the FY 2017 rates, CMS adjust over a 3-year FY 2017–FY 2019 time period because the reduction was in place over the 3-year FY 2014–FY 2016 time period.

Response: We appreciate the commenters' recognition of the unique nature of this situation and their support for prospectively removing, beginning in FY 2017, the 0.2 percent reduction to the rates put in place beginning in FY 2014, and making a temporary one-time prospective increase to the FY 2017 rates to address the effect of the 0.2 percent reduction to the rates for FYs 2014 through 2016. We do not agree with the commenter who suggested that we should adjust over a 3 year FY 2017–FY 2019 time period because the reduction was in place over the 3-year FY 2014–FY 2016 time period. The nearest prospective time period that we can use to address the effect of the 0.2 percent reduction to the rates for FYs 2014 through 2016 is FY 2017. As we stated in the proposed rule, our goal is a transparent, expedient, and administratively feasible method. Delaying addressing the effect for FYs 2014 through 2016 over 3 years rather than the more immediate 1 year method we proposed is not an expedient method of resolving this issue.

Comment: Some commenters raised concerns about the adequacy of the proposed adjustment relative to their estimates of the impact of the 2-midnight policy to date. These commenters included statements that: Stakeholders had provided CMS with data that indicated that the 2-midnight policy had been a net savings with respect to Medicare expenditures; CMS

did not address the utilization shift between inpatient and outpatient cases caused by the 2-midnight policy which CMS referred to in the FY 2014 proposed and final rules and which is in the opposite direction of what CMS assumed; CMS should adopt a rate increase to offset an asserted decline in expenditures resulting from the 2-midnight policy; contrary to CMS' assumptions about the 2-midnight policy, rather than cases shifting between inpatient and outpatient, the entire population of relevant hospital episodes declined over time; and CMS actuary's analysis was flawed for numerous reasons, including because it assumed that the entire deviation from the historical trend line was attributable to the 2-midnight policy.

Response: We believe these commenters are mischaracterizing our proposal. In making our proposal, we were not attempting to determine a new point estimate of the effect of the 2-midnight policy for the purposes of then proposing (1) a prospective adjustment to the rates for the net effect of that new estimate relative to the −0.2 percent adjustment we put in place in FY 2014 and (2) a temporary one-time adjustment to the rates in FY 2017 to address the net effects of that new estimate over the FY 2014–FY 2016 time period. Rather than determine a new point estimate, we proposed to *remove* the −0.2 percent adjustment we did make and address the effect of that adjustment for FYs 2014 through 2016. As we have indicated in prior rulemaking, we were not required by statute to make an adjustment to the rates for the effect of the 2-midnight policy. We chose to do so at the time for the reasons stated in the prior rulemaking. However, for the reasons stated in the proposed rule, we proposed to no longer make *any* adjustment for the 2-midnight policy and address the FY 2014–FY 2016 effects of the adjustment we did make. For many of the reasons commenters presented to us in prior rulemaking, we no longer are confident that the effect of the 2-midnight policy on the number of discharges paid under the IPPS may be measured in this context. As a result, we proposed to make no adjustment (and account for the past effects of the adjustment we had made), not to make a new adjustment.

We currently do not intend to revisit the issue of making an adjustment for the 2-midnight policy in future rulemaking. However, if we were to make a proposal in future rulemaking, we would take into account all of the public comments received to date on the impact of the 2-midnight policy and any public comments received on a future proposal.

Comment: Commenters indicated that a very small number of hospitals would not benefit from the adjustments to the FY 2017 rates. Hospitals that were paid under the IPPS for all or part of FY 2014, 2015, or 2016, but will not be paid under the IPPS for all of FY 2017 (either because they closed or converted to a different type of hospital) would not receive the full benefit of the payment adjustments. The commenters requested that CMS establish an exceptions process to address this issue. One commenter also indicated that new hospitals would receive the benefit of the FY 2017 adjustment even though they were not affected by the −0.2 percent adjustments for FY 2014, 2015, and 2016.

Response: We recognize that for closed, converted, or new hospitals, our proposed prospective method generally has a differential positive or negative impact compared to hospitals that were IPPS hospitals for all of the FY 2014–FY 2017 time period. We generally believe that, given the prospective nature of our method and our goal to adopt a transparent, expedient, and administratively feasible approach, these differential impacts are an appropriate consequence. However, after considering the public comments received, we agree that we should provide a process to address the situation of closed or converted hospitals. Due to the small number of hospitals impacted, we will address closed and converted hospitals as part of the cost report settlement process. These hospitals should identify themselves to their MACs so that the appropriate cost report adjustment can be applied.

Comment: Some commenters stated the multiplicative effect of the FY 2017 0.6 percent adjustment would not fully compensate hospitals for the effect of the −0.2 percent adjustment for FYs 2014 through FY 2016 for reasons that included the recent trend of a decline in inpatient admissions.

Response: We recognize that our proposed method of a prospective 1.006 adjustment for FY 2017 generally may have a differential *positive or negative* impact on an individual hospital relative to an attempt to estimate hospital by hospital the impact of the 2-midnight adjustment for FYs 2014, 2015, and 2016. As stated in the prior response, we generally believe that, given the prospective nature of our method and our goal to adopt a transparent, expedient, and administratively feasible approach, these differential impacts are an appropriate consequence. We also note that attempts to make prospective adjustments to the 1.006 factor would need to rely on estimates of factors that have been objected to by commenters in the prior rulemaking related to the −0.2 percent adjustment, such as estimates regarding projected inpatient utilization levels.

Comment: Some commenters stated that the FY 2017 adjustment to address the effects of the −0.2 percent adjustment for FYs 2014, 2015, and 2016 does not compensate hospitals that are party to the lawsuit for interest and/or all hospitals for the time value of money. Some commenters suggested that CMS refine the 1.006 percent adjustment to account for this or otherwise address the issue.

Response: We will not contest that hospitals that are party to the *Shands Jacksonville Medical Center, Inc.* v. *Burwell,* No. 14–263 (D.D.C.) and other currently pending cases that challenge the −0.2 percent adjustment should receive interest under section 1878(f)(2) of the Act. For these hospitals, we will slightly increase the 1.006 factor by a uniform factor consistent with the interest rates used for this purpose in effect for the relevant time periods for paying interest. We disagree with commenters who indicated that we should pay all hospitals interest or for the time value of money.

After consideration of the public comments we received, we are finalizing our proposal to adjust the FY 2017 IPPS rates through a permanent adjustment of 1.002 and temporary one-time prospective adjustment of 1.006, which will be removed by including a factor of (1/1.006) in the calculation of the FY 2018 rates.

V. Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment

methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under §§ 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Changes in Payments for Hospitals Located in Puerto Rico

The existing regulations at 42 CFR 412.374 relating to the capital IPPS provide for the use of a blended payment amount for prospective payments for capital-related costs to hospitals located in Puerto Rico. Accordingly, under the capital IPPS, we have historically computed a separate payment rate specific to Puerto Rico hospitals using the same methodology used to compute the national Federal rate for capital-related costs. The capital-related payment rate for hospitals located in Puerto Rico was derived using only the costs of hospitals located in Puerto Rico, while the national Federal rate for capital-related costs is derived using the costs of all acute care hospitals participating in the IPPS (including hospitals located in Puerto Rico). In general, hospitals located in Puerto Rico are paid a blend of the applicable capital IPPS Puerto Rico rate and the applicable capital IPPS Federal rate. Historically, we have established a capital IPPS blended payment rate structure for hospitals located in Puerto Rico that parallels the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico. Under existing regulations at 42 CFR 412.374, capital IPPS payments to hospitals located in Puerto Rico are computed based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS Federal rate. (For additional details on capital IPPS payments to hospitals located in Puerto Rico, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).)

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25139), section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. (For additional information on section 601 of the Consolidated Appropriations Act, 2016, we refer readers to section IV.A. of the preamble of this final rule.) As a result of the amendment made by section 601 of Public Law 114–113, on February 4, 2016, we issued Change Request 9523 which updated the payment rates for subsection (d) Puerto Rico hospitals for discharges occurring on or after January 1, 2016. Change Request 9523 can be downloaded from the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2016-Transmittals-Items/R3449CP.html*).

Consistent with historical practice, under the broad authority of the Secretary granted under section 1886(g) of the Act, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25139), we proposed to revise the calculation of capital IPPS payments to hospitals located in Puerto Rico to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, beginning in FY 2017. Accordingly, we proposed to revise § 412.374 of the regulations to provide that, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico would be based on 100 percent of the capital Federal rate; that is, payments would no longer be derived from a blend of the capital Puerto Rico rate and the capital Federal rate.

We did not receive any public comment on this proposal or the proposed revisions to § 412.374. Therefore, we are finalizing our proposal, with one technical correction modification to the proposed revisions to § 412.374. We are making a technical correction to the heading of § 412.374(e) to comport with our finalized policies and the finalized text of paragraph (e). In the proposed rule, we inadvertently stated in the heading of proposed § 412.374(e) that the policies in that paragraph are for FYs 2016 and later, instead of FY 2017 and later. In this final rule, we are revising the heading of § 412.374(e) to read ''FY 2017 and subsequent fiscal years,'' consistent with the effective date of our finalized policies, which are for discharges on or after October 1, 2016 (that is, FY 2017).

As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico will be based on 100 percent of the capital Federal rate. As we noted in the proposed rule and are noting in this final rule, this change is similar to the changes in capital IPPS payments to hospitals located in Puerto Rico beginning in FY 1998 and FY 2005 that paralleled the corresponding statutory changes in the blended payment amount calculation required for operating IPPS payments to hospitals located in Puerto Rico, as provided by section 4406 of Public Law 105–33 (62 FR 46048) and section 504 of Public Law 108–173 (69 FR 49185), respectively. As discussed in section I.I. of Appendix A (Economic Analyses) of this final rule, this change will result in a slight increase in capital IPPS payments to hospitals located in Puerto Rico because adjusted capital IPPS payments based on the capital Federal rate are generally higher than capital IPPS payments based on the capital Puerto Rico rate.

C. Annual Update for FY 2017

The annual update to the capital PPS Federal rate, as provided for at § 412.308(c), for FY 2017 is discussed in section III. of the Addendum to this final rule. Consistent with our finalized policy discussed under section V.B.3. of the preamble of this final rule to revise the calculation of capital IPPS payments to hospitals located in Puerto Rico to be based on 100 percent of the capital Federal rate (and no longer based on a blend of the capital Puerto Rico rate and the capital Federal rate), we are discontinuing the use of the Puerto Rico capital rate in the calculation of capital IPPS payments to hospitals located in Puerto Rico, effective October 1, 2016 (FY 2017).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50906 through 50954), we adopted the 2-midnight policy effective for dates of admission on or after October 1, 2013, under which an inpatient admission is generally appropriate for Medicare Part A payment if the physician (or other qualified practitioner) admits the patient as an inpatient based upon the reasonable expectation that the patient will need hospital care that crosses at least 2 midnights. At that time, our actuaries estimated that the 2-midnight policy would increase expenditures by approximately $220 million in FY 2014 due to an expected net increase in inpatient encounters. In that same final rule, consistent with the approach taken for the operating IPPS standardized amount, the Puerto Rico-specific standardized amount, and the hospital-specific payment rates, and using our authority under section 1886(g) of the Act, we made a reduction of 0.2 percent (an adjustment factor of 0.998) to the national capital Federal rate and the Puerto Rico-specific capital rate to offset the estimated increase in capital IPPS expenditures associated with the projected increase in inpatient encounters that was expected to result from the new inpatient admission guidelines (78 FR 50746 through 50747).

As discussed in section IV.O. of the preamble of the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25136 through 25138) and section IV.P. of the preamble of this final rule, in *Shands Jacksonville Medical Center, Inc.* v. *Burwell,* No. 14–263 (D.D.C.) and related cases, hospitals challenged the 0.2 percent reduction in IPPS rates to account for the estimated $220 million in additional FY 2014 expenditures resulting from the 2-midnight policy. In accordance with the Court's order, we published a notice with comment period that appeared in the December 1, 2015 **Federal Register** (80 FR 75107), which discussed the basis for the 0.2 percent reduction and its underlying assumptions and invited comments on the same in order to facilitate our further consideration of the FY 2014 reduction. In section IV.O. of the preamble of the proposed rule (81 FR 25136 through 25138), we discussed that, in considering the public comments we received on that notice with comment period and those on the same topic we received in response to the CY 2016 OPPS/ASC proposed rule, we continued to recognize that the 0.2 percent reduction issue is unique in many ways. As we discussed in that section, the 2-midnight policy itself and our implementation and enforcement of it have also evolved over time as a result of a combination of statutory, regulatory, and operational changes. Finally, in reviewing the public comments received on the December 1, 2015 notice with comment period, we also considered the fact that our actuaries' most recent estimate of the impact of the 2-midnight policy varies between a savings and a cost over the FY 2014 to FY 2015 time period. (For additional details, we refer readers to section IV.O. of the preamble of the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25136 through 25138) and section IV.P. of the preamble of this final rule.)

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25139 through 25140), we still believe the assumptions underlying the 0.2 percent reduction to the rates put in place beginning in FY 2014 were reasonable at the time we made them in 2013. Nevertheless, taking all of these factors into account, consistent with the approach proposed for the operating IPPS rates, we stated that we believe it would be appropriate to use our authority under section 1886(g) of the Act to permanently remove the 0.2 percent reduction to the capital IPPS rate beginning in FY 2017. (As explained in section V.B.3. of the proposed rule, we proposed to discontinue use of the Puerto Rico capital rate in the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017.) Specifically, we proposed to make an adjustment of (1/0.998) to the national capital Federal rate to remove the 0.2 percent reduction, consistent with the proposed adjustment to the operating IPPS standardized amount and the hospital-specific payment rates. In addition, consistent with the approach proposed for the operating IPPS standardized amount and hospital-specific payment rates and for the reasons discussed in section IV.O. of the preamble of the proposed rule, we stated that we believe it would be appropriate to use our authority under section 1886(g) of the Act to adjust the FY 2017 capital IPPS rate to address the effects of the 0.2 percent reduction to the national capital Federal rates in effect for FY 2014, FY 2015, and FY 2016 by proposing a one-time prospective adjustment of 1.006 in FY 2017 to the national capital Federal rate. For FY 2018, we also proposed to remove the effects of this one-time prospective adjustment through an adjustment of (1/1.006) to the national capital Federal rate, consistent with the approach proposed for the operating IPPS standardized amount and hospital-specific payment rates. We invited public comments on these proposals.

In section IV.P. of the preamble of this final rule, we summarize and respond to public comments on our proposals to include a permanent factor of (1/0.998) and a temporary one-time factor of (1.006) in the calculation of the FY 2017 standardized amount, the hospital-specific payment rates, and the national capital Federal rate and to include a factor of (1/1.006) in the calculation of the FY 2018 standardized amount, the hospital-specific payment rates, and the national capital Federal rate to remove the temporary one-time factor of 1.006. After consideration of the public comments and for the reasons described in section IV.P. of the preamble of this final rule, we are finalize these proposals. We note that we did not receive any public comments that

specifically addressed our proposed adjustments to the national capital Federal rate. Accordingly, as stated in section IV.P. of this final rule, we are finalizing our proposal to adjust the FY 2017 national capital Federal rate through a permanent adjustment of 1.002 and temporary one-time prospective adjustment of 1.006, which will be removed by including a factor of (1/1.006) in the calculation of the FY 2018 rates.

As we noted in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25140), in section II.D. of the preamble of that rule, we presented a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the recoupment adjustment to the standardized amounts under section 1886(d) of the Act that we proposed for FY 2017 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 631 of the ATRA. Because section 631 of the ATRA requires us to make a recoupment adjustment only to the operating IPPS standardized amount, we did not propose to make a similar adjustment to the capital IPPS rate (or to the operating IPPS hospital-specific rates). This approach is consistent with our historical approach regarding the application of the recoupment adjustment authorized by section 7(b)(1)(B) of Public Law 110–90. We refer readers to section II.D. of the preamble of this final rule for a discussion of the recoupment adjustment to the operating IPPS standardized amount for FY 2017.

VI. Changes for Hospitals Excluded From the IPPS

A. Rate-of-Increase in Payments to Excluded Hospitals for FY 2017

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applies as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, RNHCIs also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, and RNHCIs. Consistent with §§ 412.23(g), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update the target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. As we finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50156 through 50157), for FY 2017, we will continue to use the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Accordingly, for FY 2017, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2017 percentage increase in the FY 2010-based IPPS operating market basket.

For the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25140), based on IHS Global Insight, Inc.'s 2016 first quarter forecast, we estimated that the FY 2010-based IPPS operating market basket update for FY 2017 was 2.8 percent (that is, the estimate of the market basket rate-of-increase). We indicated in the proposed rule that if more recent data became available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2017. For this FY 2017 IPPS/LTCH PPS final rule, based on IHS Global Insight, Inc.'s 2016 second quarter forecast (which is the most recent data available), we calculated the FY 2010-based IPPS operating market basket update for FY 2017 to be 2.7 percent. Therefore, the FY 2017 rate-of-increase percentage that is applied to the FY 2016 target amounts in order to calculate the FY 2017 target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 2.7 percent, in accordance with the applicable regulations at 42 CFR 413.40.

B. Report on Adjustment (Exceptions) Payments

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year.

The process of requesting, adjusting, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, generally, an excluded hospital must file its cost report for the fiscal year in accordance with § 413.24(f)(2) of the regulations. The MAC reviews the cost report and issues a notice of provider reimbursement (NPR). Once the hospital receives the NPR, if its operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment. After the MAC receives the hospital's request in accordance with applicable regulations, the MAC or CMS, depending on the type of adjustment requested, reviews the request and determines if an adjustment payment is warranted. This determination is sometimes not made until more than 180 days after the date the request is filed because there are times when the request applications are incomplete and additional information must be requested in order to have a completed request application. However, in an attempt to provide interested parties with data on the most recent adjustment payments for which we have data, we are publishing data on adjustment payments that were processed by the MAC or CMS during FY 2015.

The table below includes the most recent data available from the MACs and CMS on adjustment payments that were adjudicated during FY 2015. As indicated above, the adjustments made during FY 2015 only pertain to cost reporting periods ending in years prior to FY 2015. Total adjustment payments given to excluded hospitals during FY 2015 are $19,959,036. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating costs over the ceiling, and the amount of the adjustment payments.

Class of hospital	Number	Excess cost over ceiling	Adjustment payments
Children's	3	$1,615,731	$779,321
Cancer	1	30,816,372	18,758,695
Religious Nonmedical Health Care Institution (RNHCI)	4	645,819	421,020
Total	8	−33,077,922	19,959,036

C. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project (FCHIP) Demonstration

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25140 through 25141), section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act of 2010, authorizes a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration is titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and is commonly known as the Frontier Community Health Integration Project (FCHIP) demonstration.

The authorizing statute states the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is an MRHFP grantee under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the State are counties that have 6 or less residents per square mile.

The authorizing statute stipulates several other requirements for the demonstration. Section 123(d)(2)(B) of Public Law 110–275, as amended, limits participation in the demonstration to eligible entities in not more than 4 States. Section 123(f)(1) of Public Law 110–275 requires the demonstration project to be conducted for a 3-year period. In addition, section 123(g)(1)(B) of Public Law 110–275 requires that the demonstration be budget neutral. Specifically, this provision states that in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 states that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration.

In January 2014, CMS released a request for applications (RFA) for the FCHIP demonstration. We refer readers to the RFA on the CMS Web site at: *https://innovation.cms.gov/initiatives/Frontier-Community-Health-Integration-Project-Demonstration/*. Using 2013 data from the U.S. Census Bureau, CMS identified Alaska, Montana, Nevada, North Dakota, and Wyoming as meeting the statutory eligibility requirement for participation in the demonstration. The RFA solicited CAHs in these five States to participate in the demonstration, stating that participation would be limited to CAHs in four of the States. To apply, CAHs were required to meet the eligibility requirements in the authorizing legislation, and, in addition, to describe a proposal to enhance health-related services that would complement those currently provided by the CAH and better serve the community's needs. In addition, in the RFA, CMS interpreted the eligible entity definition in the statute as meaning a CAH that receives funding through the Rural Hospital Flexibility Program. The RFA identified four intervention prongs, under which specific waivers of Medicare payment rules would allow for enhanced payment for telemedicine, nursing facility, ambulance, and home health services, respectively. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Since the due date for applications on May 5, 2014, we have assessed the feasibility of the applying CAHs' service delivery proposals, as well as the potential impacts of the payment enhancement interventions on the overall expenditures for Medicare services. In the FY 2017 IPPS/LTCH PPS proposed rule, we indicated that we would be selecting CAHs to participate in the demonstration, with the period of performance for each CAH expected to start August 1, 2016.

In the proposed rule, we indicated that we had specified the payment enhancements for the demonstration, and were basing our selection of CAHs for participation, with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration would produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration and uncertainty associated with projected Medicare utilization and costs, in the proposed rule, we proposed a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. Accordingly, if analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as of other data sources, including cost reports for these CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we indicated that we would recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. Because of the small scale of the demonstration, we stated that we did not believe it would be feasible to implement budget neutrality by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration were not

implemented, we proposed to comply with the budget neutrality requirement by reducing payments to all CAHs, not just those participating in the demonstration. We stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP demonstration is specifically designed to test innovations that affect delivery of services by the CAH provider category. We believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Based on actuarial analysis using cost report settlements for FYs 2013 and 2014, the demonstration is projected to satisfy the budget neutrality requirement and likely yield a total net savings. For the FY 2017 IPPS/LTCH PPS proposed rule, we estimated that the total impact of the payment recoupment would be no greater than 0.03 percent of CAHs' total Medicare payments within 1 fiscal year (that is, Medicare Part A and Part B). We stated in the proposed rule that the final budget neutrality estimates for the FCHIP demonstration would be based on the demonstration period, which is August 1, 2016 through July 31, 2019. The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. Therefore, we proposed that, in the event the demonstration is found not to have been budget neutral, any excess costs would be recouped over a period of 3 cost reporting years, beginning in CY 2020. We proposed a 3-year period for recoupment to allow for a reasonable timeframe for the payment reduction and to minimize any impact on CAHs' operations.

Comment: Two commenters supported the FCHIP demonstration, but believed that it is inappropriate to recoup Medicare payments from all CAHs nationwide in order to achieve budget neutrality, especially because such a reduction will apply to CAHs that are not eligible to participate in the demonstration.

Response: We appreciate the commenters' support for the FCHIP demonstration and acknowledge the concerns expressed regarding recoupment of Medicare payments from all CAHs nationwide. We emphasize that the recoupment would apply only as a contingency plan, in the event that the demonstration costs exceed savings. Our actuarial analysis has estimated that the impact would be no greater than 0.03 percent of CAHs' total Medicare payments within 1 fiscal year. In addition, we will conduct any such recoupment over a period of 3 cost reporting years, in order to allow for a reasonable timeframe for any payment reduction and minimize the impact on CAHs' operations.

We refer readers to the CMS Web site at: *https://innovation.cms.gov/initiatives/Frontier-Community-Health-Integration-Project-Demonstration/* for up-to-date information on the FCHIP demonstration. We are finalizing, as proposed, a policy that, in the event we determine that aggregate payments under the demonstration exceed the payments that would otherwise have been made, CMS will recoup payments through reductions of Medicare payments to all CAHs under both Medicare Part A and Part B. Given the 3-year period of performance for the FCHIP demonstration and the time needed to conduct the budget neutrality analysis, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped over a period of 3 cost reporting years, beginning in CY 2020.

VII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2017

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act defines an LTCH as a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act also provides an alternative definition of LTCHs: Specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and has an average inpatient length of stay (as determined by the Secretary of Health and Human Services (the Secretary)) of greater than 20 days and has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in FY 1997.

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC–DRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable

costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).

Section 231 of Consolidated Appropriations Act, 2016 (Pub. L. 114–113) provides for a temporary exception to the application of the site neutral payment rate for certain discharges representing severe wound care cases from specific LTCHs. We refer readers to the interim final rule with comment period (IFC) published in the **Federal Register** (which we will refer to as the April 21, 2016 IFC for the remainder of this preamble) implementing this provision (81 FR 23428). We are responding to public comments and finalizing the provisions of the April 21, 2016 IFC implementing this provision in section VII.A.3. of this final rule.

We received several comments that were outside the scope of the proposed rule requesting modifications to our existing regulations. We appreciate the commenters' feedback, and we will take these comments into consideration as we contemplate future revisions to the LTCH PPS that we would make through the notice-and-comment rulemaking process.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv)(I) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. Alternatively, § 412.23(e)(2)(ii) states that, for cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the PPS in 1986 and can demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease must have an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days (referred to as ''subclause (II)'' LTCHs).

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b–1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87 and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (§ 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH is currently also permitted to charge the beneficiary for services delivered on those uncovered days (§ 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to limit the charges that may be imposed on beneficiaries whose discharges are paid at the site neutral payment rate under the LTCH PPS.

In section VII.G. of the preamble of the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25173), we proposed to amend the existing regulations relating to the limitation on charges to address

beneficiary charges for LTCH services provided by subclause (II) LTCHs as part of our refinement of the payment adjustment for subclause II LTCHs under § 412.526. We also proposed to amend the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, payment for discharges occurring in cost reporting periods beginning in FY 2016 or 2017) are considered to be a site neutral payment rate payment.

We note that, as discussed in section VII.G. of the preamble of this final rule, we did not receive any public comments in response to these proposals and are finalizing them as proposed, without modification.

4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance

Claims submitted to Medicare must comply with both the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107–105), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191). Section 3 of the ASCA requires that the Medicare Program deny payment under Part A or Part B for any expenses incurred for items or services for which a claim is submitted other than in an electronic form specified by the Secretary. Section 1862(h) of the Act (as added by section 3(a) of the ASCA) provides that the Secretary shall waive such denial in two specific types of cases and may also waive such denial in such unusual cases as the Secretary finds appropriate (68 FR 48805). Section 3 of the ASCA operates in the context of the HIPAA regulations, which include, among other provisions, the transactions and code sets standards requirements codified under 45 CFR parts 160 and 162 (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct certain electronic health care transactions according to the applicable transactions and code sets standards.

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of health information technology (health IT) and promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) leads these efforts in collaboration with other agencies, including CMS and the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Through a number of activities, including several open government initiatives, HHS is promoting the adoption of health IT products, including electronic health record (EHR) technology certified under the ONC Health IT Certification Program (*https://www.healthit.gov/policy-researchers-implementers/2015-edition-final-rule*) developed to support secure, interoperable, health information exchange. We believe that the use of certified EHRs by LTCHs (and other types of providers that are ineligible for the Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support the exchange of important information across care partners and during transitions of care, and enable the reporting of electronically specified clinical quality measures (eCQMs) (as described elsewhere in this proposed rule). In 2015, ONC released a document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' (available at: *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*). In the near term, the Roadmap focuses on actions that will enable individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. The Roadmap's goals also align with the Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185) (IMPACT Act), which requires assessment data to be standardized and interoperable to allow for exchange of the data. Moreover, the vision described in the Roadmap significantly expands the types of electronic health information, information sources, and information users well beyond clinical information derived from EHRs. The Roadmap identifies four critical pathways that health IT stakeholders should focus on now in order to create a foundation for long-term success: (1) Improve technical standards and implementation guidance for priority data domains and associated elements; (2) rapidly shift and align Federal, State, and commercial payment policies from fee-for-service to value-based models to stimulate the demand for interoperability; (3) clarify and align Federal and State privacy and security requirements that enable interoperability; and (4) align and promote the use of consistent policies and business practices that support interoperability and address those that impede interoperability, in coordination with stakeholders. To support of the goals of the Roadmap, ONC released the 2016 Interoperability Standards Advisory (ISA) (available at: *https://www.healthit.gov/sites/default/files/2016-interoperability-standards-advisory-final-508.pdf*), which suggests the best available standards and implementation specifications for health IT, terminology, content/structure, and services to enable interoperability. The ISA also includes emerging standards to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these ''best available standards'' into account as they implement interoperable health information exchange across the continuum of care. A Draft 2017 Interoperability Standards Advisory will be published this summer, and will have a 60-day public comment period. The Final Interoperability Standards Advisory will be published in December 2016.

B. Modifications to the Application of the Site Neutral Payment Rate (§ 412.522)

1. Background

Section 1206 of Pathway for SGR Reform Act (Pub. L. 113–67) mandated significant changes to the LTCH PPS beginning with LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. Specifically, section 1206 required the establishment of a site neutral payment rate (as an alternative to the LTCH PPS standard Federal payment rate) for Medicare inpatient discharges from an LTCH that fails to meet certain statutorily defined criteria. Discharges that meet the statutory criteria for exclusion from the site neutral payment rate continue to be paid based on the LTCH PPS standard Federal payment rate. Discharges that do not meet the statutory criteria for exclusion are paid based on the site neutral payment rate. We implemented the application of the site neutral payment rate in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and codified the requirements in the regulations at 42 CFR 412.522. The criteria for exclusion from the site neutral payment rate specified under section 1886(m)(6)(A)(ii) of the Act and as implemented at § 412.522(b) are as follows: (1) The discharge from the LTCH does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; (2) admission to the LTCH was immediately preceded by discharge

from a subsection (d) hospital; and (3) the immediately preceding stay in a subsection (d) hospital included at least 3 days in an intensive care unit (ICU) (referred to as the ICU criterion) or the discharge from the LTCH is assigned to a MS–LTC–DRG based on the patient's receipt of ventilator services of at least 96 hours (referred to as the ventilator criterion). (We note that, for the remainder of this section of the preamble, the phrase ''LTCH PPS standard Federal payment rate case'' refers to an LTCH PPS case that meets the criteria for exclusion from the site neutral payment rate as specified under § 412.522(a)(2), and the phrase ''site neutral payment rate case'' refers to an LTCH PPS case that does not meet the statutory patient-level criteria as specified under § 412.522(a)(1) and, therefore, is paid the applicable site neutral payment rate.)

In response to the proposed rule, we received several comments related to the specific mechanics of the site neutral payment rate. However, because we did not make any proposals concerning the mechanics of the site neutral payment rate in the proposed rule, we consider these comments to be outside the scope of the proposed rule. We will take these comments under consideration for future rulemaking and provide subregulatory guidance as necessary and appropriate.

2. Technical Correction of Definition of ''Subsection (d) Hospital'' for the Site Neutral Payment Rate (§ 412.503)

In the FY 2016 IPPS/LTCH PPS final rule, we implemented section 1206(a) of Public Law 113–67, which established the new dual payment rate structure under the LTCH PPS that began with LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. Section 1206(a) required the establishment of a site neutral payment rate (as an alternate to the LTCH PPS standard Federal payment rate) under the LTCH PPS for Medicare inpatient LTCH discharges that fail to meet certain statutorily defined criteria for exclusion. Discharges that meet the statutory criteria for exclusion from the site neutral payment rate continue to be paid based on the LTCH PPS standard Federal payment rate. Discharges that do not meet the statutory criteria for exclusion are paid based on the new site neutral payment rate. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we codified the requirements for the application of the site neutral payment rate under the LTCH PPS under the regulations at § 412.522. The statutory criteria for exclusion from the site neutral payment rate include a criterion that requires that the admission to the LTCH was immediately preceded by discharge from a ''subsection (d) hospital.'' To implement this criterion for purposes of the application of the site neutral payment rate under § 412.522, we added a definition of a ''subsection (d) hospital'' under § 412.503 of the regulations. However, we made an inadvertent cross-reference error under § 412.503 by referencing ''§ 412.526'' (payment provisions regarding subclause (II) LTCH) instead of referencing ''§ 412.522'' (payment provisions regarding the site neutral payment rate) (80 FR 49767). That is, currently § 412.503 specifies that a subsection (d) hospital means ''for purposes of § 412.526,'' when the language should have read ''for purposes of § 412.522''.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25144), we proposed to revise § 412.503 to correct this cross-reference error.

Comment: Several commenters supported our proposed technical correction of the definition of a ''subsection (d) hospital'' in § 412.503. Some commenters further requested that CMS make additional changes, for example, including specific categories of hospitals in addition to hospitals paid under the IPPS, which meet the statutory and regulatory definition of a ''subsection (d) hospital,'' to this definition in order to ensure that all hospitals meeting the regulatory and statutory definition of a ''subsection (d) hospital'' are treated appropriately for purposes of the LTCH PPS. Other commenters requested that CMS make similar changes to a subregulatory transmittal related to this definition.

Response: We appreciate the commenters' support for our proposed technical correction. We believe that our regulations are sufficiently clear to ensure that all hospitals meeting the statutory definition of a ''subsection (d) hospital'' are treated appropriately for purposes of the LTCH PPS, despite the fact that certain categories of hospitals are not expressly mentioned in our regulatory definition and that our regulatory definition of a ''subsection (d) hospital'' in § 412.503, as corrected, is fully consistent with the statutory definition. However, we will take into consideration the commenters' requests as we review and amend, as appropriate, our subregulatory guidance on this issue in order to ensure that we appropriately apply the regulatory and statutory definition of a ''subsection (d) hospital'' when determining LTCH PPS payments under the dual rate payment structure at § 412.522.

After consideration of the public comments we received, we are finalizing the technical correction to the definition of a ''subsection (d) hospital'' in § 412.503 as proposed, without modification.

3. Finalization of Interim Final Rule With Comment Period: Temporary Exception to the Site Neutral Payment Rate Under the LTCH PPS for Certain Severe Wound Discharges From Certain LTCHs

In the interim final rule with comment period (IFC) that appeared in the **Federal Register** on April 21, 2016 (81 FR 23428 through 23438) (referred to as the ''April 21, 2016 IFC'' for the remainder of this section), we implemented the provisions of section 231 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) and amended our regulations at 42 CFR 412.522 to reflect those policies. Section 231 of Public Law 114–113 amended section 1886(m)(6) of the Act by revising subparagraph (A)(i) and adding new subparagraph (E), which established a temporary exception to the site neutral payment rate for certain severe wound care discharges occurring prior to January 1, 2017, from LTCHs identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997 that are located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or treated as being so located pursuant to section 1886(d)(8)(E). Because the statute contained no effective date and required rulemaking to implement, we determined that the issuance of an IFC was the most appropriate mechanism to use to ensure that the affected LTCHs received the longest period of relief under the statute.

In this final rule, we summarize the provisions of the April 21, 2016 IFC relating to the temporary exception to the site neutral payment rate for certain severe wound care discharges from certain LTCHs, summarize the public comments received, present our responses to those public comments, and state the final policies, which reflect limited modifications of the policies set forth in the April 21, 2016 IFC. However, as we did not receive any public comments on our implementing regulation text, and as the limited modifications of our policies in response to public comments do not necessitate any changes to the implementing regulation text, we are finalizing those regulatory provisions without further discussion or modification.

a. Overview of the Policies Implementing Section 231 of Public Law 114–113

As we discussed in our April 21, 2016 IFC, section 231 of Public Law 114–113 limits the temporary exception to LTCHs identified by the amendment made by section 4417(a) of the BBA (which, as we discussed in the IFC, is a phrase that has been defined through prior rulemakings) that are located in a rural area (as defined in section 1886(d)(2)(D) of the Act (providing a geographic definition of ''rural'' based on a hospital's location outside of OMB's Metropolitan Statistical Areas (MSAs)) or treated as being so located pursuant to section 1886(d)(8)(E) of the Act) (referencing IPPS' geographic reclassification rules, which required interpretation to apply it in the LTCH context). Furthermore, the statute limited the temporary exception to discharges in which the individual ''has'' a severe wound, which we interpreted as either discharges for individuals who had been successfully treated for a severe wound while receiving care in the eligible LTCH, or discharges for individuals who were discharged with a severe wound after having been treated for a severe wound while receiving care in the eligible LTCH. Finally, the statute further limited the temporary exception to severe wounds as identified within the categories listed in the statute, some of which required additional interpretation in order to implement.

As set forth in the April 21, 2016 IFC, these interpretations were then codified in amendments to § 412.522 of the LTCH PPS regulations, which, as the statute contained no effective date and as rulemaking was required to implement the statute, became effective on the IFC's publication date. Also as discussed in the IFC, we believed that our use of an IFC as the means of establishing the required interpretations (as opposed to full notice and comment rulemaking) afforded the longest period of relief possible under the authorizing statute, while preserving the opportunity to comment on our implementing policies.

For more detail on the policies adopted in the April 21, 2016 IFC, we refer readers to 81 FR 23428. We address the comments received in response to those policies, and our responses to those comments below.

b. Interpretation of the Phrase ''Identified by the Amendment Made by Section 4417(a) of the Balanced Budget Act of 1997''

As discussed in the April 21, 2016 IFC (81 FR 23428), the phrase ''identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997'' has been interpreted by CMS to mean hospitals within hospitals (HwHs) that were participating in Medicare, but excluded from the hospital IPPS on or before September 30, 1995 (that is, hospitals which are described under § 412.23(e)(2)(i)) that meet the criteria of § 412.22(f) (81 FR 23430 through 23432).

As further discussed in the April 21, 2016 IFC, § 412.22(f) generally requires that, in order to have grandfathered status, an HwH must continue to operate under the same terms and conditions, including, but not limited to, the number of beds. A limited exception to this general policy allowed eligible hospitals to increase beds between October 1, 1995, and September 30, 2003, without loss of their grandfathered status. A second exception allows grandfathered HwHs to increase square footage or decrease the number of beds for cost reporting periods beginning on or after October 1, 2006, while still retaining grandfathered status.

As the phrase ''identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997'' had already been interpreted in this manner, the April 21, 2016 IFC adopted the same meaning of the phrase for purposes of implementing section 231 of Public Law 114–113. For additional information on hospitals ''identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997,'' we refer readers to the April 21, 2016 IFC (81 FR 23431 through 23432).

Comment: While we did not receive any public comments in response to our interpretation ''identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997'' set forth in the April 21, 2016 IFC, one commenter requested clarification as to whether certain hospitals would be considered ''identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997'' (that is, a grandfathered HwH) for the purposes of the 25-percent threshold policy (discussed in section VII.F. of the preamble of this final rule). Specifically the commenter asked whether: (1) An LTCH which changed host hospitals, (2) an LTCH which is no longer co-located, (3) an LTCH which did not increase overall beds, but moved some to a remote location, and (4) an LTCH which did not increase overall beds, but moved some to a satellite location would be considered a grandfathered HwH. The commenter requested CMS to consider all of these hospitals ''grandfathered HwHs'' so long as they did not increase their overall bed capacity.

Response: We appreciate the commenter's support for excluding LTCHs which expanded bed capacity from grandfathered HwHs that are eligible for the temporary exception, consistent with the April 21, 2016 IFC. However, as we explained in that IFC, none of the hospitals described by the commenter would be considered grandfathered HwHs because none of those hospitals would meet the requirements of § 412.22(f) (requiring, with limited exceptions, that the LTCH continue to operate under the same terms and conditions). By changing host hospitals, the hospital described in scenario (1) would have changed the terms and conditions under which it operated and, therefore, does not meet the requirements of § 412.22(f). Furthermore, the LTCHs described in scenarios (2), (3), and (4) would no longer meet the definition of an ''HwH'' LTCH as the LTCHs in scenario (2) would become a freestanding LTCH, and LTCHs in scenarios (3) and (4) would be satellite LTCH facilities, none of which are HwHs. As the requirements of § 412.22(f) can only be met by HwHs, and the LTCH configurations in scenarios (2), (3) and (4) are not HwHs they are not grandfathered HwHs.

After consideration of the public comments we received, we are finalizing our interpretation of the phrase ''identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997'' as set forth is the April 21, 2016 IFC, without modification.

c. Meaning of the Phrase ''Located in a Rural Area or Treated as Being So Located''

Section 1886(m)(6)(E)(i)(I)(bb) of the Act, as added by section 231 of Public Law 114–113, limits application of the temporary exception to LTCHs that are located in a rural area (as defined in subsection (d)(2)(D)) or ''treated as being so located'' pursuant to subsection (d)(8)(E). As discussed in the April 21, 2016 IFC, section 1886(d)(2)(D) of the Act establishes a geographic definition of ''rural'' based on location outside of OMB's MSAs. This statutory definition of rural area is consistent with the existing definition of rural area under the LTCH PPS set forth at § 412.503. Therefore, in the April 21, 2016 IFC (81 FR 23432), we established that ''located

in a rural area'' in section 1886(m)(6)(E)(i)(I)(bb) of the Act refers to LTCHs which are currently located in a rural area as defined under § 412.503 (81 FR 23432). As discussed in the April 21, 2016 IFC, the phrase ''treated as being so located pursuant to subsection (d)(8)(E)'' required interpretation as section 1886(d)(8)(E) of the Act only applies to subsection (d) hospitals, and LTCHs, by definition at section 1886(b)(1) of the Act, are not subsection (d) hospitals.

Section 1886(d)(8)(B) of the Act, as applied to urban subsection (d) hospitals is implemented at § 412.103, and establishes the procedures by which an urban IPPS hospital may apply for reclassification as a rural hospital, the process for reviewing such applications, and the conditions under which applications will be approved (81 FR 23432). To apply these policies and procedures to LTCHs in the context of the temporary exception, we revised our LTCH regulations at § 412.522(b)(2) to—

- Limit reclassification applications under the LTCH PPS to grandfathered HwHs.
- Limit the application and effect of any reclassifications granted to grandfathered HwHs to the eligibility determination for the temporary exception, and
- Adopt the existing rural IPPS reclassification process and procedures as stated under § 412.103 for the LTCH PPS.

Furthermore, in adopting these policies and procedures, we highlighted that a reclassified grandfathered HwH LTCH will not be treated as rural for any other reason, including, but not limited to, the 25-percent threshold policy and wage index, and that any rural treatment under these LTCH PPS policies and procedures will expire at the same time as the temporary exception (that is, December 31, 2016).

Comment: MedPAC opposed allowing LTCHs to seek rural ''reclassification'' based on the Commission's general opposition to the current wage index system.

Response: As we explained in the April 21, 2016 IFC, we were required to give meaning to an LTCH being ''treated as being so located'' under section 1886(d)(8)(E) of the Act. We achieved this by allowing limited reclassification in the LTCH PPS context, by having it apply solely for the purpose of eligibility for the temporary exception established under section 231 of Public Law 114–113. As implemented, we believe that our policy had no effect on the MedPAC's wage index related reclassification concerns. It merely allows eligible LTCHs to reclassify as rural for the purposes of qualifying for the temporary exception to the site neutral payment rate under the LTCH PPS for certain severe wound care discharges from certain LTCHs. It is not applicable in the LTCH PPS for any other purpose, including but not limited to, the 25-percent threshold policy and the wage index, and such treatment is effective only until the expiration of the temporary exception (that is, December 31, 2016).

Furthermore, as MedPAC offered no alternative that would give meaning to the phrase ''treated as being so located'' under section 1886(d)(8)(E) of the Act, we continue to believe our interpretation to be the most appropriate way to interpret ''treated as being so located'' in this context.

Comment: One commenter supported our interpretation of ''treated as being so located'' under section 1886(d)(8)(E) of the Act in relation to section 231 of Public Law 114–113. Other commenters requested that CMS expand the scope of the temporary exception to either allow additional hospitals or discharges to be excluded from the site neutral payment rate.

Response: We appreciate the commenter's support for our implementation of the phrase ''treated as being so located'' under section 1886(d)(8)(E) of the Act in relation to section 231 of Public Law 114–113. In response to the commenters who requested expansion of the temporary exception beyond the LTCHs and discharges defined in section 231 of Public Law 114–113, as we stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49602), we do not have the authority to pay LTCH discharges that fail to meet the patient-level criteria for payment at the LTCH PPS standard Federal payment rate at a rate other than the site neutral payment rate unless the discharge meets the eligibility criteria for the temporary exception for certain severe wound discharges. Therefore, we lack the authority to implement additional exceptions as the commenters suggested.

After consideration of the public comments we received, we are finalizing our implementation of the meaning of the phrases ''located in a rural area'' under section 1886(d)(2)(D) of the Act and ''treated as being so located'' under section 1886(d)(8)(E) of the Act, without change.

d. Interpretation of the Phrase ''Individual Discharged Has a Severe Wound''

Section 1886(m)(6)(E)(i)(II) of the Act, as added by section 231 of Public Law 114–113, provides that the temporary exception for certain discharges from the application of the payment policy for site neutral payment rate cases discharged from certain LTCHs is applicable when the ''individual discharged has a severe wound.'' We stated in the April 21, 2016 IFC (81 FR 23433) that the use of the present tense in regard to the word ''has'' when addressing a severe wound is internally inconsistent. A strict and literal read of the statute would require temporary exception from the application of the payment policies for site neutral payment rate cases only representing an individual who, presently, ''has severe a wound'' at the time of his or her discharge from the LTCH and, therefore, payments for cases representing patients whose wounds are either healed or no longer severe at the time of discharge would be made under our existing regulations (that is, the LTCH would receive payment for the case discharge at the site neutral payment rate unless the discharge met the existing exclusion criteria). As we stated in the April 21, 2016 IFC (81 FR 23433), we interpreted this phrase in the provision of the statute to include discharges for cases representing patients who received treatment for a ''severe wound'' at the LTCH, regardless of whether the wound was present and severe at the time of discharge.

Comment: One commenter supported the interpretation.

Response: We appreciate the commenter's support and are finalizing our interpretation of a patient who ''has'' a severe wound as a patient who ''had'' a severe wound, without modification.

e. Statutory Definition of the Term ''Severe Wound''

Section 1886(m)(6)(E)(ii) of the Act, as added by section 231 of Public Law 114–113, defines a ''severe wound'' as a Stage 3 wound, Stage 4 wound, unstageable wound, non-healing surgical wound, infected wound, fistula, osteomyelitis or wound with morbid obesity as identified in the claim from the LTCH. For purposes of implementing this statutory definition in the April 21, 2016 IFC (81 FR 23433), after consultation with our clinical advisors, we interpreted the term ''wound'' as: An injury, usually involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment. In that same IFC, we also established that the phase ''as identified in the claim'' to mean as identified based on the ICD–10–CM diagnosis codes reported on the claim where—

• The ICD–10–CM diagnosis codes contain sufficient specificity for this purpose; or

• Through the use of a payer-specific condition code where the ICD–10–CM diagnosis codes lack sufficient specificity for this purpose.

For six of the eight statutory categories included in the statutory definition of ''severe wound'' (Stage 3 wound, Stage 4 wound, unstageable wound, non-healing surgical wound, fistula, and osteomyelitis), we stated that we believe these types of severe wounds can be identified through the use of specific ICD–10–CM diagnosis codes, which are reported on the LTCH claim. We indicated that the list of ICD–10–CM diagnosis codes that we will use to identify severe wounds for this group of six statutory categories can be found in the table entitled ''Severe Wound Diagnosis Codes by Category for Implementation of Section 231 of Public Law 114–113'' posted on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the regulation ''CMS–1664–IFC.'' Our clinical advisors compiled this list of codes by reviewing ICD–10–CM diagnosis codes for the statutorily enumerated categories of severe wounds and selecting the codes that satisfied our definition of a ''wound.'' We noted in the April 21, 2016 IFC that under our definition of a wound, the ICD–10–CM diagnosis codes used to identify severe wounds in the osteomyelitis category are also part of the ICD–10-diagnosis codes used to identify severe wounds in the fistula category and, therefore, no separate identification of ICD–10–CM diagnosis codes for osteomyelitis is necessary (81 FR 23433).

The remaining two statutory categories included in the definition of ''severe wound'' (infected wound and wound with morbid obesity), as stated in the April 21, 2016 IFC, lack ICD–10–CM diagnosis codes with sufficient specificity to identify the presence of a ''severe wound.'' This is a result of the number of codes that are used to identify wounds and infections being too numerous to identify and compile such an exhaustive list. We stated that because we cannot specify ICD–10 diagnosis codes to appropriately identify severe wounds classified in these categories, for the purposes of this provision, in the April 21, 2016 IFC, we defined a ''wound with morbid obesity'' as a wound in those with morbid obesity that require complex, continuing care including local wound care occurring multiple times a day, and an ''infected wound'' as a wound with infection requiring complex, continuing care including local wound care occurring multiple times a day. In order to operationalize these definitions in the absence of ICD–10–CM diagnosis codes, we utilize payer-only condition codes on the claim for processing (81 FR 23433).

As we stated we would in the April 21, 2016 IFC, we issued additional operational instructions regarding the use of the designated payer-only condition code in Change Request 9599, Transmittals 1654 and 1675. (We note that Change Request 9599 was originally issued on April 29, 2015 as Transmittal 1654, and reissued on June 16, 2016, as Transmittal 1675 to correct certain technical errors.) We note, as we did in the April 21, 2016 IFC, that while the use of this payer-only condition code is the most expedient operational method we have of implementing the statutory definition provided by the provisions of section 231 of Public Law 114–113 in the timeframe allowed, the continued use of a payer-only condition code may not be feasible if the scope of this provision is expanded. Given the current limitations on the number of LTCHs that meet the requirements to qualify for the exception granted by this provision under the statutory criteria (that is, grandfathered HwHs that are located in a rural area or reclassify as rural, as previously described in this section), the ability to identify the other statutory categories of severe wounds, and the limited timeframe of the exception's duration, we stated that we expected the number of claims necessitating the use of this payer-only condition code will be minimal.

Comment: Several commenters objected to the use of ''including local wound care occurring multiple times a day'' in the definitions of ''infected wound'' and ''wound with morbid obesity.'' These commenters stated that the best clinical practices do not necessarily call for local wound care multiple times a day, and, although severe, in those instances, medically appropriate care for what they believed were ''severe'' wounds would not be considered for a ''severe wound'' under the provisions implementing section 231 of Public Law 114–113. For example, some commenters construed our ''including local wound care occurring multiple times a day'' to require multiple dressing changes as a necessary criterion under these categories, and expressed concern that the use of ''including local wound care occurring multiple times a day'' would exclude discharges that did not involve dressing changes from the definition of a severe wound (and from the exclusion from the site neutral payment rate).

Response: Our use of the phrase ''including local wound care occurring multiple times a day'' was intended to be illustrative, not demonstrative. In other words, it is our intent that ''local wound care occurring multiple times a day'' is an example of a wound with infection or a wound with morbid obesity ''requiring complex, continuing care.'' To address commenters' concerns and alleviate further confusion, we are modifying the definitions of ''infected wound'' and ''wound with morbid obesity'' included in the April 21, 2016 IFC as follows. For the purposes of determining whether a discharge included treatment for a severe wound eligible for the temporary exception provided by section 231 of Public Law 114–113, in this final rule, we are establishing that an ''infected wound'' is ''a wound with infection requiring complex, continuing care'' and a ''wound with morbid obesity'' is ''a wound in those with morbid obesity that requires complex, continuing care.'' Local wound care occurring multiple times a day (which may involve dressing changes) is one way to demonstrate that a wound requires ''complex, continuing care,'' but not the only way.

Comment: Several commenters submitted requests for the inclusion of additional ICD–10 diagnosis codes that they believe qualify as descriptions of severe wounds under the categories of Stage 3 wounds, Stage 4 wounds, unstageable wounds, non-healing surgical wounds, fistula, and osteomyelitis, and, as such, should be added to the list of codes presumptively considered as ''severe wounds'' in our ICD–10 diagnosis code-based automated claims processing implementation approach (that is, they asked us to add the codes they identified to the table of ''Severe Wound Diagnosis Codes by Category for Implementation of Section 231 of Pub. L. 114–113'' posted on the CMS Web site). Several commenters also asserted that the ICD–10 diagnosis codes for necrotizing fasciitis and gangrene should be presumptively considered as ''severe wounds'' under the category of an ''infected wound'' (and, therefore, be added to the table), and should not require the use of the payer-only condition codes to identify such discharges as meeting the exception from payment at the site neutral payment rate.

Response: We reviewed all of the ICD–10 diagnosis codes requested by commenters and found that that some of those codes do meet the definition of a severe wound set forth in the April 21, 2016 IFC. These codes will be added to the final table, which will be posted on

the CMS Web site. Other suggested codes, did not meet the definition of a ''severe wound,'' and will not be added to the final table.

For example, we disagree with commenters' assertions regarding ICD–10 diagnosis codes for necrotizing fasciitis and gangrene. While we acknowledge that necrotizing fasciitis and gangrene may be serious enough to qualify as a ''severe wound'' in some cases, the ICD–10 diagnosis codes for these types of infections do not capture the severity of the wound sufficiently enough to ensure that every use of the code represents a case which would meet our definition of an ''infected wound'' under our implementation of the provisions of section 231 of Public Law 114–113. Therefore, we conclude that the suggested codes for necrotizing fasciitis and gangrene lack sufficient clinical specificity to ensure that their *every* use would be for a wound which meets our definition (which would be required to merit presumptive application of the statutory exception for certain severe wounds). We will continue to apply the payer-only condition code in instances in which wounds associated with necrotizing fasciitis and gangrene (or other infection) do qualify as severe wounds under the category of ''infected wounds.''

Comment: One commenter noted that, under the ICD–10–CM classification system, there are coding conventions that require specific sequencing of codes based on instructional notes, such as ''code first'' and ''use additional code.'' According to the commenter, these diagnosis codes describe conditions that should be reported as the principal diagnosis, followed by the code identifying a severe wound. This commenter recommended the addition of certain ICD–10 codes to account for these coding conventions.

Response: We appreciate the commenter's review of the list of ICD–10–CM diagnosis codes used to identify severe wounds for purposes of implementing section 231 of Public Law 114–113. While coding guidance is outside the scope of this final rule, we note that we collaborate with the American Hospital Association through the Coding Clinic for ICD–10–CM and ICD–10–PCS to promote proper coding. With that said, our implementation of the exception for certain ''severe wounds'' provided by the provisions of section 231 of Public Law 114–113 only requires the presence of an ICD–10 code on the claim. The sequence of the diagnosis codes on the claim is not relevant for purposes of the provision. For these reasons, we are not adopting the commenter's recommendation, but we will continue to encourage LTCHs to follow official ICD–10–CM/PCS Coding Guidelines and conventions, which can be found on the Web sites at: *http://www.cdc.gov/nchs/icd10cm.htm* and *http://www.cms.gov/medicare/coding/icd10/*.

Comment: One commenter believed that CMS was granted no discretion with regard to what constitutes a ''severe wound'' under the statute because the term was defined by the statute. The commenter requested that CMS add every ICD–10 code that identified any of the categories of wounds in our table.

Response: While we agree that the term ''severe wound'' was defined in the statute, that fact did not obviate the need to interpret the terms used by the statute to define ''severe wound.'' While the statute enumerated the universe of categories into which severe wounds would be classified, it did not define how they should be ''identified in the claim.'' Nor did the statute define what a ''wound'' is.

Thus, in order to implement the statute, we found it necessary to define ''wound,'' and to give meaning to Congress' use of the phrase ''severe wound'' in the context of the named categories. ''Infected wound'' and ''wound with morbid obesity'' cannot be interpreted in the abstract—they must be read in context, and the context is a provision granting exceptions to certain ''severe wound'' discharges. As we stated in the April 21, 2016 IFC, in order to do that, we implemented a definition of a ''wound'' (as, logically, there must be a wound in order for there to be a severe wound) and that definition must be distinct from the definition of a ''severe wound'' lest the word ''severe'' be rendered superfluous (meaning that we must define a ''wound'' in such a way as to distinguish between ''severe'' wounds, which are to be excluded from the site neutral payment rate, and ''nonsevere'' wounds, which are not to be excluded from the site neutral payment rate). We continue to believe that interpreting the statute so as to require that each of the enumerated categories require a demonstration of the condition being a ''severe'' wound is a reasonable interpretation of the statute. This is particularly important for the infected wounds and wounds with morbid obesity, as these categories lack any clinically standard definition, and represent a gambit of clinical circumstances, from a paper cut on a patient with morbid obesity or an infected cut (either of which meets the definition of a ''wound,'' but neither of which would be expected to require ''complex, continuing care'' or would be labeled ''severe'') to necrotizing fasciitis (which can represent a severe wound which requires complex, continuing care). Therefore, in developing the list of ICD–10 diagnosis codes for identifying, on the LTCH claim, Stage 3 wounds, Stage 4 wounds, unstageable wounds, non-healing surgical wounds, fistula, and osteomyelitis solely based on the presence of an ICD–10 diagnosis code, we include only such codes with sufficient clinical specificity to first, indicate the presence of a ''wound,'' and second, differentiate between severe and non-severe wounds, due to the statutory requirement that we determine what constitutes a ''severe wound'' as ''identified in the claim'' (that is, from information on the LTCH claim). As we are identifying infected wounds and wounds with morbid obesity through the use of a payer-only condition code, we established our regulatory definition of these categories so that all uses identify wounds which are severe. For these reasons, we disagree with the commenter and are not including every ICD–10 code, which could represent one of the statutory categories of wounds. To the extent that any code requested by any commenter was sufficiently specific so as to indicate a severe wound of the types listed, we have added it to our table.

Comment: Several commenters requested that CMS apply the temporary exception to all discharges where the claim includes a code for a body mass index (BMI) that indicates morbid obesity.

Response: As we stated in the April 21, 2016 IFC, the mere presence of ICD–10–CM diagnosis codes for morbid obesity paired with a code for a wound does not provide any information on the severity of the wound; that is, ICD–10 diagnosis codes do not differentiate between a diagnosis that is a ''severe'' wound and a diagnosis that is a ''nonsevere'' wound. As such, we are not making any changes to our approach for identifying wounds with morbid obesity, and will continue to identify severe wounds in the category of ''wounds with morbid obesity'' solely through the use of the payer-only condition code as established in the April 21, 2016 IFC.

After consideration of the public comments we received, as discussed previously in this section, we are revising our definitions of an ''infected wound'' and a ''wound with morbid obesity,'' and including additional ICD–10 diagnosis codes to the listing that identifies codes that will be presumptively considered severe wounds for purposes of our automated

claims processing implementation approach. All other policies implementing the provisions of section 231 of Public Law 114–113 remain the same as implemented in the April 21, 2016 IFC, without modification.

f. Provisions of This Final Rule

In summary, we are finalizing the provisions of the April 21, 2016 IFC with the following modifications: (1) We are revising our definitions of a ''wound with morbid obesity'' and an ''infected wound,'' and adding additional ICD–10 diagnosis codes to our list of such codes to identify cases that meet our established definition of a ''severe wound'' for the six severe wound categories other than the categories of a ''wound with morbid obesity'' and an ''infected wound.'' The provisions implementing section 231 of Public Law 114–113, as set forth in the April 21, 2016 IFC and discussed below, are effective for LTCH discharges from qualifying LTCHs, for discharges on or after April 21, 2016, through December 31, 2016.

g. Waived Proposed Rulemaking and Delay of Effective Date

In the April 21, 2016 IFC (81 FR 23435), we found notice-and-comment rulemaking and a delay in the effective date to be both unnecessary as well as impracticable and contrary to public interest. Section 231 of Public Law 114–113 required revision of the existing regulations to implement the LTCH wound care exception, thereby limiting any discretion we might otherwise have had to immediately implement the statutory mandate as a self-implementing statute. In addition, given the statutory expiration of the provisions of section 231 of Public Law 114–113 on January 1, 2017, we noted that the use of notice-and-comment rulemaking in the face of the congressionally imposed end date of the relief would have significantly limited the qualifying discharges to which the statute applies. We stated that by implementing and codifying the provisions of the statute through an IFC and subsequent final rule rather than full notice-and-comment rulemaking and waiving the usual 60-day delay of effective date requirement, we believed that our implementation of the waiver would ensure the maximum period of relief, consistent with our interpretation of the statute. We found, on these bases, that there was good cause to waive notice-and-comment rulemaking and the delay in effective date that would otherwise be required.

Comment: Several commenters requested that CMS make the effective date of the provision implemented in the April 21, 2016 IFC retroactive to January 1, 2016. One commenter stated that implementing the statute through an IFC is contrary to Congressional intent.

Response: As the statute did not contain an effective date and required rulemaking to implement, having a regulation with an effective date prior to the date of the rulemaking would require retroactive rulemaking. While we have the authority to engage in retroactive rulemaking, that authority is limited to situations where it is necessary to comply with a statutory requirement or for the public interest. Had the statute contained an effective date, we may have been required to perform retroactive rulemaking in order to comply with that requirement. However, as the statute did not contain an effective date, retroactive rulemaking was not required. Additionally, we do not believe that retroactive rulemaking is necessary for the public interest as, by implementing the statutory requirement through an IFC, we were able to provide a meaningful period of relief without engaging in retroactive rulemaking. With respect to the commenter's statement regarding Congressional intent, we note that the commenter provided no evidence of our having violated the Congressional intent of this statutory provision. The materials cited by the commenter, while related to wound care, rural health, and/or the LTCH PPS, were not directly related to section 231 of Public Law 114–113, nor were they Congressionally authored. In implementing section 231 of Public Law 114–113, we reviewed the legislative history and found nothing in that history that provides insight into Congress' intent. Therefore, we believe that we are not required to engage in retroactive rulemaking in implementing section 231 of Public Law 114–113.

h. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

However, in the April 21, 2016 IFC (81 FR 23435), we stated that we had requested an emergency review of the information collection referenced later in this section. In compliance with the requirement of section 3506(c)(2)(A) of the PRA, we submitted the following for emergency review to the Office of Management and Budget (OMB). We requested an emergency review and approval under 5 CFR 1320.13(a)(2)(i) of the implementing regulations of the PRA in order to implement the provisions of section 231 of Public Law 114–113 as expeditiously as possible. We stated that public harm was reasonably likely to ensue if the normal clearance procedures were followed because the approval of this information collection is essential to ensuring that otherwise qualifying grandfathered urban HWHs are not unduly delayed in attempting to obtain relief provided by the temporary exception by applying to be treated as rural before the temporary exception expires on December 31, 2016.

We stated in the April 21, 2016 IFC that, for the purposes of implementing subparagraph (E) of section 1886(m)(6) of the Act as provided by Public Law 114–113, we revised our regulations at § 412.522(b)(2)(ii)(B)(*2*) to utilize the same administrative mechanisms used in the existing rural reclassification process for urban subsection (d) hospitals under § 412.103, described later in this section. We also stated that we will allow grandfathered LTCH HwHs (previously defined in that IFC) to apply to their CMS regional office for treatment as being located in a rural area for the sole purpose of qualifying for this temporary exception from the application of the site neutral payment rate.

We stated in the April 21, 2016 IFC that, for urban subsection (d) hospitals, and now temporarily LTCHs, we implemented the rural reclassification provision in the regulations at § 412.103. In general, the provisions of § 412.103 provides that a hospital located in an urban area may be reclassified as a rural hospital if it submits an application in accordance with our established criteria. The hospital must also meet certain conditions, which include being located in a rural census tract of a MSA, or in an area designated by any law or regulation of the State as a rural area, or designated as a rural hospital by State law or regulation. Paragraph (b) of § 412.103 sets forth application

requirements for a hospital seeking reclassification as rural under that section, which includes a written application mailed to the CMS regional office that contains an explanation of how the hospital meets the condition that constitutes the request for reclassification, including data and documentation necessary to support the request. As provided in paragraphs (c) and (d) of § 412.103, the CMS regional office reviews the application and notifies the hospital of its approval or disapproval of the request within 60 days of the filing date, and a hospital that satisfies any of the criteria set forth § 412.103(a) is considered as being located in the rural area of the State in which the hospital is located as of that filing date.

We noted in the April 21, 2016 IFC that this policy only allows grandfathered LTCH HwHs to apply for this reclassification, and the rural treatment will only extend to this temporary exception for certain wound care discharges from the site neutral payment rate (meaning a grandfathered HwH LTCH will not be treated as rural for any other reason, including, but not limited to, the 25-percent threshold policy and wage index policies). We also noted that the any rural treatment under § 412.103 for a grandfathered HwH LTCH expires at the same time as this temporary provision (that is, December 31, 2016).

In the April 21, 2016 IFC (81 FR 23436), we estimated that each application will require 2.5 hours of work from each LTCH (0.5 hours to fill out the application and 2 hours of recordkeeping). Based on the current information we had received from the MACs, out of the approximately 120 current LTCHs that existed in 1995, which is a necessary but not sufficient condition to be a grandfathered HWH, there are approximately 5 hospitals that currently meet the criteria of being a grandfathered HWH and would not be precluded from submitting an application. We noted that as the MACs continue to update the list of grandfathered HWH that the number of potential applicants could increase. Because it is possible that the number of applicants could rise to 10 or more, in an abundance of caution, we treated this information collection as being subject to the PRA. Therefore, we estimated that the aggregate number of hours associated with this request across all currently estimated eligible hospitals will be 12.5 (2.5 hours per hospital for 5 hospitals). We estimated a current, average salary of $29 per hour (based on the ''2015 Median usual weekly earnings (second quartile), Employed full time, Wage and salary workers, Management, professional, and related occupations'' from the Current Population Survey, available at the Web site: *http://www.bls.gov/webapps/legacy/cpswktab4.htm*) plus 100 percent for fringe benefits ($58 per hour). Therefore, we estimated the total one-time costs associated with this request will be $725 (12.5 hours × $58 per hour).

In the April 21, 2016 IFC, we stated that written comments and recommendations from the public would be considered for this emergency information collection request if received by April 28, 2016. We requested OMB review and approval of this information collection request by May 5, 2016, with a 180-day approval period. We gave two access Web sites and a telephone number in the IFC where the public could obtain copies of a supporting statement and any related forms for the proposed collection(s).

We did not receive any public comments in response to this information collection request and, therefore, are finalizing it as it was set forth in the April 21, 2016 IFC, without modification. OMB approved the Emergency PRA package on May 9, 2016, for the aforementioned burden, which is under OMB control number 0938–0907.

i. Regulatory Impact Analysis

We have examined the impact of the April 21, 2016 IFC as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). In the April 21, 2106 IFC, we projected that two rural LTCHs would qualify for the temporary exception to the site neutral payment rate for certain LTCHs for certain discharges provided by section 231 of Public Law 114–113, based on the best data available at that time. We were not able to determine which, if any, LTCHs may be treated as rural in the future by applying and being approved for a reclassification as rural under the provisions of § 412.103. We stated that, given that LTCHs are generally concentrated in more densely populated areas, we did not expect any LTCHs to qualify under § 412.103. As such, as indicated in the April 21, 2016 IFC (81 FR 23436 through 23436), at that time, our projections related to the temporary exception to the site neutral payment rate for certain LTCHs for certain discharges provided by section 231 of Public Law 114–113, were limited to LTCHs that are geographically located in a rural area. Based on the most recent data for these two LTCHs, including the identification of FY 2014 LTCH discharges with a ''severe wound,'' we estimated the monetary impact of the IFC with respect to that LTCH PPS provision is approximately a $5 million increase in aggregate LTCH PPS payments had this statutory provision not been enacted. This estimate did not reach the economic threshold and this provision did not cause the IFC to be considered a major rule. At this time, we continue to estimate that the implementation of section 231 of Public Law 114–113 will result in approximately a $5 million increase in aggregate LTCH PPS payments had this statutory provision not been enacted, which does not reach the economic threshold and this provision did not cause the IFC to be considered a major rule.

The RFA also requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). (For details on the latest standards

for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*).

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We stated that we believe the provisions of the April 21, 2016 IFC may have an impact on some small entities, but for the reasons previously discussed in that IFC and reiterated above, we could not conclusively determine the number of such entities impacted. Because we lack data on individual hospital receipts, we stated in the April 21, 2016 IFC that we could not determine the number of small proprietary LTCHs. Therefore, we assumed that all LTCHs are considered small entities for the purpose of the RFA. MACs are not considered to be small entities. Because we acknowledged that many of the potentially affected entities are small entities, we stated that the discussion in this section regarding potentially impacted hospitals constituted our regulatory flexibility analysis. In stating our final policies in this final rule, we continue to acknowledge that many of the potentially affected entities are small entities and, therefore, the discussion in this section regarding potentially impacted hospitals, constitute our regulatory flexibility analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a metropolitan statistical area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Therefore, for purposes of the IPPS and the LTCH PPS, we will continue to classify these hospitals as urban hospitals.

The provisions of section 231 of Public Law 114–113, for which we are setting forth in this final rule, by definition affect rural LTCHs that qualify, and will result in an increase in payment for those qualifying LTCHs' discharges that meet the definition of a severe wound. However, as discussed in the April 21, 2016 IFC and as previously discussed in this section, based on the data currently available, we estimate there are only two LTCHs that currently meet the criteria. Therefore, we do not believe that the provisions of section 231 of Public Law 114–113 set forth in this final rule will have a significant impact on the operations of a substantial number of small rural LTCHs.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. The April 21, 2016 IFC did not, and this final rule will not, have any consequential effect on State, local, or tribal governments, nor will they affect private sector costs.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Because the IFC and this final rule do not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, the April 21, 2016 IFC and this final rule were reviewed by the Office of Management and Budget.

C. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2017

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA (Pub. L. 106–113).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. There are currently 758 MS–DRG groupings. For FY 2017, there will be 757 MS–DRG groupings based on the changes discussed in section II.F. of the preamble of this final rule. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple

medical problems characteristic of LTCHs.

In this section of the final rule, we provide a general summary of our existing methodology for determining the FY 2017 MS–LTC–DRG relative weights under the LTCH PPS.

As we proposed, in this final rule, in general, for FY 2017, we are using our existing methodology to determine the MS–LTC–DRG relative weights (as discussed in greater detail in section VII.C.3. of the preamble of this final rule). As we established when we implemented the dual rate LTCH PPS payment structure codified under § 412.522, beginning with FY 2016, the annual recalibration of the MS–LTC–DRG relative weights are determined: (1) Using only data from available LTCH PPS claims that would have qualified for payment under the new LTCH PPS standard Federal payment rate if that rate were in effect when claims data from time periods before the dual rate LTCH PPS payment structure applies were used to calculate the relative weights; and (2) using only data from available LTCH PPS claims that qualify for payment under the new LTCH PPS standard Federal payment rate when claims data from time periods after the dual rate LTCH PPS payment structure applies are used to calculate the relative weights (80 FR 49624). That is, under our current methodology, the MS–LTC–DRG relative weights are not used to determine the LTCH PPS payment for cases paid at the site neutral payment rate under § 412.522(c)(1) and data from cases paid at the site neutral payment rate or that would have been paid at the site neutral payment rate if the dual rate LTCH PPS payment structure had been in effect are not used to develop the relative weights. For the remainder of this discussion, we use the phrase ''applicable LTCH cases'' or ''applicable LTCH data'' when referring to the resulting claims data set used to calculate the relative weights (as described later in greater detail in section VII.C.3.c. of the preamble of this final rule). In addition, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25145), we proposed to continue to exclude the data from all-inclusive rate providers and LTCHs paid in accordance with demonstration projects, as well as any Medicare Advantage claims from the MS–LTC–DRG relative weight calculations for the reasons discussed in section VII.C.3.c. of the preamble of the proposed rule.

Furthermore, for FY 2017, in using data from applicable LTCH cases to establish proposed MS–LTC–DRG relative weights, we proposed to continue to establish low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases) using our quintile methodology in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Therefore, for purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we proposed to group all of the low-volume MS–LTC–DRGs into five quintiles based on average charges per discharge. Then, under our existing methodology, we proposed to account for adjustments made to LTCH PPS standard Federal payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG), and to make adjustments to account for nonmonotonically increasing weights, when necessary. The methodology is premised on more severe cases under the MS–LTC–DRG system requiring greater expenditure of medical care resources and higher average charges such that, in the severity levels within a base MS–LTC–DRG, the relative weights should increase monotonically with severity from the lowest to highest severity level. (We discuss each of these components of our MS–LTC–DRG relative weight methodology in greater detail in section VII.C.3.g. of the preamble of this final rule.)

Comment: A few commenters expressed concern that a number of MS–LTC–DRGs that historically have the greatest number of LTCH standard Federal rate cases each year would have lower weights for FY 2017 relative to the weights they had in prior fiscal years. The commenters believed this is counterintuitive because they expect relative weights for those MS–LTC–DRGs to increase because they have the largest number of LTCH cases and LTCH discharges are concentrated in a relatively small number of MS–LTC–DRGs. These commenters recommended that CMS analyze and report on the decreasing trend in the relative weights for high-volume MS–LTC–DRGs.

Response: We agree with the commenters that LTCH discharges are concentrated in a relatively small number of MS–LTC–DRGs, and as LTCHs gain experience under the new dual rate LTCH PPS payment structure, the concentration of cases grouped to those ''high volume'' MS–LTC–DRGs will increase based on the types of LTCH PPS standard Federal payment rate cases LTCHs treat under the new statutory patient criteria. However, we disagree with the commenters that there is a direct relationship between an increase in the number of cases in an MS–LTC–DRG and the annual change in the relative weights after recalibration. As provided under § 412.515, each MS–LTC–DRG, is assigned an appropriate weight that reflects the estimated relative cost of hospital resources used within that group compared to discharges classified within other groups. Furthermore, § 412.517(a) requires that the MS–LTC–DRG classifications and weighting factors are adjusted annually to reflect changes in treatment patterns; technology; number of discharges; and other factors affecting the relative use of hospital resources. The MS–LTC–DRG relative weights are designed to reflect the average of resources used to treat representative cases of the discharges within each MS–LTC–DRG. In general, the MS–LTC–DRG relative weights are determined by dividing the average charge for each MS–LTC–DRG by the average charge across all MS–LTC–DRGs. Accordingly, those MS–LTC–DRGs with an increase in average charge of less than the increase in average charge across all MS–LTC–DRGs will experience a reduction in their relative weight because the average charge for each of those MS–LTC–DRGs is being divided by a larger number (that is, the average charge across all MS–LTC–DRGs). (Similarly, MS–LTC–DRGs with an increase in average charge of more than the increase in average charge across all MS–LTC–DRGs will experience an increase in their relative weight because the average charge for each of those MS–LTC–DRGs is being divided by a smaller number.) (70 FR 47335)

In light of the commenters' concern, we reviewed the FY 2015 LTCH claims data used for the proposed rule and found that the average charge for the ''high volume'' MS–LTC–DRGs noted by commenters are increasing between the proposed FY 2017 relative weights as compared to the FY 2016 relative weights. However, many of these MS–LTC–DRGs experienced an increase in average charge that was less than the overall increase in the average charge for all MS–LTC–DRGs. For example, MS–LTC–DRG 207 showed an increase in average charge of 6.6 percent. However, the overall average charge for all MS–LTC–DRGs increased by over 7.5 percent. Thus, because the average charge for MS–LTC–DRG 207 increased less as compared to the increase in the overall average charge, the proposed relative weight for FY 2017 decreased a small amount (approximately 0.7 percent). The comparison of the average charge for an MS–LTC–DRGs to the average charge of all MS–LTC–DRGs

reflects the resources (and costs) used by LTCHs to treat patients in a given MS–LTC–DRG relative to the resources (and costs) used by LTCHs to treat all patients. When updated LTCH claims data for a particular MS–LTC–DRG show either an increase in the average charge of the MS–LTC–DRG that is less than the overall increase in the average charge across all MS–LTC–DRGs or a decrease in the average charge of a particular MS–LTC–DRG, we believe that the decrease in the relative weights for such MS–LTC–DRGs is appropriate because the updated LTCH claims data reflect more recent changes in treatment patterns, technology, number of discharges, and other factors affecting the relative use of hospital resources.

Comment: One commenter questioned the use of the historical LTCH claims data in the ratesetting methodology, including calculation of the MS–LTC–DRG relative weights, given that these data precede the revised dual rate LTCH PPS payment structure.

Response: As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49615), we solicited stakeholder input during the FY 2015 rulemaking cycle regarding the calculation of the MS–LTC–DRG relative payment weights under the new dual rate statutory LTCH PPS payment structure. Most commenters recommended that the MS–LTC–DRG relative weights under the new statutory structure should be calculated using only the data from cases that meet the statutory patient-level criteria for exclusion from the site neutral payment rate (or cases that would have qualified for exclusion had the dual rate LTCH PPS payment structure been in effect at the time of discharge). As we discussed in that same final rule, we believe that the costs and resource use for cases paid at the site neutral payment rate in the future may be lower on average than the costs and resource use for LTCH cases in our historical data that would have been paid at the site neutral payment rate if the statutory changes were in place when the discharges occurred, even if the proportion of site neutral payment rate cases in future data remains similar to the historical data. Therefore, we believe that the MS–LTC–DRG relative weights could become distorted over time and could also lead to less stability in the MS–LTC–DRG relative weights. For these reasons, we established our methodology for calculating the FY 2016 MS–LTC–DRG relative weights under the new dual rate LTCH PPS payment structure using only data from cases that would have been LTCH PPS standard Federal payment rate cases had the new LTCH PPS statutory patient-level criteria been in effect at the time of the discharge (80 FR 49615). We proposed to continue to employ this approach to calculate the FY 2017 MS–LTC–DRG relative weights because we continue to believe that computing the MS–LTC–DRG relative weights using only data from LTCH PPS cases that are (or would have been) paid the LTCH PPS standard Federal payment rate will result in the most appropriate payments under LTCH PPS.

After consideration of the public comments we received, we are finalizing our proposals for calculating the MS–LTC–DRG relative weights for FY 2017, without modification.

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs), or minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 86.11)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis;
- Additional or secondary diagnoses;
- Surgical procedures;
- Age;
- Sex; and
- Discharge status of the patient.

Currently, for claims submitted on the 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in Subparts I through S of Part 162. Among other requirements, by January 1, 2012, covered entities were required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code set requirements when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the Internal Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of this final rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers

to section II.D. of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

MACs enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further development (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the Medicare contractor determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Changes to the MS–LTC–DRGs for FY 2017

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in the FY 2017 IPPS/LTCH PPS proposed rule, we proposed to update the MS–LTC–DRG classifications effective October 1, 2016, through September 30, 2017 (FY 2017), consistent with the proposed changes to specific MS–DRG classifications presented in section II.F. of the preamble of the proposed rule (81 FR 25146). Accordingly, the MS–LTC–DRGs for FY 2017 presented in the proposed rule and this final rule are the same as the MS–DRGs that will be used under the IPPS for FY 2017. In addition, because the MS–LTC–DRGs for FY 2017 are the same as the MS–DRGs for FY 2017, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under GROUPER Version 34 as discussed in section II.G. of the preamble of this final rule, including the changes to the MCE software and the ICD–10–CM/PCS coding system, also will be applicable under the LTCH PPS for FY 2017. (We note the GROUPER Version 34 is based on ICD–10–CM/PCS diagnoses and procedure codes, consistent with the requirement to use ICD–10 beginning October 1, 2015.)

3. Development of the FY 2017 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment system rate by the applicable relative weight in determining payment to LTCHs for each case. In order to make these annual adjustments under the dual rate LTCH PPS payment structure, beginning with FY 2016, we recalibrate the MS–LTC–DRG relative weighting factors annually using data from applicable LTCH cases (80 FR 49614 through 49617). Under this policy, the resulting MS–LTC–DRG relative weights would continue to be used to adjust the LTCH PPS standard Federal payment rate when calculating the payment for LTCH PPS standard Federal payment rate cases.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity resulting from the adoption of the MS–LTC–DRGs, along with the change made in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure were in effect at the time of the discharge). (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

b. Development of the MS–LTC–DRG Relative Weights for FY 2017

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49625 through 49634), we presented our policies for the development of the MS–LTC–DRG relative weights for FY 2016.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25147), we proposed to continue to use our current methodology to determine the MS–LTC–DRG relative weights for FY 2017, including the application of established policies related to: The hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, the steps for calculating the MS–LTC–DRG relative

weights with a budget neutrality factor, and only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate (or, for discharges occurring prior to the implementation of the dual rate LTCH PPS payment structure, would have met the criteria for exclusion had those criteria been in effect at the time of the discharge)).

In this section, we present our methodology for determining the MS–LTC–DRG relative weights for FY 2017, and we discuss the effects of our policies concerning the data used to determine the FY 2017 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

c. Data

For this final rule, consistent with our proposals regarding the calculation of the MS–LTC–DRG relative weights for FY 2017, we obtained total charges from FY 2015 Medicare LTCH claims data from the March 2016 update of the FY 2015 MedPAR file, which are the best available data at this time, and we are using Version 34 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we used those data and the Version 34 of the MS–LTC–DRGs in establishing the FY 2017 MS–LTC–DRG relative weights in this final rule. To calculate the FY 2017 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, as we proposed, we are continuing to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we began by first evaluating the LTCH claims data in the March 2016 update of the FY 2015 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) had the dual rate LTCH PPS payment structure been in effect at the time of discharge. We identified the FY 2015 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945 and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or
- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2015 MedPAR file that reported ICD–9–CM procedure code 96.72 were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion (as FY 2015 discharges occurred prior to the adoption of ICD–10–CM/PCS). (We note that the corresponding ICD–10–PCS code for cases involving at least 96 hours of ventilation services is 5A1955Z, effective October 1, 2016) (80 FR 49626 through 49627). We note that, for purposes of developing the FY 2017 MS–LTC–DRG relative weights using our current methodology, we did not make any proposals regarding the identification of cases that would have been excluded from the site neutral payment rate under the statutory provision that provided for temporary exception from the site neutral payment rate under the LTCH PPS for certain severe wound care discharges from certain LTCHs provided by Public Law 114–113, had our implementation of that law and the dual rate LTCH PPS payment structure been in effect at the time of the discharge. At this time, it is uncertain how many LTCHs and how many cases in the claims data we are using for this final rule would have met the criteria to be excluded from the site neutral payment rate under that exception (had the dual rate LTCH PPS payment structure been in effect at the time of the discharge). Therefore, for the remainder of this section, when we refer to LTCH claims only from cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had the applicable statutes been in effect at the time of the discharge), such data do not include any discharges that would have been paid based on the LTCH PPS standard Federal payment rate under the provisions of section 231 of Public Law 114–113, had the exception been in effect at the time of the discharge.

Furthermore, consistent with our historical methodology, as we proposed, we are excluding any claims in the resulting data set that were submitted by LTCHs that are all-inclusive rate providers and LTCHs that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our proposals, we are excluding any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files. The claims that remained after these three trims (that is, the applicable LTCH data) were then used to calculate the MS–LTC–DRG relative weights for FY 2017.

In summary, in general, we identified the claims data used in the development of the FY 2017 MS–LTC–DRG relative weights in this final rule, as we proposed, by trimming claims data that would have been paid the site neutral rate had the dual payment rate structure been in effect (except for discharges which would have been excluded from the site neutral payment under the temporary exception for certain severe wound care discharges from certain LTCHs), as well as the claims data of 10 all-inclusive rate providers reported in the March 2016 update of the FY 2015 MedPAR file and any Medicare Advantage claims data. (We note that there were no data from any LTCHs that are paid in accordance with a demonstration project reported in the March 2016 update of the FY 2015 MedPAR file. However, had there been we would trim the claims data from those LTCHs as well, in accordance with our established policy.) We used the remaining data (that is, the applicable LTCH data) to calculate the relative weights for FY 2017.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25148), we proposed to continue to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2017. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR

55985). Specifically, under this methodology, we reduced the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs).

In accordance with our established methodology, for FY 2017, as we proposed, we are continuing to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.C.3.g. (Step 3) of the preamble of this final rule) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio was multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at a LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section of the proposed rule) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail below). For FY 2017, we proposed to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2017 MS–LTC–DRG relative weights (81 FR 25148).

In determining the FY 2017 MS–LTC–DRG relative weights, when necessary, as we proposed, we made adjustments to account for nonmonotonicity, as discussed in greater detail later in Step 6 of section VII.C.3.g. of the preamble of this final rule. We refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Low-Volume MS–LTC–DRGs

In order to account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, we proposed to continue to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148)). In cases where the initial assignment of a low-volume MS–LTC–DRG to a quintile resulted in nonmonotonicity within a base-DRG, as we proposed, we make adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail in section VII.C.3.g. (Step 6) of the preamble of this final rule.

In this final rule, based on the best available data (that is, the March 2016 update of the FY 2015 MedPAR files), we identified 261 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of MS–LTC–DRGs was then divided into one of the 5 low-volume quintiles, each containing 52 MS–LTC–DRGs (260/5 = 52). We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for the proposed rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5 and, therefore, as proposed, we employed our historical methodology for determining which of the low-volume quintiles contain the additional low-volume MS–LTC–DRG. However, based on the data available for this final rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases is evenly divisible by 5. Therefore, we no longer need to employ our historical methodology for determining which of the low-volume quintiles contain the additional low-volume MS–LTC–DRG. Specifically, for this final rule, after organizing the MS–LTC–DRGs by ascending order by average charge, we assigned the first 52 (1st through 52nd) of low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The 52 MS–LTC–DRGs with the highest average charge cases were assigned into Quintile 5. This results in each of the 5 low-volume quintiles containing 52 MS–LTC–DRGs. Table 13A, listed in section VI. of the Addendum to this final rule and available via the Internet on the CMS Web site, lists the composition of the low-volume quintiles for MS–LTC–DRGs for FY 2017.

In order to determine the FY 2017 relative weights for the low-volume MS–LTC–DRGs, we used the five low-volume quintiles described previously. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in

section VII.C.3.g. of the preamble of this final rule. We assigned the same relative weight and average length of stay to each of the low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases will vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the FY 2017 MS–LTC–DRG Relative Weights

In this final rule, as we proposed, we are continuing to use our current methodology to determine the FY 2017 MS–LTC–DRG relative weights.

In summary, to determine the FY 2017 MS–LTC–DRG relative weights, we grouped applicable LTCH cases to the appropriate MS–LTC–DRG, while taking into account the low-volume quintiles (as described above) and cross-walked no-volume MS–LTC–DRGs (as described later in this section). After establishing the appropriate MS–LTC–DRG (or low-volume quintile), as proposed, we calculated the FY 2017 relative weights by first removing cases with a length of stay of 7 days or less and statistical outliers (Steps 1 and 2 below). Next, as we proposed, we adjusted the number of applicable LTCH cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases (Step 3 below). After removing applicable LTCH cases with a length of stay of 7 days or less (Step 1 below) and statistical outliers (Step 2 below), which are the SSO-adjusted applicable LTCH cases and corresponding charges (step 3 below), as proposed, we calculated ''relative adjusted weights'' for each MS–LTC–DRG (or low-volume quintile) using the HSRV method.

Step 1—Remove cases with a length of stay of 7 days or less.

The first step in our calculation of the FY 2017 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the proposed FY 2017 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology and as proposed, in determining the FY 2017 MS–LTC–DRG relative weights, we removed LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—Remove statistical outliers.

The next step in our calculation of the FY 2017 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, as we proposed, we are continuing to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, we are left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this final rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 3—Adjust charges for the effects of SSOs.

As the next step in the calculation of the FY 2017 MS–LTC–DRG relative weights, consistent with our historical approach and as we proposed, we adjusted each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, we made this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the FY 2017 MS–LTC–DRG relative weights would lower the FY 2017 MS–LTC–DRG relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, as we proposed, we are continuing to adjust for SSO cases under § 412.529 in this manner because it will results in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the FY 2017 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology and as we proposed, we calculated the FY 2017 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each SSO-adjusted trimmed applicable LTCH case, we calculated a hospital-specific relative charge value by dividing the charge per discharge after adjusting for SSOs of the LTCH case (from Step 3) by the average charge per SSO-adjusted discharge for the LTCH in which the case occurred. The resulting ratio was then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each MS–LTC–DRG, we calculated the FY 2017 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the

MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent cases from Step 3 for each MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent applicable LTCH cases from Step 3 for each MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) were then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values were then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a FY 2017 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology and as we proposed, we identified the MS–LTC–DRGs for which there were no claims in the March 2016 update of the FY 2015 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under those proposed MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assigned a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of the final rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

We cross-walked each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology described above). Then, the ''no-volume'' MS–LTC–DRG was assigned the same relative weight (and average length of stay) of the MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of the final rule).

Of the 757 MS–LTC–DRGs for FY 2017, we identified 357 MS–LTC–DRGs for which there are no trimmed applicable LTCH cases (the number identified includes the 8 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed below). We assigned relative weights to each of the 357 no-volume MS–LTC–DRGs that contained trimmed applicable LTCH cases based on clinical similarity and relative costliness to 1 of the remaining 400 (757 − 357 = 400) MS–LTC–DRGs for which we calculated relative weights based on the trimmed applicable LTCH cases in the FY 2015 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as the MS–LTC–DRGs to which we cross-walked 1 of the 334 ''no volume'' MS–LTC–DRGs.) Then, we generally assigned the 334 no-volume MS–LTC–DRGs the relative weight of the cross-walked MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

We cross-walked the no-volume MS–LTC–DRG to an MS–LTC–DRG for which we calculated relative weights based on the March 2016 update of the FY 2015 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2017, the relative weights assigned based on the cross-walked MS–LTC–DRGs will result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, are expected to generally require equivalent relative resource use.

We then assigned the relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight (and average length of stay) for FY 2017. We note that, if the cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology described in Steps 1 through 4 above) was assigned to the no-volume MS–LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2017. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume MS–LTC–DRG resulted, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing relative weights.)

For this final rule, a list of the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs) for FY 2017 is shown in Table 13B, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site.

To illustrate this methodology for determining the relative weights for the FY 2017 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example, which refers to the no-volume MS–LTC–DRGs crosswalk information for FY 2017 provided in Table 13B.

Example: There were no trimmed applicable LTCH cases in the FY 2015 MedPAR file that we are using for this final rule for MS–LTC–DRG 061 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that MS–LTC–DRG 070 (Nonspecific Cerebrovascular Disorders with MCC) is similar clinically and based on resource use to MS–LTC–DRG 061. Therefore, we assigned the same relative weight (and average length of stay) of MS–LTC–DRG 70 of 0.9098 for FY 2017 to MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume will vary in the future.

Consistent with our historical practice, we used the most recent available claims data to identify the trimmed applicable LTCH cases from which we determined the relative weights in this final rule.

For FY 2017, consistent with our historical relative weight methodology and as we proposed, we are establishing a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 008); Pancreas Transplant (MS–LTC–DRG 010); and Kidney Transplant (MS–LTC–DRG 652). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these eight transplant proposed MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy and as we proposed, we are establishing a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

In this final rule, for FY 2017, as we proposed, we are establishing a relative weight equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). As we discussed when we implemented the dual rate LTCH PPS payment structure, LTCH discharges that are grouped to these 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs do not meet the criteria for exclusion from the site neutral payment rate. As such, under the criterion for a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation, there are no applicable LTCH cases to use in calculating a relative weight for the ''psychiatric and rehabilitation'' proposed MS–LTC–DRGs. In other words, any LTCH PPS discharges grouped to any of the 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs will always be paid at the site neutral payment rate, and, therefore, those MS–LTC–DRGs will never include any LTCH cases that meet the criteria for exclusion from the site neutral payment rate. However, section 1886(m)(6)(B) of the Act establishes a transitional payment method for cases that would be paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017. Under the transitional payment method for site neutral payment rate cases, for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2016, and on or before September 30, 2017, site neutral payment rate cases are paid a blended payment rate, calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate. Because the LTCH PPS standard Federal payment rate is based on the relative weight of the MS–LTC–DRG, in order to determine the transitional blended payment for site neutral payment rate cases grouped to one of the ''psychiatric or rehabilitation'' MS–LTC–DRGs in FY 2017, as we proposed, we assigned a relative weight to these MS–LTC–DRGs for FY 2017 that is the same as the FY 2015 relative weight (which is also the same as the FY 2016 relative weight). We believe that using the respective FY 2015 relative weight for each of the ''psychiatric or rehabilitation'' MS–LTC–DRGs results in appropriate payments for LTCH cases that are paid at the site neutral payment rate under the transition policy provided by the statute because there are no clinically similar MS–LTC–DRGs for which we were able to determine relative weights based on applicable LTCH cases in the FY 2015 MedPAR file data using the steps described above. Furthermore, we believe that it would be administratively burdensome and introduce unnecessary complexity to the MS–LTC–DRG relative weight calculation to use the LTCH discharges in the MedPAR file data to calculate a relative weight for those 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs to be used for the sole purpose of determining half of the transitional blended payment for site neutral payment rate cases during the transition period (80 FR 49631 through 49632).

In summary, for FY 2017, we are establishing a relative weight (and average length of stay thresholds) equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs listed previously (that is, MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946). Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site, reflects this final policy.

Step 6—Adjust the FY 2017 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the FY 2017 MS–LTC–DRG relative weights, consistent with our historical methodology and as we proposed, we are continuing to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the FY 2017 MS–LTC–DRG relative weights in this final rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site.

Step 7—Calculate the FY 2017 MS–LTC–DRG reclassification and recalibration budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). To achieve the budget neutrality requirement at § 412.517(b), under our established methodology, for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision and as we proposed, we are updating the MS–LTC–DRG classifications and relative weights for FY 2017 based on the most recent available LTCH data for applicable LTCH cases, and continuing to apply a budget neutrality adjustment in determining the FY 2017 MS–LTC–DRG relative weights.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25152 through 25153), to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we proposed to continue to use our established two-step budget neutrality methodology.

Comment: One commenter questioned how the low-volume MS–LTC–DRGs or MS–LTC–DRGs with no applicable LTCH cases impact the budget neutrality process.

Response: Under our established two-step budget neutrality methodology, we first calculated and applied a normalization factor to the recalibrated relative weights; and then we calculated and applied a budget neutrality adjustment factor. Under both of these steps, the low-volume MS–LTC–DRGs are reflected in the budget neutrality calculation, and generally MS–LTC–DRGs with no applicable LTCH cases are not reflected in the budget neutrality calculation, as explained below.

As described in the proposed rule (81 FR 25153), to calculate the proposed normalization factor for FY 2017, we grouped applicable LTCH cases using the proposed FY 2017 Version 34 GROUPER, and the recalibrated proposed FY 2017 MS–LTC–DRG relative weights to calculate the average case-mix index (CMI); we grouped the same applicable LTCH cases using the FY 2016 GROUPER Version 33 and MS–LTC–DRG relative weights and calculated the average CMI; and computed the ratio by dividing the average CMI for FY 2016 by the average CMI proposed for FY 2017. That ratio was the proposed normalization factor. Because the calculation of the normalization factor involves the relative weights for the MS–LTC–DRGs that contained applicable LTCH cases to calculate the average CMIs, any low-volume MS–LTC–DRGs are included in the calculation (and the MS–LTC–DRGs with no applicable LTCH cases are not included in the calculation).

As described in the proposed rule (81 FR 25153), to calculate the budget neutrality adjustment factor, we simulated estimated total FY 2017 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed FY 2017 normalized relative weights and GROUPER Version 34; simulated estimated total FY 2016 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2016 MS–LTC–DRG relative weights and the FY 2016 GROUPER Version 33; and calculated the ratio of these estimated total payments by dividing the simulated estimated total LTCH PPS standard Federal payment rate payments for FY 2016 by the simulated estimated total LTCH PPS standard Federal payment rate payments for FY 2017. The resulting ratio was the proposed budget neutrality adjustment factor. The calculation of the budget neutrality factor involves the relative weights for the LTCH cases used in the payment simulation, which includes any cases grouped to low-volume or to MS–LTC–DRGs with no applicable LTCH cases, and generally does not include payments for cases MS–LTC–DRG with no applicable LTCH cases. (Occasionally, a few LTCH cases (that is, those with a covered length of stay of 7 days or less, which are removed from the relative weight calculation in step 2) that are grouped to an MS–LTC–DRG with no applicable LTCH cases are included in the payment simulations used to calculate the budget neutrality factor. However, the number and payment amount of such cases have a negligible impact on the budget neutrality factor calculation).

In this final rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), as we proposed, we are continuing to use our established

two-step budget neutrality methodology. Therefore, in this final rule, in the first step of our MS–LTC–DRG budget neutrality methodology, for FY 2017, as we proposed, we calculated and applied a normalization factor to the recalibrated relative weights (the result of Steps 1 through 6 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the normalization factor for FY 2017 (the first step of our budget neutrality methodology), we used the following three steps: (1.a.) Used the most recent available applicable LTCH cases from the most recent available data (that is, LTCH discharges from the FY 2015 MedPAR file) and grouped them using the FY 2017 GROUPER (that is, Version 34 for FY 2017) and the recalibrated FY 2017 MS–LTC–DRG relative weights (determined in Steps 1 through 6 above) to calculate the average case-mix index; (1.b.) grouped the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2016 GROUPER (Version 33) and FY 2016 MS–LTC–DRG relative weights and calculated the average case-mix index; and (1.c.) computed the ratio of these average case-mix indexes by dividing the average CMI for FY 2016 (determined in Step 1.b.) by the average case-mix index for FY 2017 (determined in Step 1.a.). As a result, in determining the MS–LTC–DRG relative weights for FY 2017, each recalibrated MS–LTC–DRG relative weight was multiplied by the normalization factor of 1.28408 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produced ''normalized relative weights.''

In the second step of our MS–LTC–DRG budget neutrality methodology, as we proposed, we calculated a second budget neutrality factor consisting of the ratio of estimated aggregate FY 2017 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.a. mentioned previously) after reclassification and recalibration to estimated aggregate payments for FY 2017 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration (that is, the sum of all calculations under Step 1.b. mentioned previously).

That is, for this final rule, for FY 2017, under the second step of the budget neutrality methodology, we determined the budget neutrality adjustment factor using the following three steps: (2.a.) Simulated estimated total FY 2017 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the normalized relative weights for FY 2017 and GROUPER Version 34 (as described above); (2.b.) simulated estimated total FY 2016 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2016 GROUPER (Version 33) and the FY 2016 MS–LTC–DRG relative weights in Table 11 of the FY 2016 IPPS/LTCH PPS final rule available on the Internet, as described in section VI. of the Addendum of that final rule; and (2.c.) calculated the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the FY 2017 MS–LTC–DRG relative weights, each normalized relative weight was then multiplied by a budget neutrality factor of 1.0011126 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology to achieve the budget neutrality requirement at § 412.517(b).

Accordingly, in determining the FY 2017 MS–LTC–DRG relative weights in this final rule, consistent with our existing methodology, we applied a normalization factor of 1.28408 and a budget neutrality factor of 1.0011126. Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site, lists the MS–LTC–DRGs and their respective relative weights, geometric mean length of stay, five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)), and the ''IPPS Comparable Thresholds'' (used in determining SSO payments under § 412.529(c)(3)), for FY 2017.

D. Rebasing of the LTCH Market Basket

1. Background

The input price index (that is, the market basket) that was used to develop the LTCH PPS for FY 2003 was the ''excluded hospital with capital'' market basket. That market basket was based on 1997 Medicare cost report data and included data for Medicare-participating IRFs, IPFs, LTCHs, cancer hospitals, and children's hospitals. Although the term ''market basket'' technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that mix. Accordingly, the term ''market basket,'' as used in this section, refers to an input price index.

Beginning with RY 2007, LTCH PPS payments were updated using a 2002-based market basket reflecting the operating and capital cost structures for IRFs, IPFs, and LTCHs (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). We excluded cancer and children's hospitals from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which are implemented in regulations at 42 CFR 413.40. Those types of hospitals are not paid under a PPS. Also, the 2002 cost structures for cancer and children's hospitals are noticeably different from the cost structures for freestanding IRFs, freestanding IPFs, and LTCHs. A complete discussion of the 2002-based RPL market basket can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51756), we finalized the rebasing and revising of the 2002-based RPL market basket by creating and implementing a 2008-based RPL market basket. We also discussed the creation of a stand-alone LTCH market basket and received several public comments, all of which supported deriving a stand-alone LTCH market basket (76 FR 51756 through 51757). In the FY 2013 IPPS/LTCH PPS final rule, we finalized the adoption of a stand-alone 2009-based LTCH-specific market basket that reflects the cost structures of LTCHs only (77 FR 53467 through 53479).

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25153 through 25167), we proposed to rebase and revise the 2009-based LTCH-specific market basket. The proposed LTCH market basket is primarily based on Medicare cost report data for LTCHs for 2013, which are for cost reporting periods beginning on and after October 1, 2012, and before October 1, 2013. We proposed to use data from cost reports beginning in FY 2013 because these data are the latest available complete data for purposes of calculating cost weights for the market basket. In the following discussion, we provide an overview of the proposed LTCH market basket and describe the methodologies we proposed to use for determining the operating and capital portions of the proposed 2013-based LTCH market basket.

2. Overview of the 2013-Based LTCH Market Basket

Similar to the 2009-based LTCH-specific market basket, the proposed 2013-based LTCH market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix (that is, intensity) of goods and services purchased over time are not measured.

The index itself is constructed using three steps. First, a base period is selected (in the proposed rule, we proposed to use 2013 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect a recent mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care.

3. Development of the 2013-Based LTCH Market Basket Cost Categories and Weights

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25154), we invited public comments on our proposed methodology for deriving the 2013-based LTCH market basket. We received one general comment regarding our proposed 2013-based LTCH market basket.

Comment: One commenter supported CMS' proposed methodology to revise and rebase the LTCH market basket.

Response: We appreciate the commenter's support.

We summarize and respond to any public comments received regarding the specifics of our proposed methodology under the applicable sections below, and provide final decisions regarding each proposed methodology in the relevant section.

a. Use of Medicare Cost Report Data

The proposed 2013-based LTCH market basket consists of six major cost categories derived from the 2013 LTCH Medicare cost reports (CMS Form 2552–10), including wages and salaries, employee benefits, contract labor, pharmaceuticals, professional liability insurance, and capital. After we calculate these cost categories, we are left with a residual cost category, which reflects all other input costs other than those captured in the six cost categories above. This is the same number of cost categories derived for the 2009-based LTCH-specific market basket using the 2009 Medicare cost report data (CMS Form 2552–96). These 2013 Medicare cost reports include data for cost reporting periods beginning on and after October 1, 2012, and before October 1, 2013. We proposed to use 2013 as the base year because we believed that the 2013 Medicare cost reports represented the most recent, complete set of Medicare cost report data available to develop cost weights for an LTCH market basket. Medicare cost report data include costs for all patients, including Medicare, Medicaid, and private payer.

Because our goal is to measure cost shares for facilities that serve Medicare beneficiaries, and are reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries in LTCHs, we proposed to limit our selection of Medicare cost reports to those from LTCHs that have a Medicare average length of stay (LOS) that is within a comparable range of their total facility average LOS. We define the Medicare average LOS based on data reported on the Medicare cost report (CMS Form 2552–10) Worksheet S–3, Part I, Line 14. We believe that applying the LOS edit results in a more accurate reflection of the structure of costs for Medicare covered days. For the 2009-based LTCH-specific market basket, we used the cost reports submitted by LTCHs with Medicare average LOS within 15 percent (that is, 15 percent higher or lower) of the total facility average LOS for the hospital.

Based on our analysis of the 2013 Medicare cost reports, for the proposed 2013-based LTCH market basket, we proposed to use the cost reports submitted by LTCHs with Medicare average LOS within 25 percent (that is, 25 percent higher or lower) of the total facility average LOS for the hospital (this edit excludes 6 percent of LTCH providers). Applying the proposed trim resulted in a subset of LTCH Medicare cost reports with an average Medicare LOS of 27 days, average facility LOS of 28 days, and aggregate Medicare utilization (as measured by Medicare inpatient LTCH days as a percentage of total facility inpatient LTCH days) of 66 percent. If we were to apply the same trim as was applied for the 2009-based LTCH-specific market basket, we would exclude 11 percent of LTCH providers, but the results would be very similar with an average Medicare LOS of 27 days, average facility LOS of 27 days, and aggregate Medicare utilization of 66 percent. The 6 percent of providers that were excluded from the proposed 2013-based LTCH market basket have an average Medicare LOS of 29 days, average facility LOS of 77 days, and aggregate Medicare utilization of 12 percent. We stated that we believe that the use of this proposed trim, instead of the trim used to develop the 2009-based LTCH-specific market basket, is a technical improvement because data from more LTCHs are used while still being reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries.

Comment: One commenter requested that CMS identify whether the 6 percent of total LTCH providers that CMS excluded when applying the LOS edit had any significant characteristics whereby their exclusion could have an impact on the calculation of rates and/or weights. The commenter further inquired whether the exclusion of these providers is creating a biased system.

Response: As stated in the proposed rule, our goal when deriving cost shares for the LTCH market basket is to use Medicare cost reports for those facilities that serve Medicare beneficiaries, and

are reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries in LTCHs. Therefore, we proposed to limit our selection of Medicare cost reports to those from LTCHs that have a Medicare average LOS that is within a comparable range of their total facility average LOS. We believe that applying the LOS edit results in a more accurate reflection of the structure of costs for Medicare covered days.

In response to the comment, we performed a sensitivity analysis where we recalculated the major cost weights using the Medicare cost report data for all LTCHs, as opposed to our proposed methodology of excluding approximately 6 percent of LTCH providers based on the Medicare and total facility LOS. We found that the effect on the cost weights was small; the difference from the proposed major cost weights ranged from 0.0 percentage point to 0.7 percentage point, in absolute terms, and averaged 0.1 percentage point across the six major cost weights. We then also derived a LTCH market basket using these recalculated cost weights and found that, in any given year of the projection period, there was no difference in the growth rates between this market basket and the proposed market basket (when rounded to the tenth of one percentage point).

In summary, our analysis does not support the commenter's suggestion that the exclusion of those LTCH providers that had a Medicare LOS that was outside a comparable range of their total LOS resulted in estimates that were biased. We believe that these excluded providers are not reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries in LTCHs, and therefore should be excluded as we proposed. Furthermore, the exclusion of these providers does not have a material impact on the cost weights or market basket update.

After consideration of the public comments we received, we are adopting our proposed LOS trim methodology as final.

Using the resulting set of Medicare cost reports, we proposed to calculate cost weights for seven major cost categories of the proposed 2013-based LTCH market basket (wages and salaries, employee benefits, contract labor, professional liability insurance, pharmaceuticals, capital, and an ''all other'' residual cost category). The methodology used to develop the proposed 2013-based LTCH market basket cost weights is generally the same methodology used to develop the 2009-based LTCH-specific market basket cost weights. We describe the detailed methodology for obtaining costs for each of these seven cost categories below.

(1) Wages and Salaries Costs

We proposed to derive wages and salaries costs as the sum of inpatient salaries, ancillary salaries, and a proportion of overhead (or general service cost center) salaries as reported on Worksheet A, Column 1. Because overhead salary costs are attributable to the entire LTCH, we proposed to only include the proportion attributable to the Medicare allowable cost centers. Similar to the 2009-based LTCH-specific market basket major cost weights, we define Medicare allowable total costs (routine, ancillary and capital) as costs that are eligible for payment through the LTCH PPS. We proposed to estimate the proportion of overhead salaries that are attributed to Medicare allowable costs centers by multiplying the ratio of Medicare allowable cost centers' salaries to total salaries (Worksheet A, Column 1, Line 200) by total overhead salaries. A similar methodology was used to derive wages and salaries costs in the 2009-based LTCH-specific market basket.

We did not receive any public comments on our proposed methodology for deriving wages and salaries costs. Therefore, we are adopting our proposed methodology as final.

(2) Employee Benefit Costs

Similar to the 2009-based LTCH-specific market basket, we proposed to calculate employee benefit costs using Worksheet S3, Part II. The completion of Worksheet S–3, Part II is only required for IPPS hospitals. However, for 2013, we found that roughly 35 percent of all LTCHs voluntarily reported these data (similar to prior years). We note that this worksheet is only required to be completed by IPPS hospitals. Our analysis of the Worksheet S–3, Part II data submitted by these LTCHs indicates that we have a large enough sample to enable us to produce a reasonable employee benefits cost weight. Specifically, we found that when we recalculated the cost weight after weighting to reflect the characteristics of the universe of LTCHs (type of control (nonprofit, for-profit, and government) and by region), the recalculation did not have a material effect on the resulting cost weight. Therefore, we proposed to use Worksheet S–3, Part II data (as was done for the 2009-based LTCH-specific market basket) to calculate the employee benefit cost weight in the proposed 2013-based LTCH market basket.

We note that, effective with the implementation of CMS Form 2552–10 for cost reporting periods beginning on or after May 1, 2010, CMS began collecting employee benefits and contract labor data on Worksheet S–3, Part V, which is applicable to LTCHs. Only a few LTCHs reported these data and, therefore, we were unable to use such a small sample to accurately reflect these costs. Therefore, we encourage all LTCHs to report employee benefit and contract labor costs on Worksheet S–3, Part V.

We did not receive any public comments on our proposed methodology for deriving employee benefits costs. Therefore, we are adopting our proposed methodology as final.

(3) Contract Labor Costs

Contract labor costs are primarily associated with direct patient care services. Contract labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described below. As was done for the 2009-based LTCH-specific market basket, we proposed to derive the contract labor cost weight for the 2013-based LTCH market basket using voluntarily reported data from Worksheet S–3, Part II. Approximately 48 percent of LTCHs voluntarily reported contract labor cost on the Worksheet S–3, Part II. Our analysis of these data indicates that we have a large enough sample to enable us to produce a reasonable contract labor cost weight. Specifically, we found that when we recalculated the cost weight after weighting to reflect the characteristics of the universe of LTCHs (type of control (nonprofit, for-profit, and government) and by region), the recalculation did not have a material effect on the resulting cost weight. Therefore, as was done for the 2009-based LTCH-specific market basket, we proposed to use Worksheet S–3, Part II to calculate the contract labor cost weight in the proposed 2013-based LTCH market basket.

We did not receive any public comments on our proposed methodology for deriving contract labor costs. Therefore, we are adopting our proposed methodology as final.

(4) Pharmaceutical Costs

We proposed to calculate pharmaceutical costs using costs reported on Worksheet A, Column 7, minus the amount on Worksheet A, Column 1, for the pharmacy cost center (Line 15) and drugs charged to patients

cost center (Line 73). A similar methodology was used for the 2009-based LTCH-specific market basket using the CMS Form 2552–96.

We did not receive any public comments on our proposed methodology for deriving pharmaceutical costs. Therefore, we are adopting our proposed methodology as final.

(5) Professional Liability Insurance Costs

We proposed that professional liability insurance (PLI) costs (often referred to as malpractice costs) be equal to premiums, paid losses and self-insurance costs reported on Worksheet S2, Part I, Line 118.10, Columns 1 through 3. A similar methodology was used for the 2009-based LTCH-specific market basket using the CMS Form 2552–96.

We did not receive any public comments on our proposed methodology for deriving professional liability insurance costs. Therefore, we are adopting our proposed methodology as final.

(6) Capital Costs

We proposed that capital costs be equal to Medicare allowable capital costs as reported on Worksheet B, Part II, Column 26. We proposed to define Medicare allowable costs as cost centers: 30 through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91 and 93. A similar methodology was used for the 2009-based LTCH-specific market basket using the CMS Form 2552–96.

We did not receive any public comments on our proposed methodology for deriving capital costs. Therefore, we are adopting our proposed methodology as final.

b. Final Major Cost Category Computation

In addition to our policies to derive costs for the major cost categories for each provider using the Medicare cost report data as previously described, we proposed to address outlier cases using the following steps. First, for each provider, we proposed to divide the costs for each of the six categories by the total Medicare allowable costs to obtain cost weights for the universe of LTCH providers. We proposed to define total Medicare allowable costs reported on Worksheet B, Part I, Column 26 for cost centers: 30 through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91 and 93.

We then proposed to remove those providers whose derived cost weights fall in the top and bottom 5 percent of provider-specific derived cost weights to ensure the removal of costs for outlier cases. This trim was applied after first keeping only those providers that had a cost weight greater than zero and less than 100 percent. After the costs for outlier cases were removed in this manner, we proposed to sum the costs for each category across all remaining providers, and then divided this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the proposed 2013-based LTCH market basket for the given category. Finally, we proposed to calculate a seventh major cost weight—the residual ''All Other'' cost weight to reflect all remaining costs that are not captured in the previous six cost categories listed. We referred readers to Table VII–1 below for the resulting proposed cost weights for these major cost categories (which, as we indicate later, we are finalizing).

TABLE VII–1—MAJOR COST CATEGORIES AND THEIR RESPECTIVE COST WEIGHTS AS CALCULATED FROM MEDICARE COST REPORTS

Major cost categories	Proposed and final 2013-based LTCH market basket cost weight (percent of total costs)	2009-based LTCH-specific market basket cost weight (percent of total costs)
Wages and Salaries	41.5	40.4
Employee Benefits	6.5	7.0
Contract Labor	5.9	6.9
Professional Liability Insurance (Malpractice)	0.9	0.8
Pharmaceuticals	7.6	8.9
Capital	9.7	9.8
All Other	27.8	26.1

The wages and salaries cost weight calculated from the Medicare cost reports for the proposed 2013-based LTCH market basket was approximately 1 percentage point higher than the wages and salaries cost weight for the 2009-based LTCH-specific market basket, while the contract labor cost weight is approximately 1 percentage point lower. The proposed 2013-based pharmaceuticals cost weight also was roughly 1 percentage point lower than the cost weight for the 2009-based LTCH-specific market basket.

As we did for the 2009-based LTCH market basket, we proposed to allocate the contract labor cost weight to the wages and salaries and employee benefits cost weights based on their relative proportions under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the wages and salaries cost weight as a percent of the sum of the wages and salaries cost weight and the employee benefits cost weight. This rounded percentage was 86 percent. Therefore, we proposed to allocate 86 percent of the contract labor cost weight to the wages and salaries cost weight and 14 percent to the employee benefits cost weight. We referred readers to Table VII–2 below that shows the proposed wages and salaries and employee benefit cost weights after contract labor cost weight allocation for both the proposed 2013-based LTCH market basket (which, as we indicate later, we are finalizing) and the 2009-based LTCH-specific market basket.

TABLE VII–2—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major cost categories	Proposed and final 2013-based LTCH cost weight (percent of total costs)	2009-based LTCH-specific cost weight (percent of total costs)
Wages and Salaries	46.6	46.3
Employee Benefits	7.3	8.0
Compensation	53.9	54.3

After the allocation of the contract labor cost weight, the proposed 2013-based wages and salaries cost weight was 0.3 percentage point higher, while the employee benefit cost weight was 0.7 percentage point lower, relative to the respective cost weights for the 2009-based LTCH-specific market basket. As a result, in the proposed 2013-based LTCH market basket, the compensation cost weight was 0.4 percentage point lower than the compensation cost weight for the 2009-based LTCH-specific market basket.

We did not receive any public comments on our proposed methodology for deriving the major cost weights for the 2013-based LTCH market basket. Therefore, we are adopting our proposed methodology as final.

c. Derivation of the Detailed Operating Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2013 Medicare cost report data into more detailed cost categories, we proposed to use the 2007 Benchmark Input-Output (I–O) ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 622000, Hospitals, published by the Bureau of Economic Analysis (BEA). These data are publicly available at the following Web site: *http://www.bea.gov/industry/io_annual.htm.*

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2007. The 2007 Benchmark I–O data are derived from the 2007 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[92] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we proposed to inflate the 2007 Benchmark I–O data forward to 2013 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2007 Benchmark I–O data. We repeated this practice for each year. We then calculated the cost shares that each cost category represents of the 2007 data inflated to 2013. These resulting 2013 cost shares were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the 2013-based LTCH market basket. For example, the cost for ''Food: Direct Purchases'' represented 6.5 percent of the sum of the ''All Other'' 2007 Benchmark I–O Hospital Expenditures inflated to 2013. Therefore, the ''Food: Direct Purchases'' cost weight represented 6.5 percent of the proposed 2013-based LTCH market basket's ''All Other'' cost category (27.8 percent), yielding a ''final'' ''Food: Direct Purchases'' proposed cost weight of 1.8 percent in the proposed 2013-based LTCH market basket (0.065 × 27.8 percent = 1.8 percent).

Using this methodology, we proposed to derive 18 detailed LTCH market basket cost category weights from the proposed 2013-based LTCH market basket residual cost weight (27.8 percent). These categories are: (1) Electricity; (2) Fuel, Oil, and Gasoline; (3) Water and Sewerage; (4) Food: Direct Purchases; (5) Food: Contract Services; (6) Chemicals; (7) Medical Instruments; (8) Rubber and Plastics; (9) Paper and Printing Products; (10) Miscellaneous Products; (11) Professional Fees: Labor-Related; (12) Administrative and Facilities Support Services; (13) Installation, Maintenance, and Repair Services; (14) All Other Labor-Related Services; (15) Professional Fees: Nonlabor-Related; (16) Financial Services; (17) Telephone Services; and (18) All Other Nonlabor-Related Services.

We did not receive any public comments on our proposed methodology for deriving the detailed operating cost weights for the 2013-based LTCH market basket. Therefore, we are adopting our proposed methodology as final.

d. Derivation of the Detailed Capital Cost Weights

As described in section VII.D.3.b. of the preamble of this final rule, we proposed a capital-related cost weight of 9.7 percent as calculated from the 2013 Medicare cost reports for LTCHs after applying the proposed trims described above. We proposed to then separate this total capital-related cost weight into more detailed cost categories.

Using 2013 Medicare cost reports, we were able to group capital-related costs into the following categories: Depreciation, Interest, Lease, and Other Capital-Related costs. For each of these categories, we proposed to determine what proportion of total capital-related costs the category represents using the data reported by the LTCH on Worksheet A–7, which is the same methodology used for the 2009-based LTCH-specific market basket.

We also proposed to allocate lease costs across each of the remaining detailed capital-related cost categories as was done in the 2009-based LTCH-specific market basket. This resulted in three primary capital-related cost categories in the proposed 2013-based LTCH market basket: Depreciation, Interest, and Other Capital-Related costs. Lease costs are unique in that they are not broken out as a separate cost category in the proposed 2013-based LTCH market basket. Rather, we proposed to proportionally distribute these costs among the cost categories of Depreciation, Interest, and Other Capital-Related, reflecting the assumption that the underlying cost structure of leases is similar to that of capital-related costs in general. As was done for the 2009-based LTCH-specific market basket, we proposed to assume that 10 percent of the lease costs as a proportion of total capital-related costs (62.3 percent) represents overhead and to assign those costs to the Other Capital-Related cost category accordingly. Therefore, we assumed that approximately 6.2 percent (62.3 percent

[92] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

× 0.1) of total capital-related costs represent lease costs attributable to overhead, and we proposed to add this 6.2 percent to the 5.9 percent Other Capital-Related cost category weight. We then proposed to distribute the remaining lease costs (56.1 percent, or 62.3 percent − 6.2 percent) proportionally across the three cost categories (Depreciation, Interest, and Other Capital-Related) based on the proportion that these categories comprised of the sum of the Depreciation, Interest, and Other Capital-Related cost categories (excluding lease expenses). For example, the Other Capital-Related capital cost category represented 15.5 percent of all three cost categories (Depreciation, Interest, and Other Capital-Related) prior to any lease expenses being allocated. This 15.5 percent was applied to the 56.1 percent of remaining lease expenses so that another 8.7 percent of lease expenses as a percent of total capital-related costs was allocated to the Other Capital-Related cost category. Therefore, the resulting proposed Other Capital-Related cost weight was 20.8 percent (5.9 percent + 6.2 percent + 8.7 percent). This is the same methodology used for the 2009-based LTCH-specific market basket. The proposed allocation of these lease expenses are shown in Table VII–3.

Finally, we proposed to further divide the Depreciation and Interest cost categories. We proposed to separate the Depreciation cost category into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We also proposed to separate the Interest cost category into the following two categories: (1) Government/Nonprofit; and (2) For-profit.

To disaggregate the depreciation cost weight, we needed to determine the percent of total depreciation costs for LTCHs (after the allocation of lease costs) that are attributable to building and fixed equipment, which we hereafter refer to as the ''fixed percentage.'' We proposed to use depreciation and lease data from Worksheet A–7 of the 2013 Medicare cost reports, which is the same methodology used for the 2009-based LTCH-specific market basket. Based on the 2013 LTCH Medicare cost report data, we determined that depreciation costs for building and fixed equipment account for 39 percent of total depreciation costs, while depreciation costs for movable equipment account for 61 percent of total depreciation costs. As mentioned above, we proposed to allocate lease expenses among the Depreciation, Interest, and Other Capital cost categories. We determined that leasing building and fixed equipment expenses accounted for 86 percent of total leasing expenses, while leasing movable equipment expenses accounted for 14 percent of total leasing expenses. We proposed to sum the depreciation and leasing expenses for building and fixed equipment, as well as sum the depreciation and leasing expenses for movable equipment. This resulted in the proposed building and fixed equipment depreciation cost weight (after leasing costs are included) representing 73 percent of total depreciation costs and the movable equipment depreciation cost weight (after leasing costs are included) representing 27 percent of total depreciation costs.

To disaggregate the interest cost weight, we needed to determine the percent of total interest costs for LTCHs that are attributable to government and nonprofit facilities, which we hereafter refer to as the ''nonprofit percentage,'' because price pressures associated with these types of interest costs tend to differ from those for for-profit facilities. We proposed to use interest costs data from Worksheet A–7 of the 2013 Medicare cost reports for LTCHs, which is the same methodology used for the 2009-based LTCH-specific market basket. The nonprofit percentage determined using this method was 23 percent.

As we stated in the proposed rule, ultimately, if finalized, these detailed capital cost shares would be applied to the total capital-related cost weight determined in section VII.D.3.b. of the preamble of this final rule to separate the total capital-related cost weight of 9.7 percent into more detailed cost categories and weights.

We did not receive any public comments on our proposed methodology for deriving the detailed capital cost weights for the 2013-based LTCH market basket. Therefore, we are adopting our proposed methodology as final. Table VII–3 below provides the proposed and final detailed capital cost shares obtained from the Medicare cost reports.

TABLE VII–3—DETAILED CAPITAL COST WEIGHTS FOR THE 2013-BASED LTCH MARKET BASKET

Cost categories	Proposed and final cost shares obtained from Medicare cost reports (percent of total costs)	Proposed and final detailed capital cost shares after allocation of lease expenses (percent of total costs)
Depreciation	22.0	54.8
Building and Fixed Equipment	16.1	40.1
Movable Equipment	5.9	14.7
Interest	9.8	24.4
Government/Nonprofit	2.2	5.6
For-profit	7.6	18.8
Lease	62.3	
Other	5.9	20.8

Note: Total may not add to 100 due to rounding.

e. 2013-Based LTCH Market Basket Cost Categories and Weights

Similar to the 2012-based IRF and 2012-based IPF market baskets, the proposed and final 2013-based LTCH market basket does not include separate cost categories for Apparel, Machinery and Equipment, and Postage. Due to the small weights associated with these detailed categories and relatively stable price growth in the applicable price proxy, we proposed to include the Apparel and Machinery and Equipment in the Miscellaneous Products cost category and the Postage in the All-Other Nonlabor-Related Services cost category. We note that the machinery

and equipment expenses are for equipment that is paid for in a given year and not depreciated over the asset's useful life. Depreciation expenses for movable equipment are reflected in the capital-related cost weight of the 2013-based LTCH market basket. For the 2013-based LTCH market basket, we also proposed to include a separate cost category for Installation, Maintenance, and Repair Services in order to proxy these costs by a price index that better reflects the price changes of labor associated with maintenance-related services.

We did not receive any public comments on our proposed detailed operating cost weights for the 2013-based LTCH market basket. Therefore, we are adopting our proposed detailed operating cost weights as final.

Table VII–4 below shows the proposed and final cost categories and weights for the final 2013-based LTCH market basket compared to the 2009-based LTCH-specific market basket.

TABLE VII–4—2013-BASED LTCH COST WEIGHTS COMPARED TO 2009-BASED LTCH COST WEIGHTS

Cost category	Proposed and final 2013-based LTCH cost weight	2009-based LTCH cost weight
Total	100.0	100.0
Compensation	53.9	54.3
Wages and Salaries	46.6	46.3
Employee Benefits	7.3	8.0
Utilities	2.2	1.8
Electricity	1.0	1.4
Fuel, Oil, and Gasoline	1.1	0.3
Water & Sewerage	0.1	0.1
Professional Liability Insurance	0.9	0.8
All Other Products and Services	33.2	33.3
All Other Products	16.3	19.5
Pharmaceuticals	7.6	8.9
Food: Direct Purchases	1.8	3.4
Food: Contract Services	1.1	0.5
Chemicals	0.7	1.3
Medical Instruments	2.4	2.1
Rubber & Plastics	0.6	1.3
Paper and Printing Products	1.2	1.2
Apparel	.....	0.3
Machinery and Equipment	.....	0.1
Miscellaneous Products	0.8	0.4
All Other Services	16.9	13.7
Labor-Related Services	8.3	5.3
Professional Fees: Labor-related	3.5	2.3
Administrative and Facilities Support Services	0.9	0.5
Installation, Maintenance, and Repair Services	2.0	
All Other: Labor-related Services	1.9	2.6
Nonlabor-Related Services	8.6	8.4
Professional Fees: Nonlabor-related	3.6	5.3
Financial services	2.9	1.0
Telephone Services	0.7	0.5
Postage	.....	0.8
All Other: Nonlabor-related Services	1.4	0.7
Capital-Related Costs	9.7	9.8
Depreciation	5.3	5.7
Fixed Assets	3.9	3.8
Movable Equipment	1.4	1.9
Interest Costs	2.4	2.4
Government/Nonprofit	0.5	0.7
For Profit	1.8	1.7
Other Capital-Related Costs	2.0	1.7

Note: Detail may not add to total due to rounding.

4. Selection of Price Proxies

After computing the cost weights for the 2013-based LTCH market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the proxy for Professional Liability Insurance, all of the proxies that we proposed for the operating portion of the 2013-based LTCH market basket are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- *Producer Price Indexes*—Producer Price Indexes (PPIs) measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that hospitals purchase as inputs because PPIs better reflect the actual price changes encountered by hospitals. For example, we proposed to use a PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because hospitals generally purchase drugs directly from a wholesaler. The PPIs that we proposed to use measure price changes at the final stage of production.

- *Consumer Price Indexes*—Consumer Price Indexes (CPIs) measure change in the prices of final goods and

services bought by the typical consumer. Because they may not represent the price encountered by a producer, we proposed to use CPIs only if an appropriate PPI was not available, or if the expenditures were more like those faced by retail consumers in general rather than by purchasers of goods at the wholesale level. For example, the CPI for food purchased away from home is used as a proxy for contracted food services.

▪ *Employment Cost Indexes*—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. We believe that the proposed PPIs, CPIs, and ECIs selected met these criteria.

Table VII–7 lists the price proxies that we proposed for the 2013-based LTCH market basket. Below we present a detailed explanation of the price proxies that we proposed for each cost category weight. We note that many of the proxies that we proposed to use for the 2013-based LTCH market basket are the same as those used for the 2009-based LTCH-specific market basket. For further discussion on the 2009-based LTCH market basket, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53479).

a. Price Proxies for the Operating Portion of the 2013-Based LTCH Market Basket

(1) Wages and Salaries

We proposed to use the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code CIU1026220000000I) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(2) Employee Benefits

We proposed to use the ECI for Total Benefits for All Civilian Workers in Hospitals to measure the price growth of this cost category. This ECI is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code CIU10162200000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(3) Electricity

We proposed to use the PPI Commodity for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(4) Fuel, Oil, and Gasoline

We proposed to change the proxy used for the Fuel, Oil, and Gasoline cost category. The 2009-based LTCH-specific market basket uses the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411) to proxy these expenses.

For the proposed 2013-based LTCH market basket, we proposed to use a blend of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411) and the PPI Commodity for Natural Gas (BLS series code WPU0531). Our analysis of the Bureau of Economic Analysis' 2007 Benchmark Input-Output data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]), shows that petroleum refineries expenses accounts for approximately 70 percent and natural gas accounts for approximately 30 percent of the fuel, oil, and gasoline expenses. Therefore, we proposed to use a blended proxy of 70 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411) and 30 percent of the PPI Commodity for Natural Gas (BLS series code WPU0531). We believe that these two price proxies are the most technically appropriate indices available to measure the price growth of the Fuel, Oil, and Gasoline cost category in the 2013-based LTCH market basket.

(5) Water and Sewage

We proposed to use the CPI for Water and Sewerage Maintenance (All Urban Consumers) (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(6) Professional Liability Insurance

We proposed to use proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Index. To generate these estimates, we collected commercial insurance premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This is the same price proxy used in the 2009-based LTCH-specific market basket.

(7) Pharmaceuticals

We proposed to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(8) Food: Direct Purchases

We proposed to use the PPI Commodity for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(9) Food: Contract Services

We proposed to use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(10) Chemicals

We proposed to continue to use a four-part blended PPI composed of the PPI Industry for Industrial Gas Manufacturing (BLS series code PCU325120325120P), the PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519), and the PPI Industry for Soap and Cleaning Compound Manufacturing (BLS series code PCU32561–32561). We proposed to update the blended weights using 2007 Benchmark I–O data, which we also proposed to use for the 2013-based LTCH market basket. The 2009-based LTCH-specific market basket included the same blended chemical price proxy, but used the 2002 Benchmark I–O data to determine the weights of the blended chemical price index. The 2007 Benchmark I–O data show more weight for organic chemical products and less weight for inorganic chemical products compared to the 2002 Benchmark I–O data.

Table VII–5 below shows the proposed (which, as we indicate later, we are finalizing) weights for each of the four PPIs used to create the blended PPI.

TABLE VII–5—BLENDED CHEMICAL PPI WEIGHTS

Name	Proposed and final 2013-based LTCH weights (percent)	2009-Based LTCH weights (percent)	NAICS
PPI Industry for Industrial Gas Manufacturing	32	35	325120
PPI Industry for Other Basic Inorganic Chemical Manufacturing	17	25	325180
PPI Industry for Other Basic Organic Chemical Manufacturing	45	30	325190
PPI Industry for Soap and Cleaning Compound Manufacturing	6	10	325610

(11) Medical Instruments

We proposed to use a blend for the Medical Instruments cost category. The 2007 Benchmark Input-Output data show an approximate 50/50 split between Surgical and Medical Instruments and Medical and Surgical Appliances and Supplies for this cost category. Therefore, we proposed to use a blend composed of 50 percent of the PPI Commodity for Surgical and Medical Instruments (BLS code WPU1562) and 50 percent of the PPI Commodity for Medical and Surgical Appliances and Supplies (BLS code WPU1563). The 2009-based LTCH-specific market basket used the single, higher level PPI Commodity for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156). We stated in the proposed rule that we believe that the proposed price proxy better reflects the mix of expenses for this cost category as obtained from the 2007 Benchmark I–O data.

(12) Rubber and Plastics

We proposed to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(13) Paper and Printing Products

We proposed to use the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(14) Miscellaneous Products

We proposed to use the PPI Commodity for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(15) Professional Fees: Labor-Related

We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(16) Administrative and Facilities Support Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(17) Installation, Maintenance, and Repair Services

We proposed to use the ECI for Total Compensation for All Civilian Workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this new cost category. Previously, these costs were included in the ''All Other: Labor-Related Services'' category and were proxied by the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I). We stated in the proposed rule that we believe that this index better reflects the price changes of labor associated with maintenance-related services and its incorporation represents a technical improvement to the market basket.

(18) All Other: Labor-Related Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(19) Professional Fees: Nonlabor-Related

We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same price proxy that we are using for the Professional Fees: Labor-related cost category and the same price proxy used in the 2009-based LTCH-specific market basket.

(20) Financial Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(21) Telephone Services

We proposed to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(22) All Other: Nonlabor-Related Services

We proposed to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We stated in the proposed rule that we believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices as they are already captured elsewhere in the market basket. This is the same price proxy used in the 2009-based LTCH-specific market basket.

We did not receive any public comments on our proposed price proxies for the operating portion of the 2013-based LTCH market basket. Therefore, we are adopting our proposed price proxies for the operating

portion of the 2013-based LTCH market basket as final.

b. Price Proxies for the Capital Portion of the 2013-Based LTCH Market Basket

(1) Capital Price Proxies Prior to Vintage Weighting

We proposed to apply the same price proxies to the detailed capital-related cost categories as were applied in the 2009-based LTCH-specific market basket, which are described and provided in Table VII–7. We also proposed to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is the same method that was used for the 2009-based LTCH-specific market basket and is described in section VII.D.4.b.(2) of the preamble of this final rule.

We proposed to proxy the Depreciation: Building and Fixed Equipment cost category by BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type); the Depreciation: Movable Equipment cost category by the PPI Commodity for Machinery and Equipment (BLS series code WPU11); the Nonprofit Interest cost category by the average yield on domestic municipal bonds (Bond Buyer 20-bond index); the For-Profit Interest cost category by the average yield on Moody's Aaa bonds (Federal Reserve); and the Other Capital-Related cost category by the CPI–U for Rent of Primary Residence (BLS series code CUUS0000SEHA). We stated in the proposed rule that we believe that these are the most appropriate proxies for LTCH capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

We did not receive any public comments on our proposed price proxies for the capital portion of the 2013-based LTCH market basket. Therefore, we are adopting our proposed price proxies for the capital portion of the 2013-based LTCH market basket as final.

(2) Vintage Weights for Price Proxies

Because capital is acquired and paid for over time, capital-related expenses in any given year are determined by both past and present purchases of physical and financial capital. We stated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25161) that the vintage-weighted capital-related portion of the 2013-based LTCH market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital-related purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We proposed to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

Capital-related costs are inherently complicated and are determined by complex capital-related purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for LTCH capital-related costs. The capital-related component of the proposed 2013-based LTCH market basket reflects the underlying stability of the capital-related acquisition process.

To calculate the vintage weights for depreciation and interest expenses, we first needed a time series of capital-related purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital-related purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital-related data to meet this need. Data we obtained from the American Hospital Association (AHA) did not include annual capital-related purchases. However, we were able to obtain data on total expenses back to 1963 from the AHA. Consequently, we proposed to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then proposed to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2013. We separated these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as determined earlier. From these annual depreciation amounts, we derived annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. While data are not available that are specific to LTCHs, we believe that this information for all hospitals serves as a reasonable alternative for the pattern of depreciation for LTCHs. We used the AHA data and methodology to derive the FY 2010-based IPPS capital market basket (78 FR 50604), and the capital components of the 2012-based IRF (80 FR 47062) and 2012-based IPF market baskets (80 FR 46672).

To continue to calculate the vintage weights for depreciation and interest expenses, we also needed to account for the expected lives for building and fixed equipment, movable equipment, and interest for the 2013-based LTCH market basket. We proposed to calculate the expected lives using Medicare cost report data for LTCHs. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. Using this proposed method, we determined the average expected life of building and fixed equipment to be equal to 18 years, and the average expected life of movable equipment to be equal to 8 years. For the expected life of interest, we believe that vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that for the 2009-based LTCH-specific market basket, we used 2009 Medicare cost reports for LTCHs to determine the expected life of building and fixed equipment and movable equipment (77 FR 53467 through 53479). The 2009-based LTCH-specific market basket was based on an expected average life of building and fixed equipment of 20 years and an expected average life of movable equipment of 8 years.

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. We then calculated a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage

weights, we proposed to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as provided earlier in this final rule. For the interest vintage weights, we proposed to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital-related purchase time series specific to each asset type, we proposed to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 18 years, and in the case of movable equipment, 8 years). For each asset type, we proposed to use the time series of annual capital-related purchase amounts available from 2013 back to 1964. These data allow us to derive thirty-three 18-year periods of capital-related purchases for building and fixed equipment and interest, and forty-three 8-year periods of capital-related purchases for movable equipment. For each 18-year period for building and fixed equipment and interest, or 8-year period for movable equipment, we proposed to calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 18-year or 8-year period. This calculation was done for each year in the 18-year or 8-year period and for each of the periods for which we have data. We then calculated the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data.

We did not receive any public comments on our proposed vintage weights for the 2013-based LTCH market basket. Therefore, we are adopting our proposed vintage weights as final.

The vintage weights for the capital-related portion of the proposed and final 2013-based LTCH market basket and the 2009-based LTCH-specific market basket are presented in Table VII–6 below.

TABLE VII–6—2013-BASED LTCH MARKET BASKET AND 2009-BASED LTCH-SPECIFIC MARKET BASKET VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year [1]	Building and fixed equipment		Movable equipment		Interest	
	2013-Based 18 years	2009-Based 20 years	2013-Based 8 years	2009-Based 8 years	2013-Based 18 years	2009-Based 20 years
1	0.044	0.034	0.104	0.102	0.029	0.021
2	0.046	0.037	0.110	0.108	0.031	0.024
3	0.048	0.039	0.117	0.114	0.034	0.026
4	0.050	0.042	0.124	0.123	0.037	0.029
5	0.051	0.043	0.128	0.129	0.039	0.032
6	0.051	0.045	0.132	0.134	0.042	0.035
7	0.051	0.046	0.140	0.142	0.043	0.037
8	0.052	0.047	0.145	0.149	0.046	0.040
9	0.053	0.049	.....	.....	0.049	0.043
10	0.056	0.051	.....	.....	0.054	0.047
11	0.058	0.053	.....	.....	0.059	0.050
12	0.059	0.053	.....	.....	0.063	0.053
13	0.061	0.053	.....	.....	0.068	0.055
14	0.062	0.054	.....	.....	0.072	0.059
15	0.062	0.055	.....	.....	0.076	0.062
16	0.063	0.057	.....	.....	0.080	0.068
17	0.066	0.059	.....	.....	0.086	0.073
18	0.067	0.059	.....	.....	0.091	0.077
19	.....	0.061	.....	.....	.....	0.082
20	.....	0.062	.....	.....	.....	0.086
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

[1] Vintage weight in the last year (for example, year 18 for the 2013-based LTCH market basket) is applied to the most recent data point and prior vintage weights are applied going back in time. For example, year 18 vintage weight is applied to the 2017q3 price proxy level, year 17 vintage weight is applied to the 2016q3 price proxy level, and so forth.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table VII–6 is applied to the most recent data point. We have provided on the CMS Web site an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found under the following CMS Web site link: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* in the zip file titled ''Weight Calculations as described in the IPPS FY 2010 Proposed Rule.''

c. Summary of Price Proxies of the 2013-Based LTCH Market Basket

Table VII–7 below shows both the operating and capital price proxies that we proposed and are using as final for the 2013-based LTCH market basket.

TABLE VII–7—PRICE PROXIES FOR THE 2013-BASED LTCH MARKET BASKET

Cost description	Price proxies	Weight
Total		100.0
Compensation		53.9
Wages and Salaries	ECI for Wages and Salaries for All Civilian Workers in Hospitals	46.6
Employee Benefits	ECI for Total Benefits for All Civilian Workers in Hospitals	7.3
Utilities		2.2
Electricity	PPI Commodity for Commercial Electric Power	1.0
Fuel, Oil, and Gasoline	Blend of the PPI Industry for Petroleum Refineries and PPI Commodity for Natural Gas.	1.1
Water & Sewerage	CPI–U for Water and Sewerage Maintenance	0.1
Professional Liability Insurance		0.9
Malpractice	CMS Hospital Professional Liability Insurance Premium Index	0.9
All Other Products and Services		33.2
All Other Products		16.3
Pharmaceuticals	PPI Commodity for Pharmaceuticals for human use, prescription	7.6
Food: Direct Purchases	PPI Commodity for Processed Foods and Feeds	1.8
Food: Contract Services	CPI–U for Food Away From Home	1.1
Chemicals	Blend of Chemical PPIs	0.7
Medical Instruments	Blend of the PPI Commodity for Surgical and Medical Instruments and PPI Commodity for Medical and Surgical Appliances and Supplies.	2.4
Rubber & Plastics	PPI Commodity for Rubber and Plastic Products	0.6
Paper and Printing Products	PPI Commodity for Converted Paper and Paperboard Products	1.2
Miscellaneous Products	PPI Commodity for Finished Goods Less Food and Energy	0.8
All Other Services		16.9
Labor-Related Services		8.3
Professional Fees: Labor-related	ECI for Total Compensation for Private Industry Workers in Professional and Related.	3.5
Administrative and Facilities Support Services	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support.	0.9
Installation, Maintenance & Repair Services	ECI for Total Compensation for Civilian Workers in Installation, Maintenance, and Repair.	2.0
All Other: Labor-related Services	ECI for Total Compensation for Private Industry Workers in Service Occupations.	1.9
Nonlabor-Related Services		8.6
Professional Fees: Nonlabor-related	ECI for Total Compensation for Private Industry Workers in Professional and Related.	3.6
Financial services	ECI for Total Compensation for Private Industry Workers in Financial Activities.	2.9
Telephone Services	CPI–U for Telephone Services	0.7
All Other: Nonlabor-related Services	CPI–U for All Items Less Food and Energy	1.4
Capital-Related Costs		9.7
Depreciation		5.3
Fixed Assets	BEA chained price index for nonresidential construction for hospitals and special care facilities—vintage weighted (18 years).	3.9
Movable Equipment	PPI Commodity for machinery and equipment—vintage weighted (8 years).	1.4
Interest Costs		2.4
Government/Nonprofit	Average yield on domestic municipal bonds (Bond Buyer 20 bonds)—vintage weighted (18 years).	0.5
For Profit	Average yield on Moody's Aaa bonds—vintage weighted (18 years)	1.8
Other Capital-Related Costs	CPI–U for Rent of Primary Residence	2.0

Note: Sum of the cost weights for the detailed categories may not add to total cost weight for subcategory or total market basket due to rounding.

d. FY 2017 Market Basket Update for LTCHs

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25164), for FY 2017 (that is, October 1, 2016, through September 30, 2017), we proposed to use an estimate of the proposed 2013-based LTCH market basket to update payments to LTCHs based on the best available data. Consistent with historical practice, we estimate the LTCH market basket update for the LTCH PPS based on IHS Global Insight, Inc.'s (IGI's) forecast using the most recent available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Based on IGI's first quarter 2016 forecast with history through the fourth quarter of 2015, the projected market basket update for FY 2017 was 2.7 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, in the proposed rule, we proposed a market basket update of 2.7 percent for FY 2017. Furthermore, because the proposed FY 2017 annual update was based on the most recent market basket estimate for the 12-month period (2.7 percent) at the time of the proposed rule, we also proposed that if more recent data became subsequently available (for example, a more recent estimate of the market basket), we would use such data, if appropriate, to determine the FY 2017 annual update in the final rule.

Based on IGI's second quarter 2016 forecast with history through the first quarter of 2016, the projected market basket update for FY 2017 is 2.8 percent. Therefore, consistent with our

historical practice of estimating market basket increases based on the best available data, we are finalizing a market basket update of 2.8 percent for FY 2017 based on the 2013-based LTCH market basket. (As discussed in greater detail in section V.A.2. of the Addendum to this final rule, we are establishing an annual update of 1.75 percent to the LTCH PPS standard Federal payment rate for FY 2017 under § 412.523(c)(3)(xiii) of the regulations.)

Using the current 2009-based LTCH-specific market basket and IGI's second quarter 2016 forecast with history through the first quarter of 2016, the FY 2017 market basket update would also be 2.8 percent (before taking into account any statutory adjustment). Table VII–8 below compares the final 2013-based LTCH market basket and the 2009-based LTCH-specific market basket percent changes.

TABLE VII–8—2013-BASED LTCH MARKET BASKET AND 2009-BASED LTCH-SPECIFIC MARKET BASKET PERCENTAGE CHANGES, FY 2011 THROUGH FY 2019

Fiscal Year (FY)	2013-Based LTCH market basket index percent change	2009-Based LTCH market basket index percent change
Historical data:		
FY 2011	2.3	2.6
FY 2012	1.9	2.3
FY 2013	2.0	2.3
FY 2014	1.8	1.9
FY 2015	1.8	2.2
Average 2011–2015	2.0	2.3
Forecast:		
FY 2016	2.0	2.2
FY 2017	2.8	2.8
FY 2018	2.9	2.9
FY 2019	3.1	3.1
Average 2016–2019	2.7	2.8

Note: That these market basket percent changes do not include any further adjustments as may be statutorily required.
Source: IHS Global Insight, Inc. second quarter 2016 forecast.

Over the time period covering 2011 through 2015, the average growth rate of the 2013-based LTCH market basket is roughly 0.3 percentage point lower than the 2009-based LTCH-specific market basket. The lower growth rate is primarily a result of the lower pharmaceutical cost weight in the 2013-based market basket compared to the 2009-based LTCH-specific market basket. Historically, the price growth of pharmaceutical costs has exceeded the price growth rates for most of the other market basket cost categories. Therefore, a lower pharmaceutical cost weight would, all else equal, result in a lower market basket update. As stated above, the pharmaceutical cost weights for the 2013-based LTCH market basket and the 2009-based LTCH-specific market basket are based on the 2013 and 2009 Medicare cost report data for LTCHs, respectively.

e. FY 2017 Labor-Related Share

As discussed in section V.B. of the Addendum to this final rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS payments to account for differences in LTCH area wage levels (§ 412.525(c)). The labor-related portion of the LTCH PPS standard Federal payment rate, hereafter referred to as the labor-related share, is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index.

The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. As discussed in more detail below and similar to the 2009-based LTCH-specific market basket, we classify a cost category as labor-related and include it in the labor-related share if the cost category is defined as being labor-intensive and its cost varies with the local labor market. As stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49798), the labor-related share for FY 2016 was defined as the sum of the FY 2016 relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related Services; Administrative and Facilities Support Services (formerly referred to as Administrative and Business Support Services); All Other: Labor-related Services; and a portion of the Capital Costs from the 2009-based LTCH-specific market basket.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25165), we proposed to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. Given this, based on our definition of the labor-related share and the cost categories in the proposed 2013-based LTCH market basket, we proposed to include in the labor-related share for FY 2017 the sum of the FY 2017 relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services; and a portion of the Capital-Related cost weight from the proposed 2013-based LTCH market basket. As noted in section VII.D.3.e. of the preamble of this final rule, for the proposed 2013-based LTCH market basket, we proposed and are finalizing the creation of a separate cost category for Installation, Maintenance, and Repair services. These expenses were previously included in the ''All Other Labor-related Services'' cost category in the 2009-based LTCH-specific market basket, along with other services, including, but not limited to, janitorial, waste management, security, and dry cleaning/laundry services. Because these services tend to be labor-intensive and are mostly performed at the facility (and, therefore, unlikely to be purchased in the national market), we continue to believe that they meet our definition of labor-related services.

For the development of the 2009-based LTCH-specific market basket, in an effort to more accurately determine the share of professional fees for services such as accounting and auditing services, engineering services, legal services, and management and

consulting services that should be included in the labor-related share, we used data from a survey of IPPS hospitals regarding the proportion of those fees that go to companies that are located beyond their own local labor market. The results from this survey were then used to separate a portion of the Professional Fees cost category into labor-related and nonlabor-related costs. These results and our allocation methodology are discussed in more detail in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766). For the proposed 2013-based LTCH market basket, we proposed to apply these survey results using this same methodology to separate the Professional Fees cost category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. We stated in the proposed rule that we believe that using the survey results serves as an appropriate proxy for the purchasing patterns of professional services for LTCHs because they also are providers of institutional care.

In addition to the professional services listed above, we proposed to classify expenses under NAICS 55, Management of Companies and Enterprises, into the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories, as was done for the 2009-based LTCH-specific market basket. The NAICS 55 industry is mostly comprised of corporate, subsidiary, and regional managing offices (otherwise referred to as home offices). As stated above, we classify a cost category as labor-related and include it in the labor-related share if the cost category is labor-intensive and if its costs vary with the local labor market. We believe that many of the costs associated with NAICS 55 are labor-intensive and vary with the local labor market. However, data indicate that not all LTCHs with home offices have home offices located in their local labor market. Therefore, we proposed to include in the labor-related share only a proportion of the NAICS 55 expenses based on the methodology described below.

For the 2009-based LTCH-specific market basket, we used data primarily from the Medicare cost reports and a CMS database of Home Office Medicare Records (HOMER) (a database that provides city and State information (addresses) for home offices) and determined that 13 percent of the total number of LTCHs that had home offices had those home offices located in their respective local labor markets—defined as being in the same Metropolitan Statistical Area (MSA). Therefore, we classified 13 percent of these costs into the ''Professional Fees: Labor-related Services'' cost category and the remaining 87 percent into the ''Professional Fees: Nonlabor-related Services'' cost category. For a detailed discussion of this analysis, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53478).

For the proposed 2013-based LTCH market basket, we conducted a similar analysis of home office data. For consistency, we believe that it is important for our analysis on home office data to be conducted on the same LTCHs used to derive the proposed 2013-based LTCH market basket cost weights. The Medicare cost report requires a hospital to report information regarding their home office provider. Approximately 56 percent of LTCHs reported some type of home office information on their Medicare cost report for 2013 (for example, home office number, city, state, zip code, or name). For those providers for which we were able to identify which MSA the LTCH's home office was located, we then compared the home office MSA with the LTCH facility's MSA.

We found that 7 percent of the LTCHs with home offices had those home offices located in the same MSA as their facilities. We then concluded that these providers were located in the same local labor market as their home office. As a result, we proposed to apportion the NAICS 55 expense data by this percentage. Therefore, we proposed to classify 7 percent of these costs into the ''Professional Fees: Labor-related Services'' cost category and the remaining 93 percent of these costs into the ''Professional Fees: Nonlabor-related Services'' cost category.

Using this proposed method and the IGI forecast for the first quarter 2016 of the proposed 2013-based LTCH market basket, the proposed LTCH labor-related share for FY 2017 was the sum of the FY 2017 relative importance of each labor-related cost category.

We did not receive any public comments on our proposed methodology for determining the FY 2017 labor-related share based on the 2013-based LTCH market basket. Therefore, we are finalizing our methodology as proposed.

Consistent with our policy to update the labor-related share with the most recent available data, the labor-related share for this final rule reflects IGI's second quarter 2016 forecast of the 2013-based LTCH market basket. Table VII–9 below shows the FY 2017 relative importance labor-related share using the 2013-based LTCH market basket and the FY 2016 relative importance labor-related share using the 2009-based LTCH-specific market basket.

TABLE VII–9—LTCH LABOR-RELATED SHARE

	FY 2017 Final labor-related share [1]	FY 2017 Proposed labor-related share [2]	FY 2016 Final labor-related share [3]
Wages and Salaries	46.5	46.6	44.6
Employee Benefits	7.3	7.3	8.1
Professional Fees: Labor-Related	3.5	3.5	2.2
Administrative and Facilities Support Services	0.9	0.9	0.5
Installation, Maintenance, and Repair Services [4]	2.1	2.1	
All Other: Labor-Related Services	1.9	1.9	2.5
Subtotal	62.2	62.3	57.9
Labor-related portion of capital (46%)	4.3	4.3	4.1
Total Labor-Related Share	66.5	66.6	62.0

[1] Based on the 2013-based LTCH market basket, IHS Global Insight, Inc. 2nd quarter 2016 forecast.
[2] Based on the proposed 2013-based LTCH market basket, IHS Global Insight, Inc. 1st quarter 2016 forecast.
[3] **Federal Register**, 80 FR 49478.
[4] Installation, Maintenance, and Repair Services costs were previously included in the All Other: Labor-Related Services cost weight of the 2009-based LTCH-specific market basket.

The labor-related share for FY 2017 is the sum of the FY 2017 relative importance of each labor-related cost category, and reflects the different rates of price change for these cost categories between the base year (2013) and FY 2017. The sum of the relative importance for FY 2017 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, All Other: Labor-Related Services) is 62.2 percent, as shown in Table VII–9 above. As we proposed, we established that the portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2009-based LTCH-specific market basket (77 FR 53478). Because the relative importance for capital-related costs is 9.3 percent of the 2013-based LTCH market basket in FY 2017, as we proposed, we are taking 46 percent of 9.3 percent to determine the labor-related share of capital-related costs for FY 2017 (.46 × 9.3). The result is 4.3 percent, which we added to 62.2 percent for the operating cost amount to determine the total labor-related share for FY 2017. Therefore, the labor-related share that we used for the LTCH PPS in FY 2017 is 66.5 percent. This labor-related share is determined using the same methodology as employed in calculating all previous LTCH labor-related shares.

The FY 2017 labor-related share using the 2013-based LTCH market basket is 4.5 percentage points higher than the FY 2016 labor-related share using the 2009-based LTCH-specific market basket. The primary reason for a higher labor-related share, which we describe in more detail below, is a result of the change in the quantity of labor, particularly for professional services, outpacing the change in quantity of products (which are not included in the labor-related share) between 2009 and 2013, which more than offsets the faster relative growth in prices for products.

Roughly three-quarters of the 4.5 percentage points difference is the result of higher base year cost weights for the Professional Fees: Labor-Related, Administrative and Facilities Support Services, All Other: Labor-Related services, and Installation, Maintenance, and Repair services cost categories for the 2013-based LTCH market basket compared to the 2009-based LTCH-specific market basket. We refer to these cost categories collectively as ''Labor-Related Services.'' As stated earlier, installation, maintenance and repair costs were previously classified in the All Other: Labor-Related Services cost category of the 2009-based LTCH-specific market basket.

In aggregate, the base year cost weights for the Labor-Related Services cost categories in the 2013-based LTCH market basket are 3.0 percentage points higher than the 2009-based LTCH-specific market basket cost weights. As described in section VII.D.3.e. of the preamble of this final rule, the detailed cost categories of the LTCH market basket (including the Labor-Related Services cost categories) are derived by multiplying the ''All Other'' residual cost weight (which reflects all remaining costs that are not captured in the six major cost category weights calculated using the LTCH Medicare Cost Report data (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, and Capital)) by the detailed cost weights calculated from the Benchmark I–O data. Therefore, the differences between the Labor-Related Services cost weights between the 2013-based LTCH market basket and the 2009-based LTCH-specific market basket are a function of the change in the ''All Other'' residual cost category weight and changes to the Benchmark I–O data. Approximately 0.6 percentage point of the 3.0 percentage points difference is attributable to the higher ''All Other'' residual cost category weight of the 2013-based LTCH market basket compared to the 2009-based LTCH-specific market basket, while the remaining 2.4 percentage points is due to the changes in the Benchmark I–O cost weights derived from the 2007 data used in the 2013-based LTCH market basket and the 2002 data used in the 2009-based LTCH-specific market basket.

Roughly one-quarter of the 4.5 percentage points difference between the FY 2017 labor-related share using the 2013-based LTCH market basket and the FY 2016 labor-related share using the 2009-based LTCH-specific market basket is a result of the Compensation cost weight. There are two key factors causing this differential. First, using the 2013 Medicare cost reports, we calculated a Compensation cost weight that is 53.9 percent for the 2013-based LTCH market basket, which reflects both the change in price and change in quantity of compensation. This is 0.9 percentage point higher than the FY 2013 relative importance moving average using the 2009-based LTCH-specific market basket (53.0 percent), which only reflects relative price changes between 2009 and 2013. Second, the relative price growth from FY 2013 to the payment year between the 2009-based LTCH-specific market basket and the 2013-based LTCH market basket also contributes to the difference. For the 2009-based LTCH-specific market basket, the relative importance for compensation decreases from 53.0 percent in FY 2013 to 52.6 percent in FY 2016, a reduction of 0.4 percentage point. For the 2013-based LTCH market basket, the base weight of 53.9 percent in 2013 is 0.1 percentage point lower than the relative importance in FY 2017 (53.8 percent). These two factors combined produce the 1.2 percentage point difference in the relative importance for compensation in FY 2016 and FY 2017 as shown in Table VII–9.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care.

E. Changes to the LTCH PPS Payment Rates and Other Changes to the LTCH PPS for FY 2017

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal prospective payment rates is currently set forth at 42 CFR 412.515 through 412.536. In this section, we discuss the factors that are used to update the LTCH PPS standard Federal payment rate for FY 2017, that is, effective for LTCH discharges occurring on or after October 1, 2016 through September 30, 2017. Under the dual rate LTCH PPS payment structure required by statute, beginning with FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at § 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

For details on the development of the initial FY 2003 standard Federal rate, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the LTCH PPS standard Federal rate as implemented under § 412.523(c)(3), we refer readers to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (68 FR 25682 through 25684); RY 2006 LTCH PPS final rule (70 FR 24179 through 24180); RY 2007 LTCH PPS final rule (71 FR 27819 through 27827); RY 2008 LTCH PPS final rule (72 FR 26870 through 27029); RY 2009 LTCH PPS final rule (73 FR 26800 through 26804); FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444); FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51773); FY 2013 IPPS/LTCH PPS final rule (77 FR 53479 through 53481); FY 2014 IPPS/LTCH PPS final rule (78 FR 50760 through 50765); FY 2015 IPPS/LTCH PPS final rule (79 FR 50176 through 50180) and FY 2016 IPPS/LTCH PPS final rule (80 FR 49634 through 49637).

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25167 through 25169), we presented our proposed policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2017, which includes the annual market basket update. Consistent with our historical practice of using the best data available, we also proposed to use more recent data to determine the FY 2017 annual market basket update to the LTCH PPS standard Federal payment rate in the final rule.

The application of the update to the LTCH PPS standard Federal payment rate for FY 2017 is presented in section V.A. of the Addendum to this final rule. The components of the proposed and final annual market basket update to the LTCH PPS standard Federal payment rate for FY 2017 are discussed below, including the reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2017 as required by the statute (as discussed in section VII.E.2.d. of the preamble of this final rule). In addition, we are making an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level adjustment for FY 2017 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4) (as discussed in section V.B. of the Addendum to this final rule).

2. FY 2017 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476). In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25153 through 25167), we proposed to rebase and revise the 2009-based LTCH-specific market basket, primarily based on Medicare cost report data for LTCHs for 2013, which we are adopting in this final rule after consideration of public comments. We refer readers to section VII.D. of the preamble of the proposed rule and this final rule for a complete discussion of the LTCH market basket and a description of the methodologies we used for determining the operating and capital-related portions of the 2013-based LTCH market basket.

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year'' (which are discussed in more detail in section VII.C.2.b. of the preamble of this final rule.) We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Market Basket Under the LTCH PPS for FY 2017

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we adopted a 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. The 2009-based LTCH-specific market basket is based solely on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. For additional details on the development of the 2009-based LTCH-specific market basket, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476).

For FY 2017, as noted earlier, we are rebasing and revising the 2009-based LTCH-specific market basket to reflect a 2013 base year. As explained in section VII.D. of the preamble of this final rule, we used 2013 Medicare cost reports because these represent the most recent, complete set of Medicare cost report data for purposes of calculating cost weights for the LTCH market basket, and we believe that the 2013-based LTCH market basket appropriately reflects the cost structure of LTCHs. In this final rule, we are using the 2013-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2017, as we proposed.

c. Revision of Certain Market Basket Updates As Required by the Affordable Care Act

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year through 2019, any annual update to the LTCH PPS standard Federal payment rate shall be reduced:

- For rate year 2010 through 2019, by the ''other adjustment'' specified in sections 1886(m)(3)(A)(ii) and (m)(4)(F) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment (which we refer to as ''the multifactor productivity (MFP) adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

Section 1886(b)(3)(B)(xi)(II) of the Act defines the MFP adjustment as equal to the 10-year moving average of changes

in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). Under our methodology, the end of the 10-year moving average of changes in the MFP coincides with the end of the appropriate fiscal year update period. In addition, the MFP adjustment that is applied in determining any annual update to the LTCH PPS standard Federal payment rate is the same adjustment that is required to be applied in determining the applicable percentage increase under the IPPS under section 1886(b)(3)(B)(i) of the Act, as they are both based on a fiscal year. (We refer readers to section IV.A.1. of the preamble of FY 2016 IPPS/LTCH PPS final rule for more information on the current MFP adjustment.)

d. Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, as added by section 3004(a) of the Affordable Care Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under § 412.523(c)(4) of the regulations. (As previously noted, although the language of section 3004(a) of the Affordable Care Act refers to years 2011 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.) The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage point reduction to any update under § 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (§ 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year (§ 412.523(c)(4)(iii)). Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year (§ 412.523(c)(4)(ii)). We discuss the application of the 2.0 percentage point reduction under § 412.523(c)(4)(i) in our discussion of the annual market basket update to the LTCH PPS standard Federal payment rate for FY 2017 in section VII.E.2.e. of the preamble of this final rule. (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VII.C. of the preamble of this final rule.)

e. Annual Market Basket Update Under the LTCH PPS for FY 2017

Consistent with our historical practice, we estimate the market basket update and the MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's second quarter 2016 forecast, the FY 2017 full market basket increase for the LTCH PPS using the finalized 2013-based LTCH market basket is 2.8 percent, as discussed in section VII.D.4.d. of the preamble of this final rule. The current estimate of the MFP adjustment for FY 2017 based on IGI's second quarter 2016 forecast is 0.3 percent, as discussed in section VII.E.2.c. of the preamble of this final rule. Consistent with our historical practice, as we proposed, we used a more recent estimate of the market basket increase and the MFP adjustment to determine the FY 2017 market basket update and the MFP adjustment for FY 2017 in this final rule.

For FY 2017, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment (''the MFP adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, as we proposed, we reduced the full FY 2017 market basket increase by the FY 2017 MFP adjustment. To determine the market basket update for LTCHs for FY 2017, as reduced by the MFP adjustment, consistent with our established methodology, we subtracted the FY 2017 MFP adjustment from the FY 2017 market basket update. Furthermore, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate for FY 2017 be reduced by the ''other adjustment'' described in paragraph (4), which is 0.75 percentage point for FY 2017. Therefore, following application of the productivity adjustment, as we proposed, we further reduced the adjusted market basket update (that is, the full market basket increase less the MFP adjustment) by the ''other adjustment'' specified by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act. (For additional details on our established methodology for adjusting the market basket increase by the MFP and the ''other adjustment'' required by the statute, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

For FY 2017, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. Therefore, the update to the LTCH PPS standard Federal payment rate for FY 2017 for LTCHs that fail to submit quality reporting data under the LTCH QRP, the full LTCH PPS market basket increase, subject to an adjustment based on changes in economy-wide productivity (''the MFP adjustment'') as required under section 1886(m)(3)(A)(i) of the Act and an additional reduction required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act, will also be further reduced by 2.0 percentage points.

In this final rule, in accordance with the statute, we reduced the FY 2017 full market basket increase of 2.8 percent (based on IGI's second quarter 2016 forecast of the 2013-based LTCH market basket) by the FY 2017 MFP adjustment of 0.3 percentage point (also based on IGI's second quarter 2016 forecast). Following application of the productivity adjustment, the adjusted market basket update of 2.5 percent (2.8 percent minus 0.3 percentage point) was then further reduced by 0.75 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) of the Act. Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are establishing an annual market basket update under to the LTCH PPS standard Federal payment rate for FY 2017 of 1.75 percent (that is, the most recent estimate of the LTCH PPS market basket

increase of 2.8 percent, less the MFP adjustment of 0.3 percentage point, and less the 0.75 percentage point required under section 1886(m)(4)(F) of the Act). Accordingly, we are finalizing our proposed revision to § 412.523(c)(3) by adding a new paragraph (xiii), which specifies that the LTCH PPS standard Federal payment rate for FY 2017 is the LTCH PPS standard Federal payment rate for the previous LTCH PPS year updated by 1.75 percent, and as further adjusted, as appropriate, as described in § 412.523(d). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under § 412.523(c)(3)(xiii) in conjunction with § 412.523(c)(4), we further reduced the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points in accordance with section 1886(m)(5) of the Act. Accordingly, we are establishing an annual update to the LTCH PPS standard Federal payment rate of −0.25 percent (that is, 1.75 percent minus 2.0 percentage points) for FY 2017 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. As stated above, consistent with our historical practice, we used a more recent estimate of the market basket and the MFP adjustment to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2017 under § 412.523(c)(3)(xiii) in this final rule. (We note that, consistent with historical practice, we also adjusted the FY 2017 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with § 412.523(d)(4) (as discussed in section V.B. of the Addendum to this final rule).)

3. Update Under the Payment Adjustment for ''Subclause (II)'' LTCHs

Under the LTCH PPS payment adjustment for ''subclause (II) LTCHs'' at § 412.526(c)(1)(ii), we established that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount (used to determine the adjusted payment for Medicare inpatient operating costs under reasonable cost-based reimbursement rules) will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197). For FY 2017, in accordance with § 412.526(c)(2)(ii) of the regulations, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25169), we proposed that, for cost reporting periods beginning during FY 2017, the update to the target amount for the payment adjustment for ''subclause (II)'' LTCHs would be 2.8 percent, which was the estimated market basket update for FY 2017 to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis (that is, the applicable annual rate-of-increase percentage under § 413.40(c)(3)(viii)), which is discussed in section VI. of the preamble of the proposed rule, is the FY 2017 rate-of-increase percentage estimate for updating the target amounts, and is equal to the estimated percentage increase in the FY 2010-based IPPS operating market basket, in accordance with applicable regulations at § 413.40(c)(3)(viii).

Based on IGI's 2016 first quarter forecast, with historical data through the 2015 fourth quarter, in the proposed rule, we estimated that the FY 2010-based IPPS operating market basket update for FY 2017 was 2.8 percent (that is, the estimate of the market basket rate-of-increase). Therefore, we proposed that the rate-of-increase percentage that would be applied to the FY 2016 target amounts in order to determine the FY 2017 target amounts for ''subclause (II) LTCHs'' under § 412.526(c)(1)(i) was 2.8 percent. This is the same applicable annual rate-of-increase percentage that would be provided for FY 2017 under § 413.40(c)(3), as discussed in section VI. of the preamble of the proposed rule. Consistent with our historical practice of using the best available data, we also proposed we would use a more recent estimate of the market basket increase to determine the FY 2017 rate-of-increase percentage to determine the FY 2017 target amounts for ''subclause (II) LTCHs'' in this final rule.

Comment: Commenters agreed with the proposed rate-of-increase percentage to determine the FY 2017 target amounts for ''subclause (II) LTCHs'' and understood that it was subject to change based on more recent data in the final rule.

Response: We appreciate the commenters' review and agreement with our proposal regarding the rate-of-increase percentage for ''subclause (II) LTCHs'' for FY 2017.

Accordingly, for this final rule, we used IGI's 2016 second quarter forecast, with historical data through the 2016 first quarter, to estimate the final FY 2010-based IPPS operating market basket update for FY 2017 of 2.7 percent (that is, the estimate of the market basket rate-of-increase). Therefore, the rate-of-increase percentage that will apply to the FY 2016 target amounts in order to determine the target amount for cost reporting periods beginning in FY 2017 for ''subclause (II) LTCHs'' under § 412.526(c)(1)(i) is 2.7 percent. As proposed, this rate-of-increase percentage is the same as the estimated market basket update for FY 2017 to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis (that is, the applicable annual rate-of-increase percentage under § 413.40(c)(3)(viii)), which is discussed in section VI. of the preamble of this final rule.

F. Modifications to the ''25-Percent Threshold Policy'' Payment Adjustments (§§ 412.534 and 412.536)

The ''25-percent threshold policy'' is a per discharge payment adjustment in the LTCH PPS that is applied to payments for Medicare patient discharges from an LTCH when the number of such patients originating from any single referring hospital is in excess of the applicable threshold for a given cost reporting period (such threshold is generally set at 25 percent, with exceptions for rural and urban single or MSA-dominant hospitals). If an LTCH exceeds the applicable threshold during a cost reporting period, payment for the discharge that puts the LTCH over its threshold and all discharges subsequent to that discharge in the cost reporting period from the referring hospital are adjusted at cost report settlement (discharges not in excess of the threshold are unaffected by the 25-percent threshold policy). Each cost reporting period begins a new threshold determination; therefore, subsequent cost reporting periods are unaffected by exceeding the applicable percentage threshold requirements in a prior period.

The adjusted payment amount for those discharges that are subject to the current 25-percent threshold policy is calculated as the lesser of the applicable LTCH PPS payment amount or the IPPS equivalent amount. We note that the IPPS equivalent amount under the 25-percent threshold policy differs somewhat from the IPPS comparable per diem amount applicable under the site neutral payment rate policy at § 412.522(c)(1)(i) and the short-stay outlier (SSO) policy at § 412.529(d)(4). For a discussion of the calculation of the IPPS comparable per diem amount under § 412.529(d)(4) and the IPPS equivalent amount under existing §§ 412.534(f) and 412.536(e), including details on the differences in the calculations, we refer readers to our response to comments in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50772).

The 25-percent threshold policy was originally established in the FY 2005 IPPS final rule for LTCH hospital-

within-hospitals (HwHs) and satellites (69 FR 49191 through 49214). It addressed patient shifting driven by financial considerations, rather than patient benefit. Specifically, it addressed the negative incentives that may result from the co-location of facilities which can create incentives for behaviors which result in two hospital stays, and two Medicare payments, for what was essentially one episode of patient care—and a financial windfall for both providers, as compared to acute care hospitals that were not co-located with an LTCH. It also addressed statutory limits for LTCHs, namely concerns that these LTCHs were, in essence, behaving as long-term care ''units'' of the co-located hospitals (an arrangement prohibited under section 1886(d)(1)(B) of the Act). In order to discourage such activities, CMS initially established a payment adjustment at § 412.534 for discharges in which the patient was admitted to the LTCH location from a co-located referring hospital in excess of an applicable percentage threshold. Implementation was phased in, but ultimately was generally set at a 25-percent threshold after specified phase-in periods. A full discussion of the original 25-percent threshold policy is contained in the FY 2005 IPPS final rule (69 FR 49191 through 49214).

While initially limited to co-located facilities, in keeping with the suggestions of MedPAC and other commenters, CMS noted that it would continue to monitor claims data for signs that common ownership between hospitals that did not share a location also encouraged discharge and admission decisions based on payment rather than clinical considerations (69 FR 49202 through 19203). This continued monitoring, including analysis of discharge patterns from the FY 2005 MedPAR files, identified additional patterns of patient shifting and worrisome admission practices between LTCHs and referring hospitals that were not co-located that were similar to the patterns identified in the FY 2004 MedPAR files between co-located LTCHs and their host hospitals. In response to these findings, we expanded the 25-percent threshold policy in the RY 2008 LTCH PPS final rule to include all LTCHs and LTCH satellite facilities through the amendment of § 412.534 (including those certain LTCHs which had been grandfathered from the original policy established in the FY 2005 rule) and the addition of § 412.536 (governing patients admitted from hospitals not co-located with the LTCH). A full discussion of this policy can be found in the RY 2008 LTCH PPS final rule (72 FR 26919 through 26944).

The resulting 25-percent threshold policy was to have been phased in over 3 years, and, when fully implemented, the 25-percent threshold policy would have applied to nearly all LTCHs or LTCH satellites and remote locations admitting patients from any hospital, regardless of the location or ownership of the referring hospital. (For the remainder of this section, we refer to the policies under § 412.534 and § 412.536 and new § 412.538 collectively as the ''25-percent threshold policy'' unless otherwise indicated.) However, several laws mandated delayed implementation of the policy, including, most recently, section 1206 of the Pathway for Sustainable Growth Rate (SGR) Reform Act (Pub. L. 113–67). Section 1206(b)(1)(B) provides a permanent exemption from the application of the 25-percent threshold policy for co-located LTCHs that were excluded from the original policy in the FY 2005 IPPS final rule. Section 1206(b)(1)(A) extended prior moratoria on the full implementation of the 25-percent threshold policy until cost reporting periods beginning on or after either July 1, 2016 (for LTCHs subject to 42 CFR 412.534) or October 1, 2016 (for LTCHs subject to 42 CFR 412.536). For more details on the various laws that delayed the full implementation of the 25 percent threshold policy, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50356 through 50357).

With the impending expiration of the most recent statutory delay of the full implementation of the 25-percent threshold policy and the recent implementation of a dual rate payment system for the revised LTCH PPS for cost reporting periods beginning on or after October 1, 2015, we have received many questions concerning the mechanics of the revised payment system, especially in relation to the application of the 25-percent threshold policy under § 412.534 and § 412.536, and how those sections will interact. The questions generally involved how CMS would implement the policy for LTCHs with multiple locations. Other questions included how site neutral payment rate discharges would be treated under the policy and how CMS would determine whether a hospital was located in a rural or MSA-dominant area. As a result of the confusion reflected in those questions, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25169 through 25173), we proposed to revise our existing policies in an effort to simplify the application of the 25-percent threshold policy.

Specifically, we proposed to sunset both §§ 412.534 and 412.536 and adopt a unified 25-percent threshold policy at new § 412.538. We stated in the proposed rule that if finalized, this proposal would apply to payments for discharges occurring on or after October 1, 2016. The applicable percentage thresholds would generally remain at 25 percent. In keeping with our current policy at § 412.534(h) and § 412.536(a)(2), under proposed new § 412.538(a), we proposed that the adjustment would not be applicable to ''subclause (II)'' LTCHs described at section 1886(d)(1)(B)(iv)(II) of the Act and § 412.23(e)(2)(ii) or, consistent with the statute and as codified in the regulations at § 412.534(a) and § 412.536(a)(1)(ii), those HwHs described in § 412.23(e)(2)(i) that meet the criteria in § 412.22(f) (''grandfathered HwHs''). (Section 1206(b)(1)(B) of the Pathway for SGR Reform Act provides for a statutory exclusion from the 25-percent threshold policy for ''grandfathered HwHs,'' which was codified in the regulations at § 412.534(a) and § 412.536(a)(1)(ii) in the FY 2015 IPPS/LTCH PPS final rule at (79 FR 50186).)

In keeping with our current policy at § 412.534(c)(2) and § 412.536(h)(2), we further proposed that LTCH discharges that reached high-cost outlier status at the referring hospital would not be subject to the 25-percent threshold policy (that is, LTCH discharges which had been high-cost outlier cases at the referring hospital would only be included in an LTCH's total Medicare discharges and, therefore, would not count as having been admitted from that referring hospital. In other words, LTCH discharges that were high-cost outlier cases at the referring hospital would not be counted in the numerator (but would be counted in the denominator) when determining whether the LTCH exceeded the applicable percentage threshold from that referring hospital). As we discussed in the FY 2005 IPPS final rule, we continue to believe that it is appropriate to treat high-cost outlier cases as though they had come from a different hospital because a case which reaches high-cost outlier status has received a full complement of services and, therefore, any transfer from a hospital to an LTCH cannot be said to be premature or inappropriate. In addition, consistent with our current policy, under this proposal, both the LTCH PPS standard Federal payment rate cases and the site neutral payment rate cases would be subject to the 25-percent threshold policy at proposed new § 412.538 and, therefore, would be

included in the determination of whether an LTCH has exceeded its applicable threshold. In conjunction with this proposal, we proposed to make conforming changes to § 412.522(c)(2) (adjustments for payments under the site neutral payment rate) and § 412.525(d)(5) (adjustments for payments under the LTCH PPS standard Federal payment rate) to include the proposed adjustment for the limitation on LTCH admissions from referring hospitals (that is, the proposed revised 25-percent threshold policy) under new § 412.538. Lastly, we also proposed that Medicare Advantage (MA) discharges would not be considered under the revised 25-percent threshold policy at proposed new § 412.538, consistent with our current policy. (Consistent with these proposals, for the remainder of this section, when we refer to ''Medicare discharges,'' we mean a hospital's Medicare discharges that were not paid under an MA plan (and in the case of an LTCH, all LTCH PPS discharges, that is, both the LTCH PPS standard Federal payment rate cases and the site neutral payment rate cases).)

Under our proposed revised 25-percent threshold policy at proposed new § 412.538, we proposed to calculate the numerator and denominator for the ''applicable percentage threshold'' by using the CMS Certification Number (CCN) on hospital claims submitted to Medicare. Specifically, we proposed determining whether the applicable percentage threshold was exceeded based on the Medicare discharges from the entire LTCH that were admitted from each referring hospital. The CCN is used on Medicare claims to identify the hospital that discharged the patient and, therefore, we believed that using the CCN to identify the discharging LTCH and the referring hospital is an appropriate and administratively straight-forward process to implement this proposed revision. We stated that we believed that this approach would simplify the application of the 25-percent threshold policy because it would provide transparency in identifying both the discharging LTCH and the referring hospital. Under this proposed approach, an LTCH's percentage of Medicare discharges from a given referring hospital would be determined during settlement of a cost report by dividing the LTCH's total number of Medicare discharges in the cost reporting period (based on the CCN on the claims) that were admitted directly from a given referring hospital (again determined by the CCN on the referring hospital's claims) that did not receive a high-cost outlier payment (based on the referring hospital's claims) by the LTCH's total number of Medicare discharges in the cost reporting period. In other words, at cost report settlement, each LTCH's Medicare discharges from a given referring hospital (that did not receive a high-cost outlier payment) during that cost reporting period would be evaluated chronologically based on the discharge date from the LTCH, such that the Medicare discharge that results in the LTCH exceeding or remaining in excess of its applicable percentage threshold would be subject to the payment adjustment at proposed new § 412.538(c). We proposed that attribution of the Medicare discharge from a specific LTCH and a specific referring hospital would be determined according to the CCN on the Medicare claim submitted by the provider (that is, the LTCH's CCN would be determined from the LTCH's claim; the referring hospital's CCN by its claim), which generally comprises all locations of a single hospital (and for a single LTCH, includes satellite facilities and remote locations, as applicable). For example, the CCN of an LTCH with 3 locations is ''902000'' and the CCN of a specific referring hospital with 2 locations is ''900001.'' During its cost reporting period, LTCH ''902000'' has a total of 60 Medicare discharges (10 discharges from the first location, 20 discharges from the second location, and 30 discharges from the third location). Of those 60 Medicare discharges, 25 Medicare discharges (that did not receive a high-cost outlier payment) came directly from hospital ''900001'' (10 discharges from the first location, and 15 discharges from the second location). LTCH ''902000's'' percentage of Medicare discharges from referring hospital ''900001'' would be calculated as 25 divided by 60, or 41.7 percent. The location of the discharging LTCH and the referring hospital is not relevant, and only the aggregate Medicare discharge counts would be used in the proposed calculation when determining if a payment adjustment under proposed new § 412.538 is applicable at cost report settlement.

Under proposed new §§ 412.538 (b) and (c), we proposed, in general, that payment would be adjusted for LTCH Medicare discharges originating from a single referring hospital during a given cost reporting period when that Medicare discharge results in a percentage of Medicare discharges (that did not receive a high-cost outlier payment) from that referring hospital that exceeds that LTCH's applicable percentage threshold (that is, exceeds ''25 percent'' of that LTCH's total Medicare discharges). In other words, in general, we would continue to calculate separate percentages for each hospital from which an LTCH admits patients, and compare those referring hospitals' percentage of Medicare discharges (excluding those cases that received a high-cost outlier payment) to the LTCH's applicable percentage threshold, and the payment adjustment would then be applied to any of the Medicare discharges that cause the LTCH to exceed or remain in excess of the applicable percentage threshold. Medicare discharges not in excess of the applicable threshold (which includes those that received a high-cost outlier payment at the referring hospital) would continue to be unaffected by the 25-percent threshold policy. As adjusted, the net payment amount to an LTCH for each of its Medicare discharges beyond the applicable percentage threshold would continue to be the lesser of the applicable LTCH PPS payment amount or an IPPS equivalent amount. The IPPS equivalent amount under the current 25-percent threshold policy is set forth in existing regulations at § 412.534(f) and § 412.536(e). As we proposed to sunset these provisions, we proposed to codify the existing definition of ''IPPS equivalent amount'' under our proposed revised 25-percent threshold policy at proposed new § 412.538(f). (For a detailed description of the calculation of the IPPS equivalent amount, we refer readers to the RY 2007 LTCH PPS proposed rule (71 FR 4698 through 4700), which was finalized in the corresponding final rule (71 FR 27875)). As noted previously, the IPPS equivalent amount under the 25-percent threshold policy differs somewhat from the IPPS comparable amount applicable under the site neutral payment rate and the SSO policy (78 FR 50772).

In addition, consistent with our existing policy at § 412.534(d) and § 412.536(c), under proposed new § 412.538(f), we proposed a 50-percent applicable threshold for rural LTCHs (as defined under § 412.503) in lieu of the generally applicable 25-percent threshold. We stated in the proposed rule that if finalized, payment to such LTCHs would not be adjusted unless the rural LTCH's Medicare discharges from a single referring hospital (excluding those that received a high-cost outlier payment), exceeded 50 percent of the LTCH's total Medicare discharges (that is, we would continue to apply an applicable percentage threshold of 50 percent from any single referring hospital to rural LTCHs).

We also proposed to maintain at proposed new § 412.538(e)(3) the current special treatment of an LTCH

located in an MSA with an MSA-dominant hospital at § 412.534(e) and § 412.536(d). As defined in those regulations, an MSA-dominant hospital is a hospital that has discharged more than 25 percent of the total hospital's Medicare discharges in the MSA in which it is located. For LTCHs located in an MSA-dominant area (that is located in an MSA with an MSA-dominant hospital), the LTCH's applicable percentage threshold would continue to be the percentage of total Medicare hospital discharges in the MSA from the MSA-dominant hospital during the LTCH's applicable cost reporting period, but in no case is less than 25 percent or more than 50 percent. (That is, as is the case under our current policy, for an LTCH located in an MSA-dominant area, it would have a single applicable percentage threshold for all of that LTCH's referring hospitals under the special treatment provided under proposed new § 412.538(e)(3).) We proposed to use our existing definition of ''MSA-dominant hospital'' under both § 412.534(e) and § 412.536(d) of the regulations to also define the term under § 412.103. Further, we proposed to codify definitions for the terms ''MSA'' (which we proposed to define as an Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget) and ''MSA-dominant area'' (which we proposed to define as an MSA in which an MSA-dominant hospital is located) under § 412.103. (Information on OMB's MSA delineations based on the 2010 standards can be found at: *http://www.whitehouse.gov/sites/default/files/omb/assets/fedreg_2010/06282010_metro_standards-Complete.pdf*.)

Under this proposed special treatment at §§ 412.538(e)(2) and (3) for LTCHs with multiple locations, we further proposed that all locations of the LTCH paid under the LTCH PPS must be rural or located in an MSA-dominant area (as applicable); otherwise the special treatment would not apply and the applicable percentage threshold would be 25 percent. Under our existing regulations, the applicable percentage threshold for each location is determined independently of any other location of the hospital (meaning that, if an LTCH had one rural and one urban location, the applicable percentage threshold for the rural location would be 50 percent and the applicable percentage threshold for the urban location would be 25 percent). However, under our proposal, the applicable percentage threshold would apply to the LTCH as a whole entity (based on its CCN). Therefore, we stated that we believe that it would be appropriate to apply the rural and MSA-dominant ''special'' applicable percentage thresholds based on the LTCH as a whole as well. Furthermore, we stated that we believe that LTCHs with locations that do not fall in these special treatment categories would have sufficient access across its locations to admit patients from multiple hospitals such that, as a whole, the LTCH should be able to draw from a diverse enough population to meet the proposed 25-percent threshold policy criteria. For these reasons, at that time we did not believe that it would be appropriate or necessary to apply these special percentages unless the LTCH is exclusively rural or located exclusively in an MSA-dominant area (as applicable). Therefore, we proposed to require all locations of an LTCH to be rural or located within an MSA-dominant area in order to qualify for special treatment under proposed new §§ 412.538(e)(2) and (3) (that is, an adjusted applicable percentage threshold).

Comment: MedPAC supported CMS' proposal to continue to apply the 25-percent policy to all discharges, including site neutral payment rate cases. In addition, MedPAC noted that the effect of the new dual rate payment system on LTCHs and their admission practices, including their relationship with referring hospitals, is not yet understood, and therefore it is appropriate to maintain the 25-percent policy and apply it to all discharges.

Response: We appreciate MedPAC's support of our proposal.

Comment: Several commenters requested that CMS rescind the 25-percent policy. Many of these commenters argued that because of the new statutory patient-level criteria in the LTCH PPS, the 25-policy threshold policy is unnecessary. Some commenters stated that CMS indicated in prior rulemakings that the revised LTCH PPS would render the 25-percent threshold policy unnecessary. Other commenters argued that the policy does not specifically aid beneficiaries. Some commenters suggested ''updating'' the policy in light of changes in the statute that occurred after the 25-percent threshold policy was established, such as the IMPACT Act, or to exclude discharges from Centers for Medicare and Medicaid Innovations (Innovation Center) payment models from application of the policy. One commenter stated that repealing the policy was consistent with CMS' decision to exclude grandfathered HwHs from the policy. Some commenters suggested that, as an alternative to repealing the policy, CMS extend the statutory moratorium on the implementation of the policy for an additional 2 years, until the expiration of the moratorium of new LTCHs (under current law, that moratorium expires October 1, 2017), or, in the alternative, until the transition to the application of the site neutral payment rate has been completed and analyzed. Some other commenters stated that CMS had told Congress that CMS would not change the 25-percent threshold policy until the effects of the application of the site neutral payment rate had been analyzed, or until CMS had delivered its Report to Congress on the 25-percent threshold policy.

Response: As we stated both in the proposed rule and many times during our modifications to the 25-percent threshold policy, there is a statutory preclusion on LTCH units under section 1886(d)(1)(B) of the Act. The clinical criteria are not relevant to this preclusion (that is, the patient-level clinical criteria to determine which patients are ''appropriate'' for the LTCH PPS standard Federal payment rate did not change the statutory preclusion on LTCH ''units'' in hospitals). The clinical criteria also are not relevant to preventing two Medicare payments for what is essentially one episode of care. Therefore, we believe that the 25-percent threshold policy is still warranted in order to ensure compliance with this statutory prohibition and to prevent Medicare from making two payments for what is essentially one episode of care. We disagree with commenters' arguments that the 25-percent threshold policy does not aid beneficiaries, given that one of our goals in implementing the 25-percent threshold policy is to protect the Medicare Trust Fund, which will help to ensure access to care for Medicare beneficiaries. Additionally, whether our policies that enforce the statutory preclusion on LTCH units benefits beneficiaries is not relevant to our duty to enforce the preclusion on LTCH units.

With regard to the commenters who requested that we ''update'' the 25-percent threshold policy in light of changes in the statute, none of the changes removed the statutory preclusion on LTCH units or addressed the prevention of two Medicare payments for what is essentially one episode of care. In response to the request to exclude discharges paid under an Innovation Center payment model from the policy, to the extent the payment under the model is based in-part on the LTCH PPS payment rates,

we believe it is appropriate for the LTCH PPS payment rates portion of the payment to be subject to the applicable 25-percent threshold policy. The Innovation Center payment model status is irrelevant to the establishment of PPS payment policy in other contexts as well, for example in IPPS ratesetting. The comment asserting that repeal of the 25-percent threshold policy is consistent with CMS' decision to exclude grandfathered HwHs from that policy is factually inaccurate. As we stated in the proposed rule, CMS implemented the regulatory exclusion for grandfathered HwHs as that exclusion was required by section 1206(b)(1)(B) of the Pathway for SGR Reform Act (Pub. L. 113–67). Aside from subclause (II) LTCHs, no other LTCHs were provided such statutory exclusion. With respect to the comment that CMS indicated we would repeal the policy, we note that we received substantially similar comments in response to the FY 2016 IPPS/LTCH PPS proposed rule. We reiterate what we stated in response to those comments that we did not indicate in prior rulemakings that these policies were unnecessary. We stated that, at that time, the policies may no longer be necessary in light of the intended changes to the LTCH PPS (80 FR 49613).

In regard to the suggestion that we extend the statutory moratorium on the full implementation of the 25-percent threshold policy, we do not believe it is necessary to further delay its application. As discussed previously, we believe the 25-percent threshold policy is still warranted to ensure compliance with this statutory prohibition and to prevent Medicare from making two payments for what is essentially one episode of care. Furthermore, we disagree with commenters that we made any assurances to keep the 25-percent threshold policy unchanged until the transition to the site neutral payment rate had been completed or analyzed. As we stated in the proposed rule, given the impending expiration on the statutory moratorium on the full implementation of the 25-percent threshold policy, we received many questions concerning the mechanics of the revised payment system, especially in relation to the application of the 25-percent threshold policy under § 412.534 and § 412.536, and how those sections will interact. The questions generally involved how CMS would implement the policy for LTCHs with multiple locations. Other questions included how site neutral payment rate discharges would be treated under the policy and how CMS would determine whether a hospital was located in a rural or MSA-dominant area. In light of the widespread confusion expressed by stakeholders, we proposed revisions to our current 25-percent threshold policy that would clarify the policy and would allow for greater ease of understanding and implementation. We continue to believe that such modifications are appropriate and warranted. In regard to the commenter who requested that we wait until the Report to Congress on the 25-percent threshold policy has been delivered to Congress, we note that the referenced report was delivered in June 2015 and is, and has been, available upon request.

Comment: Several commenters requested that CMS exclude either site neutral payment rate or LTCH PPS standard Federal payment rate discharges from the 25-percent threshold policy. Many of the commenters who requested the exclusion of site neutral discharges asserted that applying the 25 percent policy to these discharges would result in ''double penalization,'' while commenters who requested the exclusion of LTCH PPS standard Federal rate payment rate discharges asserted that it was not appropriate to reduce payment for cases meeting the patient-level clinical criteria under the dual rate LTCH PPS payment structure. Some commenters asserted that it may be difficult for LTCHs to admit patients with at least 3 days of ICU treatment without exceeding their applicable percentage thresholds.

Response: As we stated earlier, the patient-level clinical criteria and site neutral payment rate are not relevant to the statutory preclusion on LTCH units. Excluding certain discharges paid under the LTCH PPS from the 25-percent threshold policy would fundamentally undermine the policy. In regard to concerns of ''double penalization'' for site neutral payment rate discharges under the 25-percent threshold policy, under our current regulations, in general, it is not possible for a site neutral payment rate discharge to receive a payment adjustment (that is, a lower payment) due to the 25-percent threshold policy. This is because site neutral payment rate discharges are generally paid the lower of the IPPS comparable amount or the estimated costs of the case, and, should the hospital's applicable percentage threshold be exceeded, the hospital would generally be paid the least of the IPPS equivalent amount, the IPPS comparable amount, or the cost. However, the IPPS equivalent amount and the IPPS comparable amount would generally be expected to be equivalent to one another. As such, we would not expect those paid at the site neutral rate to suffer any consequence as a result of the adjustment under the 25-percent rule policy. We note that we considered excluding site neutral payment rate discharges from both the numerator and denominator of the calculation. However, we did not propose this policy because whether a discharge is paid at the LTCH PPS standard Federal payment rate or the site neutral payment rate is not germane to whether an LTCH is behaving as a unit, and, given this overriding concern, we do not believe it is appropriate to exclude site neutral payment rate discharges from the 25-percent threshold policy. While we understand the concerns of commenters that, in certain areas, one or two IPPS hospitals may account for a disproportionate percentage of ICU days, we note, again, that the clinical criteria did not change the statutory preclusion on LTCH units. Furthermore, such IPPS hospital discharges admitted to the LTCH after receiving a high-cost outlier payment are treated as if they were admitted from another referring hospital for purposes of the 25-percent threshold policy (and therefore would not be counted as a discharge from that referring hospital). In addition, special treatment is provided for rural and MSA-dominant LTCHs, as discussed previously.

Comment: One commenter requested clarification as to why CMS did not include a specific exception under the proposed 25-percent threshold policy at new § 412.538 for LTCHs receiving admissions from urban-single IPPS hospitals, as is provided under the current 25-percent threshold policies at §§ 412.534 and 412.536, along with the proposed continued special treatment for rural and MSA-dominant LTCHs, which allows such LTCHs to have an increased applicable threshold. Other commenters requested that CMS modify the existing definition of ''MSA-dominant hospital'' to allow additional hospitals to qualify for the increased applicable threshold, for example hospitals located in Micropolitan areas or ''distinct regions'' within MSAs to be subject to an increased threshold.

Response: As we stated in the proposed rule, our proposed modification of the 25-percent threshold policy is meant to provide simplicity and clarity. We proposed to maintain the current special treatment of an LTCH located in an MSA with an MSA-dominant hospital at § 412.534(e) and § 412.536(d). As defined in those regulations, an MSA-dominant hospital is a hospital that has discharged more

than 25 percent of the total hospitals' Medicare discharges in the MSA in which it is located. This proposed definition of MSA-dominant hospitals encompass hospitals referred to in the current regulations as ''single urban hospitals'' (that is, the only other hospital in the MSA) because such a hospital, by definition, would have discharged more than 25 percent of the total hospital Medicare discharges in the MSA in that it would have discharged 100 percent of the total hospital Medicare discharges in the MSA. For this reason, we saw no reason to specifically mention urban-single hospitals as a separate category of hospitals subject to special treatment (that is, an increased applicable threshold). Although we are not changing the regulation text in response to this comment, we note that because urban-single hospitals are MSA-dominant hospitals, LTCHs receiving patients from urban-single hospitals will be subject to the same applicable threshold as all MSA-dominant hospitals. With respect to the commenter requesting an increased threshold for Micropolitan statistical areas, we note that these areas are treated as rural for the purposes of the 25-percent threshold policy. With respect to the request to provide an increased threshold for ''distinct regions'' of MSAs, although the commenter provided one anecdotal example of what it believed should be considered a ''distinct region,'' it did not offer a definition of the term or set out criteria for what would be considered a ''distinct region'' within an MSA, and, even if it had, adoption of such a concept is outside the scope of the proposed rule. With that said, as the commenter provided no policy specifics or recommendations, we cannot evaluate the ''distinct region'' suggestion and continue to believe that the use of MSAs is reasonable.

Comment: Several commenters requested that CMS increase the applicable threshold for rural and MSA-dominant LTCHs to 75 percent. These commenters argued that these LTCHs would face difficulty complying with the proposed applicable thresholds. One commenter requested that CMS increase the applicable threshold for all LTCHs.

Response: The proposed applicable thresholds for rural and MSA-dominant LTCHs are consistent with the applicable thresholds under the current 25-percent threshold policy once the statutory moratorium on the full application of that policy expires. While we understand the concerns raised by commenters, we continue to believe the applicable thresholds originally established under the existing 25-percent threshold policy are appropriate because of the statutory prohibition on LTCH units, which does not include an exception for rural or MSA-dominant hospitals. We established the increased applicable threshold in order to acknowledge that these hospitals do not have access to the range of referral sources other hospitals do, while at the same time realizing the need to prevent the existence of LTCH units, which is prohibited by the statute. Similarly, we do not believe it is appropriate to increase the applicable threshold for non-MSA dominant LTCHs. For these reasons, we are not adopting the commenters' suggestions to increase the applicable thresholds from the proposed values.

Comment: Several commenters objected to CMS' proposal to identify LTCHs and referring hospitals based on CCNs, and to apply the policy to all locations operating under a CCN. Some commenters argued that this would make it harder for LTCHs with multiple locations to comply with the policy, while other commenters argued that this disadvantaged hospitals that may have multiple campuses operating under the same CCN because the application of the 25-percent threshold policy on a location-specific basis can allow an LTCH with multiple locations to discharge more patients admitted from a single referring hospital without receiving adjusted payment under the regulations. Other commenters requested that CMS continue applying the policy on a location-specific basis. Some commenters expressed concern for LTCHs with ''one primary referring hospital.''

Response: As we stated in the proposed rule, we believe that identifying LTCHs and their referring hospitals based on CCN rather than individual location or locations would simplify the application of the 25-percent threshold policy because it provides transparency in identifying both the discharging LTCH and the referring hospital, and alleviate confusion in the industry. We proposed these changes in response to questions from the provider community which indicated a great deal of confusion surrounding the intricacy of the interactions between the current 25-percent threshold policies at § 412.534 and § 412.536. By basing the policy on LTCHs and referring hospitals as a whole, we believe that hospitals will more easily understand how a given discharge will be counted in the application of the policy. To the extent that the proposed changes make it ''harder'' for LTCHs to comply with the policy, we note that the goal of the policy is to prevent inappropriate patient shifting and LTCHs behaving as units of referring hospitals. In regard to LTCHs that may have been able to increase their overall admittance of patients from a single referring source under the location-based 25-percent threshold by spreading such admissions across locations, thereby increasing the opportunity for inappropriate patient shifting and allowing the LTCH as a whole to behave as a unit, such arrangements directly contradict our goals, and were a failing of the current policy. For these reasons, we believe that using CCNs rather than location as the basis for the 25-percent threshold policy is more appropriate, given our policy concerns and goals. While we understand that hospitals may operate multiple campuses under the same CCN, as explained previously, we nonetheless believe that application based on CCN is the simplest and generally most accurate way to determine the referral source of an LTCH discharge for both CMS and LTCHs. As for concerns about LTCHs with ''one primary referring hospital,'' we would like to state that this is the exact type of arrangement the 25-percent threshold policy is meant to deter as a way of ensuring the statutory prohibition of LTCH units is followed. Furthermore, we remind commenters that LTCH discharges that reach high cost outlier status at the referring hospital would not be subject to the 25-percent threshold policy (that is, such discharges would only be included in an LTCH's total Medicare discharges and would not count as having been admitted from that referring hospital), and to the extent the LTCH is exclusively located in an MSA-dominant area or rural area, the LTCH would have an increased applicable threshold under proposed special treatment for exclusively MSA-dominant or exclusively rural LTCHs. As no commenters offered an alternative to CCN application (other than a request to maintain the current location-specific approach, which caused considerable confusion and proved problematic for the reasons discussed previously), we are not making changes in response to these comments.

Comment: Several commenters objected to CMS' proposal to require all locations of an LTCH to be rural or MSA-dominant in order for the hospital to be subject to an increased applicable threshold. Many of these commenters stated that if one location of the LTCH was rural or MSA-dominant, the

hospital should be subject to the increased applicable threshold.

Response: The exception for rural and MSA-dominant LTCHs was made to address the reality that LTCHs in those circumstances may not have access to the range of referral sources other LTCHs do while achieving the policy goal of preventing the creation of *de facto* LTCH units. We believe that the increased applicable threshold initially established under the old policy and continued into the streamlined policy strikes the appropriate balance of these competing concerns. As we stated in the proposed rule, we believe that it would be appropriate to apply the rural and MSA-dominant ''special'' applicable percentage thresholds based on the LTCH as a whole because LTCHs with locations that do not fall in these special treatment categories would have sufficient access across its locations to admit patients from multiple hospitals such that, as a whole, the LTCH should be able to draw from a diverse enough population to meet the proposed 25-percent threshold policy criteria. We note that although commenters opposed our proposal to require all locations of an LTCH to be rural or MSA-dominant in order for the hospital to be subject to an increased applicable threshold, they did not offer any direct counter argument against our belief that multisite LTCHs should be able to draw as a whole from a diverse population. For these reasons, we continue to believe that it is appropriate to require all locations of LTCHs to be rural or MSA-dominant for a hospital to be eligible for an increased applicable threshold, and are not adopting the commenters' suggestions to provide for an increased applicable threshold if one location of the LTCH was either rural or MSA-dominant.

Comment: Several commenters objected to CMS' proposal to apply the revised 25-percent threshold policy based on discharge date rather than cost reporting period. Some commenters argued this was inconsistent with the historical application of the 25-percent threshold policy. Other commenters stated that the proposed discharge-based start date of October 1, 2016 is inconsistent with the current statutory moratorium on the full application of the 25-percent threshold policy.

Response: Our intent in proposing to apply the 25-percent threshold policy based on discharge date rather than cost reporting period was to avoid perpetuation of the status quo in which different LTCHs are subject to the existing 25-percent threshold policies under § 412.534 and § 412.536 at different times. By proposing to apply the policy based on discharge date rather than cost reporting period, all LTCHs would be subject to the same policy at the same time, which we believed would provide for greater transparency and administrative simplicity of the policy for both LTCHs and CMS. However, upon review, we agree with commenters who stated that our proposed implementation based solely on discharge date is contrary to the current statutory moratorium on the full implementation of the current 25-percent threshold policy. Therefore, in this final rule, we are revising our regulations to specify that the revised 25-percent threshold policy at § 412.538 is applicable for discharges occurring on or after October 1, 2016, that occur in cost reporting periods beginning on or after July 1, 2016 (for hospitals that had not been subject to § 412.534), or October 1, 2016 (for hospitals that had been subject to § 412.534). This revision will allow us to comply with the current statutory moratorium and apply the new, revised 25-percent threshold policy at § 412.538 consistently to all LTCHs upon its expiration. Therefore, in this final rule, we are revising our regulations to specify that an LTCH will be subject to the revised 25-percent threshold policy at § 412.538 for discharges occurring on or after October 1, 2016, that occur in its cost reporting periods for which it is no longer subject to any statutory moratorium on the full implementation of the current 25-percent threshold policy. In other words, the first time an LTCH will be subject to the adjustment policy at § 412.538 is for its discharges occurring on or after October 1, 2016, that occur in its first cost reporting period that begins after the statutory moratoria on the full implementation of the current 25-percent threshold policy expire for the LTCH.

Specifically, we are revising our regulations to specify that the revised 25-percent threshold policy at § 412.538 is applicable for discharges occurring on or after October 1, 2016, that occur in cost reporting periods beginning on or after July 1, 2016 (for hospitals that had not been subject to § 412.534), or October 1, 2016 (for hospitals that had been subject to § 412.534). This revision will allow us to comply with the current statutory moratorium and apply the new, revised 25-percent threshold policy at § 412.538 consistently to all LTCHs upon the expiration of the current statutory moratorium. The current 25-percent threshold policy at § 412.534 is only applicable to LTCHs (other than ''subclause (II)'' LTCHs) that have at least one co-located location, that is, LTCH HwHs and satellite facilities of LTCHs (except ''grandfathered HwHs'' which are exempt as provided by the statute). The current 25-percent threshold policy at § 412.536 is applicable to all LTCHs (other than ''subclause (II)'' LTCHs and grandfathered HwHs'' which are exempt as provided by the statute).

Considering the two 25-percent threshold policies contemporaneously, LTCHs that are not subject to § 412.534 (that is, LTCHs which do not include a co-located location) are only subject to the adjustments at § 412.536. On the other hand, LTCHs that are subject to the adjustment at § 412.534 also are subject to the adjustment at § 412.536 (that is, they are LTCHs subject to both policies at § 412.534 and § 412.536). Under current law, the moratorium on the full application of the 25-percent threshold policy under § 412.536 expires beginning with LTCH cost reporting periods beginning on or after July 1, 2016, while the moratorium on the full application of the 25-percent threshold policy under § 412.534 expires beginning with LTCH cost reporting periods beginning on or after October 1, 2016. Consequently, although LTCHs that are subject to both policies at § 412.534 and § 412.536 will no longer be under the moratorium on the full application of § 412.536 beginning with their cost reporting periods beginning on or after July 1, 2016, these LTCHs will continue to be under the moratorium on the full application of § 412.534 until their cost reports beginning on or after October 1, 2016. As such, for LTCHs that are subject to both policies at § 412.534 and § 412.536, the provision of new § 412.538 cannot apply to all of such LTCHs' discharges until their cost reports beginning on or after October 1, 2016. Consistent with the premise of our proposal to simplify and consolidate the current 25-percent threshold policies under new § 412.538, we are establishing that, for LTCHs that have been subject to both policies at § 412.534 and § 412.536 (that is, those LTCHs that include co-located locations), § 412.538 will apply for discharges occurring in cost reporting periods beginning on or after October 1, 2016. Under our finalized policy, this means that § 412.536 will apply to all locations of all LTCHs upon the expiration of the LTCH's statutory moratorium, which expires on a rolling cost reporting period basis (that is, an LTCH's first cost reporting period beginning on or after July 1, 2016) until the LTCH becomes subject to the revised policy at § 412.538. For LTCHs that were not subject to the policy at

§ 412.534 (that is, those LTCHs that do not include co-located locations and, therefore, had only been subject to the policy at § 412.536), § 412.538 will apply for discharges occurring on or after October 1, 2016, in cost reporting periods beginning on or after July 1, 2016, which coincides with the statutory expiration on the full application of § 412.536. An LTCH will remain subject to the policies at § 412.534 and/or § 412.536 as applicable until it transitions to the new policy at § 412.538. We also are making conforming changes to our proposed sunset dates for §§ 412.534 and 412.536.

Comment: Several commenters supported the proposal to exclude Medicare Advantage discharges from the calculation of the 25-percent threshold policy.

Response: We appreciate the commenters' support and are adopting our proposal as final, without modification, to exclude Medicare Advantage discharges in the application of the 25-percent threshold policy.

Comment: One commenter stated that paragraphs (g) and (h) of proposed new § 412.538 were missing from the proposed regulation text.

Response: Upon review of the proposed regulation text of § 412.538, we found that in the proposed text of paragraph (e)(3), which would codify the proposed special treatment for LTCHs located in an MSA with an MSA-dominant hospital, we found, as commenters noted, erroneous citations to a definition of ''MSA-dominant hospital'' in ''paragraph (h)(3)(ii) of this section.'' However, our proposal was to add the definition of ''MSA-dominant hospital'' to § 412.503, and new § 412.538 did not include paragraphs (g) or (h). We appreciate the commenter bringing this cross-reference error to our attention, and in this final rule have corrected the text of paragraph (e)(3) of § 412.538 to cite the definition of ''MSA-dominant hospital'' as defined in § 412.503.

Comment: One commenter requested clarification about whether certain LTCHs would be considered grandfathered HwHs (and thus excluded from the 25-percent threshold policy).

Response: We respond to this comment in section VII.B.3. of the preamble of this final rule where we discuss finalization of an IFC (CMS–1664–IFC), which implements the temporary exception from the site neutral payment rate for certain severe wound discharges from certain LTCHs provided by the Consolidated Appropriations Act, 2016.

Out-of-Scope Comments: We note we also received several comments outside the scope of the proposed rule seeking subregulatory guidance which we intend to address in the future as appropriate.

We did not receive any public comments regarding our proposal to add definitions of ''MSA,'' ''MSA-dominant area,'' and ''MSA-dominant hospital'' to § 412.503 and, therefore, are adopting those proposals as final without modification.

After consideration of the public comments we received, we are adopting the new 25-percent threshold policy, as proposed, with one exception. In response to comments, we are revising §§ 412.534, 412.536, and 412.538 to reflect the cost reporting period-based end dates of the moratoria under the current statute, as discussed previously. For hospitals that had not been subject to the policy at § 412.534, the revised policy is effective for discharges occurring on or after October 1, 2016. For hospitals that had been subject to the policy at § 412.534, the revised policy is effective for discharges occurring on or after October 1, 2016, in cost reporting periods beginning on or after October 1, 2016. Prior to transition to the single 25-percent threshold policy, a hospital is subject to both policies at §§ 412.534 and 412.536 to the same extent it would have been absent the revisions to the policy. Under this single 25-percent threshold policy, LTCH PPS payment for LTCH discharges from a single referring hospital in excess of the LTCH's applicable percentage threshold for that referring hospital will be adjusted, unless the LTCH is excepted from the adjustment under § 412.538(a)(2)(3). In addition, as we proposed, we are establishing that the applicable percentage threshold will generally be 25 percent (with special treatment for exclusively rural LTCHs and exclusively MSA-dominant LTCHs). The 25-percent threshold policy will be applicable to all LTCHs except ''subclause (II)'' LTCHs and ''grandfathered HwHs.'' Under these policies, LTCH discharges that reached high-cost outlier status at the referring hospital from which the patient was discharged directly to the LTCH will be treated as though they had come from a different referring hospital and, therefore, will not be counted as a Medicare discharge from that referring hospital. We also are establishing that MA discharges will not be included in this policy. In addition, the revised 25-percent threshold policy will apply to all LTCH PPS discharges (that is, both LTCH PPS standard Federal payment rate and site neutral payment rate cases).

Under this revised policy, we will evaluate the ''applicable percentage threshold'' based on the sum of the locations covered by the LTCH's and referring hospitals' Medicare provider agreement, and implement this policy using the LTCH's and the referring hospitals' CCN. As we proposed, we are establishing that an LTCH's percentage of Medicare discharges from a given hospital will be determined by dividing the LTCH's number of Medicare discharges in the cost reporting period (based on the LTCH's CCN) that were admitted directly from a given referring hospital (based on the hospital's CCN) that did not receive a high-cost outlier payment during the stay at that referring hospital by the LTCH's total number of Medicare discharges in the cost reporting period (based on the LTCH's CCN). Under new § 412.538, as applicable, the LTCH PPS payment will be adjusted at cost report settlement for the LTCH Medicare discharge that caused the LTCH to exceed its applicable threshold and all discharges subsequent to that discharge. Medicare discharges not in excess of the applicable percentage threshold will continue to be unaffected by the 25-percent threshold policy (that is, the payment for such discharges will not be adjusted). As adjusted, the payment amount for an LTCH Medicare discharge that is found to exceed the applicable percentage threshold will continue to receive the lesser of the applicable LTCH PPS payment amount or an IPPS equivalent amount.

G. Refinement to the Payment Adjustment for ''Subclause II'' LTCHs

As part of our FY 2015 IPPS/LTCH PPS rulemaking cycle, under the authority provided by section 1206(d)(2) of the Pathway to SGR Reform Act (Pub. L. 113–67), we adopted an adjustment to the LTCH PPS payment for LTCHs classified under section 1886(d)(1)(B)(iv)(II) of the Act (''subclause (II) LTCHs''), which are described in 42 CFR 412.23(e)(2)(ii). Under this adjustment, subclause (II) LTCHs receive payment under the LTCH PPS that is generally equivalent to an amount determined under the reasonable cost-based payment rules for both operating and capital-related costs under 42 CFR part 413 (that is, an amount generally equivalent to an amount determined under the TEFRA payment system methodology, which could be called a ''TEFRA-like'' methodology). For more information on this adjustment, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50193 through 50197). As initially adopted, this ''TEFRA-like'' payment

adjustment for subclause (II) LTCHs did not incorporate the limitation on charges to Medicare beneficiaries policies under the TEFRA payment system. Alignment of the limitation on charges to beneficiaries and related billing requirements would result in administrative simplification for the cost report submission and settlement process under the payment adjustment for subclause (II) LTCHs specified at § 412.526.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25173), we therefore proposed to revise the limitation on charges to beneficiaries policy and related billing requirements for subclause (II) LTCHs to reflect what is done in the TEFRA payment system context for cost reporting periods beginning on or after October 1, 2016, which would align our beneficiary charge policies (and related billing procedures) with the reasonable cost-based ''TEFRA-like'' payment adjustment under § 412.526. The adjusted LTCH PPS payment to subclause (II) LTCHs under § 412.526 is considered the full LTCH PPS payment (that is, the LTCH PPS standard Federal payment rate or site neutral payment rate, as applicable), and as such, under current policy that payment applies to the LTCH's costs for services furnished until the high-cost outlier threshold is met (existing § 412.507(a)). Under this proposal, for a subclause (II) LTCH, the Medicare payment would only apply to the LTCH's costs incurred for the days used to calculate the Medicare payment (that is, days for which the patient has a benefit day available). Furthermore, in addition to the applicable Medicare deductible and coinsurance amounts (and for items and services as specified under § 489.20(a)), we proposed to specify that the LTCH may only charge the beneficiary for services provided during the stay that were not the basis for the adjusted LTCH PPS payment amount under § 412.526. We stated in the proposed rule that if the proposal is finalized, subclause (II) LTCHs would be treated the same as IPPS-excluded hospitals paid under the TEFRA payment system for purposes of the limitation on charges to beneficiaries and related billing requirements.

In the FY 2017 proposed rule, using the broad authority conferred upon the Secretary under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, in conjunction with the authority provided under section 1206(d)(2) of Pub. L. 113–67, we proposed to revise § 412.507 to specify the limit on allowable charges to beneficiaries treated at subclause (II) LTCHs as is done under the TEFRA payment system in order to align our beneficiary charge policies with the reasonable cost-based ''TEFRA-like'' payment adjustments under § 412.526. Specifically, we proposed to revise § 412.507 to specify that, for cost reporting periods beginning on or after October 1, 2016, the Medicare payment made to subclause (II) LTCHs (as defined at § 412.23(e)(2)(ii)) only applies to the hospital's costs on the days used to calculate the Medicare payment (that is, days for which the patient has a benefit day available). Furthermore, we proposed under proposed revised § 412.507 to specify that, for cost reporting periods beginning on or after October 1, 2016, the hospital may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts (under §§ 409.82, 409.83 and 409.87) for items and services as specified under § 489.20(a), and for services provided during the stay that were not the basis for the adjusted LTCH PPS payment amount under § 412.526.

Comment: Two commenters supported the proposal to modify § 412.507 to provide that subclause (II) LTCHs would be subject to the same billing requirements applicable to hospitals that are paid on a reasonable-cost basis under the TEFRA payment system. The commenters also recommended that CMS make conforming changes to the applicable section of the Medicare Claims Processing Manual, the Medicare claims processing system, and cost report instructions.

Response: We appreciate the commenters' support of our proposed changes to align our beneficiary charge policies under § 412.507 with the reasonable cost-based ''TEFRA'' payment adjustments. As we indicated in the proposed rule and noted above, if finalized, subclause (II) LTCHs would be treated the same as PPS-excluded hospitals paid under the TEFRA payment system for purposes of the limitation on charges to beneficiaries and related billing requirements. Furthermore, if adopted, we would make conforming changes to the Medicare claims processing instructions, the Medicare claims processing system, and cost report instructions, as applicable.

After consideration of the public comments we received, we are finalizing our proposed changes to § 412.507 for subclause (II) LTCHs, as proposed, without modification.

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

We seek to promote higher quality and more efficient healthcare for Medicare beneficiaries. This effort is supported by the adoption of widely agreed-upon quality measures. We have worked with relevant stakeholders to define quality measures for most settings and to measure various aspects of care for most Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, care coordination, and improving patient outcomes.

We have implemented quality reporting programs for multiple care settings, including:

- Hospital inpatient services under the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program);
- Hospital outpatient services under the Hospital Outpatient Quality Reporting (OQR) Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP));
- Care furnished by physicians and other eligible professionals under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI));
- Inpatient rehabilitation facilities under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (also referred to as the LTCHQR Program);
- PPS-exempt cancer hospitals under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program;
- Home health agencies under the home health quality reporting program (HH QRP); and
- Hospice facilities under the Hospice Quality Reporting Program.

We have also implemented the End-Stage Renal Disease Quality Incentive Program, Hospital Readmissions Reduction Program, HAC Reduction Program, and Hospital VBP Program (described further below) that link payment to performance.

In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. Our goal for the future is to align the clinical quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the reporting burden on providers will be reduced. As appropriate, we will consider the adoption of clinical quality measures with electronic specifications so that the electronic collection of performance information is a seamless component of care delivery. Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, adoption of measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and reporting burden to hospitals. We believe that in the near future, collection and reporting of data elements through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs, and that hospitals will be able to switch primarily to EHR-based data reporting for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We also have implemented a Hospital VBP Program under section 1886(o) of the Act, described in the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547). We most recently adopted additional policies for the Hospital VBP Program in section IV.H. of the preamble of this final rule. Under the Hospital VBP Program, hospitals receive value-based incentive payments based on their performance with respect to performance standards for a performance period for the fiscal year involved. The measures under the Hospital VBP Program must be selected from the measures (other than readmission measures) specified under the Hospital IQR Program as required by section 1886(o)(2)(A) of the Act.

In selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework we have developed for the Hospital VBP Program. Because measures adopted for the Hospital VBP Program must first have been adopted and reported under the Hospital IQR Program, these two programs are linked and the reporting infrastructure for the programs overlap. We view the Hospital VBP Program as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality healthcare for its beneficiaries. Value-based purchasing is an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations.

We also view the HAC Reduction Program, authorized by section 1886(p) of the Act, as added by section 3008 of the Affordable Care Act, and the Hospital VBP Program, as related but separate efforts to reduce HACs. The Hospital VBP Program is an incentive program that awards payments to hospitals based on quality performance on a wide variety of measures, while the HAC Reduction Program creates a payment adjustment resulting in payment reductions for poorly performing hospitals based on their rates of HACs.

In the FY 2017 IPPS/LTCH PPS proposed rule, we proposed changes to the following Medicare quality reporting systems:

- In section VIII.A. (81 FR 25174 through 25205), the Hospital IQR Program.
- In section VIII.B. (81 FR 25205 through 25213), the PCHQR Program.
- In section VIII.C. (81 FR 25213 through 25238), the LTCH QRP.
- In section VIII.D. (81 FR 25238 through 25244), the IPFQR Program.

In addition, in section VIII.E. of the preamble of the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25244 through 25247), we proposed changes to the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs.

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of the Hospital IQR Program

We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692) for the measures we have adopted for the Hospital IQR Program measure set through the FY 2019 payment determination and subsequent years.

b. Maintenance of Technical Specifications for Quality Measures

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49640 through 49641) for a discussion of the maintenance of technical specifications for quality measures for the Hospital IQR Program. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50202 through 50203) for additional detail on the measure maintenance process.

In addition, we believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates to the measure specifications for measures we have adopted for the Hospital IQR Program so that these measures remain up-to-date. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203) for our policy for using a subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program. We recognize that some changes made to measures undergoing maintenance review are substantive in nature and might not be appropriate for adoption using a subregulatory process. We will continue to use rulemaking to adopt substantive updates made to measures we have adopted for the Hospital IQR Program.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25174), we did not propose any changes to our policies on the measures maintenance process or for using the subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program.

c. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act was amended by the Deficit Reduction Act (DRA) of 2005. Section 5001(a) of the DRA requires that the Secretary establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50776 through 50778) for a more detailed discussion about public display of quality measures.

The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. For more information on measures reported to *Hospital Compare,* we refer readers to

the Web site at: *http://www.medicare.gov/hospitalcompare.* Other information not reported to *Hospital Compare* may be made available on other CMS Web sites, such as *https://data.medicare.gov.*

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25174 through 25175), we did not propose any changes to these policies.

2. Process for Retaining Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513), for our finalized measure retention policy. Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt these measures for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25175), we did not propose any changes to this policy.

3. Removal and Suspension of Hospital IQR Program Measures

a. Considerations in Removing Quality Measures From the Hospital IQR Program

As discussed above, we generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets except when we specifically propose to remove, suspend, or replace a measure. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204) for more information on the criteria we consider for removing quality measures. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643) for more information on the additional factors we consider in removing quality measures and the factors we consider in order to retain measures. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204), we also finalized our proposal to clarify the criteria for determining when a measure is ''topped-out.'' In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25175), we did not propose any changes to these policies.

b. Removal of Hospital IQR Program Measures for the FY 2019 Payment Determination and Subsequent Years

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25175 through 25178), we proposed to remove the following 15 measures for the FY 2019 payment determination and subsequent years. Some of these measures we proposed to remove in their entirety; one of these measures, VTE–6 Incidence of Potentially Preventable Venous Thromboembolism, we proposed to remove just in the electronic form as discussed further below:

- AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142);
- AMI–7a: Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival;
- AMI–10: Statin Prescribed at Discharge;
- HTN: Healthy Term Newborn (NQF #0716);
- PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147);
- SCIP–Inf–1a: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision (NQF #0527);
- SCIP–Inf–2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528);
- SCIP–Inf–9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero;
- STK–4 Thrombolytic Therapy (NQF #0437);
- VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373);
- VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram);
- VTE–5: Venous Thromboembolism Discharge Instructions;
- VTE–6: Incidence of Potentially Preventable Venous Thromboembolism;
- Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and
- Participation in a Systematic Clinical Database Registry for General Surgery.

We received general comments related to the collective removal of these 15 measures (13 eCQMs, including 2 measures in chart form, and 2 structural measures). We discuss these general comments first; comments specific to individual measures are discussed further below.

Comment: The majority of commenters supported the proposed removal of 13 eCQMs from the Hospital IQR Program beginning with the FY 2019 payment determination in an effort to move quality measurement toward outcomes measures. Many commenters stated their belief that these measures were topped out, and that the measures' complexity could not be captured in an electronic form. A number of commenters also stated their belief that the eCQM measure specifications were not feasible to implement. Others noted removing these measures would decrease administrative burden, minimize confusion among providers regarding Hospital IQR Program data submission, and align the Hospital IQR Program with other quality measurement efforts.

Response: We thank the commenters for their support of our proposal to remove 13 eCQMs in an effort to move quality measurement toward outcomes measures.

Comment: Several commenters supported CMS' efforts to reduce reporting burden on hospitals, but expressed concern with the timeline of the proposal to remove 13 eCQMs beginning with the FY 2019 payment determination because hospitals may need time to adjust workflows and work with IT vendors to add support for measures not previously supported and ensure valid eCQMs are submitted. Commenters encouraged CMS to consider the time, effort, and resources expended on reporting these measures when deciding to remove them from the Hospital IQR Program. One commenter noted that EHR vendors will phase out support for these measures and clinicians may become skeptical about benefits to workflow changes related to future measures if measures are continuously added and removed. Another commenter urged CMS to provide more lead time for the removal of measures that hospitals have dedicated so many resources to developing and implementing. Specifically, the commenter requested that for FY 2019, CMS maintain the current requirements of reporting 4 eCQMs out of the current list of 28, and remove the 13 measures proposed for removal for FY 2020 in order to give hospitals more time to plan and prepare for implementation.

Response: We understand the commenters' concern with removing eCQMs that have been previously reported and implemented in an existing EHR workflow, and we acknowledge the time, effort, and resources that hospitals expend on reporting these measures. However, we believe that removal of the 13 eCQMs beginning with the FY 2019 payment determination will be less burdensome to hospitals overall than continuing to keep them in the Hospital IQR Program. Our decision to remove measures from the Hospital IQR Program is an extension of our programmatic goal to continually refine the measure set and

to ensure that it consists of quality performance standards as well as aligns with the Medicare and Medicaid EHR Incentive Program. It is one of our goals to expand electronic reporting in the Hospital IQR Program, which we believe will ultimately reduce burden on hospitals as compared with chart-abstracted data reporting and improve patient outcomes by providing more robust data to support quality improvement efforts. We intend to introduce additional eCQMs into the program as eCQMs that support our program goals become available.

In addition, we believe that the FY 2019 payment determination is the appropriate time to require eCQM reporting because hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and Hospital IQR Program (3 years of voluntary reporting and 3 years of reporting as part of a pilot). Furthermore, for the CY 2016 reporting period/FY 2018 payment determination, hospitals are required to submit one quarter's worth of data for 4 eCQMs for the Hospital IQR Program (80 FR 49694). As we stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49696), we believe that it is appropriate to require reporting and validation of eCQMs given that measures available now and those being developed for the future are increasingly based on electronic standards.

We will continue working to provide hospitals with the education, tools, and resources necessary to help reduce eCQM reporting burden and more seamlessly account for the removal/addition of eCQMs. Further, we will also consider the issues associated with new software, workflow changes, training, et cetera as we continue to improve our education and outreach efforts for eCQM submission and validation. We try to be as proactive as possible in providing lead time about the removal of measures from the Hospital IQR Program measure set. With regard to the measures being removed for the FY 2019 payment determination, we signaled our intent to remove these measures in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49644 through 49645). We refer readers to section VIII.A.8.a. of the preamble of this final rule for a discussion of our final policy regarding the number of eCQMs required for submission for the FY 2019 payment determination and subsequent years.

Comment: A few commenters suggested that topped-out measures not be removed from the Hospital IQR Program measure set. One commenter opposed the proposal to remove the eCQMs that are topped out, stating that the measures should not be retired until the eCQM reporting process and validation have matured. The commenter further stated that allowing hospitals the option to electronically report topped-out measures would provide them with an opportunity to test the accuracy of their EHR reporting systems. Another commenter requested that any topped-out eCQM that is removed from the Hospital IQR Program be kept on reserve so that performance can be monitored as necessary to ensure that performance and/or adherence to best practices do not decline. In addition, the commenter suggested that an alternative use of topped-out measures is inclusion as components of composite measures. Another commenter recommended that CMS implement a periodic auditing system of measures designated as topped-out. The commenter expressed the opinion that such a system would ensure that performance remains satisfactorily high and also detect reductions in the quality of care.

Response: We disagree that measures should not be retired until the eCQM reporting process and validation have matured. While we recognize the benefit of testing the accuracy of EHR reporting systems and performance monitoring to ensure best practices do not decline, we must balance the costs of continued inclusion of these measures in the program and monitoring of successful measures that have high levels of performance with the adoption of other measures which have greater opportunities for improvement in clinical quality.

Comment: One commenter expressed concern that nine out of 15 eCQMs proposed for required reporting in the Hospital IQR Program are ''topped-out'' and suggested that CMS remove the following nine measures: AMI–8a—Primary PCI within 90 minutes of Hospital Arrival; STK–02—Discharged on Antithrombotic Therapy; STK–03—Anticoagulation Therapy for Atrial Fibrillation/Flutter; STK–05—Antithrombotic Therapy by End of Hospital Day 2; STK–06—Discharged on Statin; STK–08—Stroke Education; STK–10—Assessed for Rehab; VTE–01—Venous Thromboembolism Prophylaxis; VTE–02—ICU VTE Prophylaxis. The commenter also expressed concern about the audit requirements for these measures as EHRs are updated and requested clarification of the data field requirements.

Response: While we acknowledge commenter's concern regarding retaining eCQMs that are topped-out in their chart-abstracted form, we note that we take several factors into consideration when retaining or removing measures from the program. We refer readers to the FY 2016 IPPS/LTCH PPS final rule where we discuss our measure removal and retention factors (80 FR 49641). These measures are not being considered for removal in this final rule because we believe that these measures have other valuable factors that warrant retention in the program, such as: Alignment with CMS Quality Strategy goals; alignment with other CMS programs, including other quality reporting programs, or the EHR Incentive Program; and supporting efforts to move facilities towards reporting electronic measures.

With regard to the commenter's concerns regarding ''audit requirements,'' we interpret this to refer to changes in eCQM technical mapping that may need to occur after an EHR is updated/upgraded. All Hospital IQR Program eCQM electronic specifications and technical release notes are readily available at the eCQI (Electronic Clinical Quality Improvement) Resource Center: *https://ecqi.healthit.gov/eh*. We encourage hospitals to test electronic capture of data following updates and upgrades or to work with their vendors to do so. Further, we encourage hospitals to internally test their preparedness to submit eCQM data prior to annual reporting using an available presubmission testing tool for electronic reporting—such as the CMS Pre-Submission Validation Application (PSVA), which can be downloaded for free from the Secure File Transfer (SFT) section of the QualityNet Secure Portal at: *https://cportal.qualitynet.org/QNet/pgm_select.jsp*. We will also continue working to provide hospitals and vendors with education on eCQM data reporting fields and elements.

Comment: A few commenters did not support the removal of any of these 13 eCQMs because it would reduce the number of eCQMs available for hospitals to select for reporting. One commenter indicated that this proposal would reduce hospitals' flexibility in choosing to report measures that are meaningful to them and that align with their internal efforts to improve quality.

Response: We understand the commenters' concerns with respect to allowing hospitals' flexibility to choose to report on measures that are meaningful to internal quality improvement efforts. However, as we stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641), we strive to ensure that our measure set consists of quality standards that align with the

National Quality Strategy and our priorities for quality improvement as outlined in the CMS Quality Strategy, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMSQuality-Strategy.pdf*. Our decision to remove measures from the Hospital IQR Program measure set is an extension of our programmatic goal to continually refine the measure set and ensure that it consists of quality performance standards. We again refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641) for our considerations in removing and retaining measures as well as section VIII.A.8.a. of the preamble of this final rule, where we finalize a policy to require submission of 8 eCQMs out of 15 available eCQMs for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination.

Comment: A commenter did not support the removal of measures because it can hinder ongoing measurement and reduce performance improvements. The commenter requested that CMS maintain a library of measures that are not included in the Hospital IQR Program so that hospitals and vendors can still support monitoring and improving these removed measures.

Response: We disagree with commenter that the removal of these measures may hinder measurement and reduce performance improvement. Although hospitals are not publicly reporting data for measures that have been removed from the Hospital IQR Program, hospitals are encouraged to continue to monitor data for continuous quality improvement. We appreciate the commenter's suggestion to maintain a library of eCQMs that have been removed from the Hospital IQR Program and will take it into consideration for the future.

Comments related to removal of specific measures are discussed in more detail below.

(1) Removal of Structural Measures

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25175, we proposed to remove two structural measures for the FY 2019 payment determination and subsequent years: (1) Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and (2) Participation in a Systematic Clinical Database Registry for General Surgery, based on removal factor 4—performance on these measures does not result in better patient outcomes (80 FR 49641). These measures were originally adopted in the RHQDAPU Program FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43870 through 43872) to monitor participation in systematic clinical database registries for the Hospital IQR Program. By design, the measures do not provide information on patient outcomes, because hospitals are asked only whether they participate in registries. In the future, we will consider other more effective measures to include in the program. As a result, we believe that the burden to retain these measures outweigh the benefits. Therefore, we proposed to remove these two structural measures from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

Comment: Many commenters supported the proposed removal of the two structural measures from the Hospital IQR Program because removing these measures ensures that the measure set only includes measures that result in better patient outcomes. A number of commenters asserted that the measures do not provide pertinent information on patient outcomes, do not reflect performance on process or outcomes, and do not add value to the Hospital IQR Program's measure set. Some commenters also noted that removing these measures would decrease the annual reporting burden on hospitals.

Response: We thank the commenters for their support.

Comment: A few commenters supported the proposed removal of the two structural measures from the Hospital IQR Program, but suggested that this removal be implemented for the FY 2018 payment determination, instead of the FY 2019 payment determination.

Response: We thank the commenters for their support and suggestion. However, we will implement the removal of these measures for the FY 2019 payment determination as proposed, because the FY 2019 payment determination is the earliest we can feasibly operationalize the removal.

Comment: One commenter expressed concern with the proposed removal of the Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care measure, because it has seen improvement from this participation. The commenter suggested that any future quality measures should match the registry's quality measures to encourage alignment.

Response: We continue to believe that registries may facilitate valuable quality improvement feedback to hospitals that may be more meaningful beyond the information reported to the Hospital IQR Program as structural measures. However, at this time we are unable to collect this additional quality improvement data since we do not maintain the registries. The structural measures themselves, as part of the Hospital IQR Program, do not provide information on patient outcomes; hospitals are asked only whether they participate in registries. Thus, we believe it is important to consider other measures that provide more meaningful and detailed information regarding quality of care and patient outcomes while balancing program burdens. We note that we are committed to promoting alignment in quality measures when feasible; however, many registry measures are proprietary.

Comment: One commenter opposed the proposed removal of the ''Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care'' because public reporting of this measure is a lever to promote continued hospital participation in a nursing-sensitive data registry. The commenter expressed concern that if this measure were not included in the Hospital IQR Program, the role of nursing professionals would be diminished in the program. The commenter further noted that this measure is low burden to report and urged CMS to retain this measure until nursing sensitive process and outcome measures are developed as eCQMs and reported in the Hospital IQR Program.

Response: We appreciate the commenter's position to retain this measure, however, we note that the main intent of this structural measure was to assess the level of registry participation. Because this measure does not provide information on patient outcomes or quality of care, we believe it is important to remove it from the program at this time in light of the burden of reporting and consider other measures that provide more meaningful and detailed information regarding quality of care and patient outcomes. We believe that hospitals committed to participating in a nursing registry will continue to do so. We agree with the commenter that providing quality care requires all members of the care team, including nurses, and we will continue to consider measures for the Hospital IQR Program that incorporate the importance of communication and coordination among members of the care team. We will also consider the development of nursing sensitive process and outcome measures for the Hospital IQR Program in the future.

Comment: One commenter opposed the proposed removal of the ''Participation in a Systematic Clinical

Database Registry for General Surgery'' from the Hospital IQR Program because it believed that the inclusion of this measure encourages hospital participation in risk-adjusted, audited clinical data registries. Further, the commenter asserted that inclusion of such a measure helps CMS ensure that hospital and physician programs are in alignment.

Response: We note that the main intent of this structural measure was to assess the level of registry participation. When considering measures for the Hospital IQR Program, we attempt to align with other programs whenever feasible, but because this measure does not provide information on patient outcomes or quality of care, we believe it is important to remove it from the program at this time in light of the overall burden of reporting. We do not believe that the removal of this measure will dis-incentivize hospitals committed to participating in registries for quality improvement.

After consideration of the public comments we received, we are finalizing the removal of these two structural measures from the Hospital IQR Program for the FY 2019 payment determination and subsequent years as proposed.

(2) Removal of ''Topped-Out'' Chart-Abstracted Measures

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25175, we proposed to remove two measures in their chart-abstracted forms: (1) STK–4: Thrombolytic Therapy (NQF #0437) and (2) VTE–5: VTE Discharge Instructions, because measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures)—removal factor 1 (80 FR 49641). The chart-abstracted version of STK–4 was adopted into the program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51634); and the chart-abstracted version of VTE–5 was adopted into the program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51636). One factor we consider in determining whether a measure should be retained or removed from the program is whether the measure is ''topped-out.'' We have previously adopted two criteria for determining the ''topped-out'' status of Hospital IQR Program measures: (1) Statistically indistinguishable performance at the 75th and 90th percentiles; and (2) truncated coefficient of variation ≤0.10 (80 FR 49642). These measures meet both of these criteria. We believe that the burdens of retaining these measures outweigh the benefits, and therefore, we proposed to remove the chart-abstracted versions of STK–4 and VTE–5 for the FY 2019 payment determination and subsequent years.

Comment: Many commenters supported the proposal to remove two chart-abstracted measures, STK–4 and VTE–5, on the grounds that these measures are topped-out and offer little room for performance improvement among hospitals. Commenters also noted that removing these measures would reduce administrative burden on hospitals and would move CMS quality measurement efforts away from the use of clinical process measures and more toward outcomes measures.

Response: We thank the commenters for their support of our proposal to remove two chart-abstracted measures in an effort to move quality measurement toward outcomes measures.

Comment: One commenter supported the removal of the topped out chart-abstracted measures, but encouraged CMS to apply new stroke and VTE measures to ensure continual quality improvement.

Response: We thank the commenter for the support. We will consider new stroke and VTE measures for future rulemaking.

Comment: One commenter supported the removal of the STK–4 and VTE–5 chart-abstracted measures, but encouraged us to retain them as eCQMs.

Response: We believe that the burden of retaining both the STK–4 and VTE–5 measures as eCQMs outweighs the benefits. In addition to both measures being topped out, we also considered other factors such as feasibility of data collection and alignment with other programs. In the case of VTE–5, a majority of hospitals do not have the ability to capture the required eCQM data elements needed for VTE–5 and therefore data collection is not feasible. Furthermore, removing these two measures in both chart-abstracted and eCQM forms aligns the Hospital IQR Program measure set with the Medicare and Medicaid EHR Incentive Programs' measure sets. We refer readers to section VIII.E.2.b. of the preamble to this final rule for the Medicare and Medicaid EHR Incentive Programs' measure sets.

Comment: One commenter did not support the proposed removal of VTE–5 because changes in practice patterns, including shorter hospital stays after major surgery, make clear discharge planning around VTE prevention more important moving forward. The commenter expressed the opinion that removing this measure would reduce accountability for appropriate transitions of care for patients at risk of VTE.

Response: Topped-out measures represent care standards that have been widely adopted by hospitals. Measure performance among hospitals is so high and unvarying for VTE–5 that meaningful distinctions and improvements in performance can no longer be made. We believe that hospitals committed to providing quality care will continue to provide good quality care consistent with standard practice. In the past, we have retained the electronic versions of some topped-out measures for reasons such as promoting alignment between programs or to provide an opportunity to monitor topped-out measures for performance decline. In this case, VTE–5 is not only topped-out, but also, as stated above, a majority of hospitals do not have the ability to capture the required eCQM data elements needed for VTE–5. In addition, removing VTE–5 promotes alignment with the Medicare and Medicaid EHR Incentive Programs. Finally, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we received anecdotal comments about performance level differences between chart-abstracted and eCQM data. We do not have sufficient data to be able to confirm or refute the accuracy of those comments (79 FR 50258), but these comments have prompted us to reconsider our position that topped-out eCQMs provide an opportunity for CMS to meaningfully monitor topped-out measures for performance decline at this time. In consideration of all of these factors, we do not believe that the burden of retaining the electronic version to allow the comparison to old data outweighs the benefit. Therefore, we believe that removal of VTE–5 in both chart-abstracted and eCQM form is appropriate.

Comment: One commenter did not support the removal of the STK–4 chart-abstracted measure because the commenter believes there is still a performance gap among hospitals for this measure, and recent inclusion and exclusion criteria released earlier this year may increase the number of patients eligible for this treatment. The commenter suggested that CMS retain the STK–4 measure.

Response: We disagree with the commenter that a performance gap among hospitals exists. We note that STK–4 is topped-out in its chart-abstracted form, which under our definition means that measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.

While we acknowledge that revised measure specifications have been submitted to NQF, the revised measure would be required to proceed through the pre-rulemaking process for measure selection before it could be considered for adoption in the Hospital IQR Program. For details regarding the pre-rulemaking process we refer commenter to *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html*.

Comment: One commenter requested that any topped-out chart-abstracted measure that is removed from the Hospital IQR Program be kept on reserve so that performance can be monitored as necessary to ensure that performance and/or adherence to best practices do not decline. In addition, the commenter suggested that an alternative use of topped-out measures could instead be used as components of composite measures.

Response: We currently do not have authority to maintain a ''reserve'' status for quality measures in the Hospital IQR Program. If we interpret the commenter to mean that CMS should retain the measures in the program as is, we disagree, and a new composite measure would be required to proceed through the pre-rulemaking process for measure selection before it could be proposed in formal rulemaking. For details regarding the pre-rulemaking process we refer commenter to *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html*. We believe that topped-out measures represent quality care standards that have been widely adopted by hospitals, and retention of these measures, in the absence of other mitigating factors such as alignment with other programs, independently or as components of a composite measure, is unnecessary because hospitals will continue to perform well on these measures. Further, we must balance the costs and burden of continued reporting and monitoring of a successful measure with high levels of performance with the adoption of other measures where there are greater opportunities for improvement in clinical quality. As stated above, we also considered other factors such as alignment with other programs, and determined that removal of STK–4 and VTE–5 promotes alignment with the Medicare and Medicaid EHR Incentive Programs. However, we will take the commenter's recommendation into consideration for the future if statutory changes are made to the program.

After consideration of the public comments we received, we are finalizing the removal of STK–4: Thrombolytic Therapy (NQF #0437) and VTE–5: VTE Discharge Instructions for the FY 2019 payment determination and subsequent years as proposed.

(3) Removal of Certain eCQMs

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25175, we proposed to remove the electronic versions of AMI–7a, HTN, PN–6, SCIP–Inf–9, VTE–3, VTE–4, VTE–5, VTE–6, STK–4, AMI–2, AMI–10, SCIP–Inf–1a, and SCIP–Inf–2a, beginning with the FY 2019 payment determination. Each measure is discussed in more detail below.

(a) Removal of eCQMs in Alignment With the Medicare and Medicaid EHR Incentive Programs

We proposed to remove 13 eCQMs from both the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs in order for hospitals to focus on a smaller, more specific subset of eCQMs while keeping the programs aligned.

We refer readers to sections VIII.A.8.a. and VIII.A.10.d. of the preamble of this final rule for details on eCQM reporting requirements for the Hospital IQR Program in alignment with the Medicare and Medicaid EHR Incentive Programs. We also refer readers to section VIII.A.3.b.(3) of the preamble of this final rule for discussion on the removal of these 13 eCQMs from the Medicare and Medicaid EHR Incentive Programs. We believe that a coordinated reduction in the overall number of eCQMs in both programs would reduce burden on hospitals and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of eCQMs. We proposed these changes in response to public comments for the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49694), which recommended that CMS adopt a lesser number of eCQMs.

Comment: Many commenters supported the removal of 13 eCQMs from the Hospital IQR Program measure set.

Response: We thank the commenters for their support.

(i) AMI–7a

We proposed to remove the AMI–7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival eCQM, because performance or improvement on this measure does not result in better patient outcomes—removal factor 4 (80 FR 49641). In the FY 2016 IPPS/LTCH PPS final rule, we removed the chart-abstracted version of AMI–7a because the reporting burden outweighed the benefit of posting very few hospitals' measure rates. This measure's specifications resulted in very high denominator exclusion rates. Consequently, the vast majority of abstracted AMI cases were excluded from AMI–7a measure rates. Most acute myocardial infarction (AMI) patients receive percutaneous coronary intervention (PCI) instead of fibrinolytic therapy (80 FR 49647). We do not believe that the mode of reporting (eCQM versus chart-abstracted) would cause the number of cases reported to differ since most AMI patients would still receive PCI instead of fibrinolytic therapy. In the FY 2016 IPPS/LTCH PPS final rule, we retained the electronic version of this measure for alignment purposes with the Medicare and Medicaid EHR Incentive Programs (80 FR 49644). As discussed above, we proposed to focus on a smaller, more specific subset of eCQMs in both the Hospital IQR and Medicare and Medicaid EHR Incentive Programs. As a result, the burdens related to retaining this measure outweigh the benefits. Therefore, we proposed to remove the AMI–7a eCQM from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

Comment: A commenter supported the removal of the AMI–7a because most AMI patients receive percutaneous coronary intervention instead of fibrinolytic therapy and the measure does not reflect current clinical practice.

Response: We thank the commenter for its support of our proposal to remove AMI–7a because it does not reflect current clinical practice.

Comment: One commenter did not support the proposal to remove the AMI–7a measure because fibrinolytic therapy is still recommended when PCI cannot be performed within 120 minutes of first medical contact. Because it is still an important process of care, the commenter recommended that CMS find ways to reduce collection burden instead of removing the measure from the Hospital IQR Program. The commenter also expressed concern that removing this measure could cause unintended consequences, particularly for patients in rural settings where there could be prolonged times to transfer a patient to a PCI-capable hospital.

Response: As discussed above, in the FY 2016 IPPS/LTCH PPS final rule, we previously removed the chart-abstracted version of AMI–7a because the reporting burden outweighed the benefit of public reporting on very few hospitals' measure rates. This measure's specifications resulted in very high

denominator exclusion rates, and consequently, the vast majority of abstracted acute myocardial infarction (AMI) cases were excluded from AMI–7a measure rates. Further, most AMI patients receive percutaneous coronary intervention (PCI) instead of fibrinolytic therapy (80 FR 49647). While we acknowledge the commenter's concern regarding unintended consequences, particularly in rural settings, we carefully weighed the benefits and burden of retaining this eCQM in the program. Due to the high exclusion rates, we do not believe that trying to reduce the collection burden of AMI–7a will reduce the exclusion rates or otherwise outweigh the reporting costs to hospitals of retaining the measure in the Hospital IQR Program. As discussed above, we intend to focus on a smaller, more specific subset of eCQMs in both the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs. We remain committed to monitoring for unintended consequences, such as changes in AMI patient outcomes over time, by examining the results of other outcome measures in the Hospital IQR Program, specifically MORT–30–AMI and READM–30–AMI. We will revise the measure set through future rulemaking if needed.

After consideration of the public comments we received, we are finalizing the removal of the AMI–7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival eCQM from the Hospital IQR Program for the FY 2019 payment determination and subsequent years as proposed.

(ii) STK–4, AMI–2, AMI–10, SCIP–Inf–1a, and SCIP–Inf–2a

We proposed to remove the: (1) STK–4: Thrombolytic Therapy (NQF #0437); (2) AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142); (3) AMI–10: Statin Prescribed at Discharge; (4) SCIP–Inf–1a: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision (NQF #0527); and (5) SCIP–Inf–2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528) eCQMs, because measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made—removal factor 1 (80 FR 49641). We note that the NQF has changed the endorsement designations of the AMI–2, AMI–10, SCIP–Inf–1a, and SCIP–Inf–2a chart-abstracted measures and eCQM versions to either ''reserve status'' or ''endorsement removed'' (available at: *http://www.qualityforum.org/QPS/QPSTool.aspx*), because there is no opportunity for improvement.

We refer readers to section VIII.A.3.b.(2) of the preamble of this final rule for discussion of our proposal also to remove the chart-abstracted form of the STK–4 measure due to ''topped-out'' status. The electronic version of the STK–4 measure was adopted into the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50784) to promote programmatic alignment, as it was a part of a measure set that was already included in the Medicare and Medicaid EHR Incentive Programs' Electronic Reporting Pilot for Eligible Hospitals and CAHs (75 FR 44418 and 76 FR 74489).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50781), we removed the chart-abstracted versions of AMI–2 and AMI–10 due to ''topped-out'' status. However, as noted in FY 2015 IPPS/LTCH PPS final rule (79 FR 50245), we readopted these measures, though only in the electronic form, because we believed that we should continue aligning the Hospital IQR Program and the Medicare EHR Incentive Program in order to minimize reporting burden and to facilitate the transition to reporting of eCQMs. We believed that voluntary reporting of these measures would further that aim. In addition, we believed that allowing hospitals the option to electronically report ''topped-out'' measures would provide them with an opportunity to test the accuracy of their EHR reporting systems.

Similarly, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50208), we removed the chart-abstracted versions of SCIP–Inf–1a and SCIP–Inf–2a, previously referred to as SCIP–Inf–1 and SCIP–Inf–2 respectively, due to their ''topped-out'' status. However, as stated in that rule, we retained the electronic versions of these measures, because we believed this provided us with an opportunity to monitor ''topped-out'' measures for performance decline. It also simplified alignment between the Hospital IQR Program and Medicare EHR Incentive Program for eligible hospitals and provided a more straightforward approach to educate stakeholders on electronic reporting options (79 FR 50208).

As discussed above, we proposed to focus on a smaller, more specific subset of eCQMs for the Hospital IQR Program and both the Medicare and Medicaid EHR Incentive Programs. Therefore, in light of their ''topped out'' status, the burden of retaining these measures outweighs the benefits. Thus, we proposed to remove the STK–4, AMI–2, AMI–10, SCIP–Inf–1a, and SCIP–Inf–2a eCQMs from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

Comment: A commenter supported the removal of the following eCQMs: SCIP–Inf–1a: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision (NQF #0527), SCIP–Inf–2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF # 0528), SCIP–Inf–9: Urinary Catheter Removed on Postoperative Day 2 (POD2) With Day of Surgery Being Day Zero, and PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP). The commenter stated that removing these measures from the Hospital IQR Program helps to reduce data collection burden, rid the program of measures that no longer add value, and allow hospitals to focus on measures that demonstrate areas for improvement.

Response: We thank the commenter for its support.

Comment: One commenter expressed concern regarding the proposed removal of the SCIP–Inf–1a: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision (NQF #0527) measure due to a concern that the removal of this measure could result in unintended reduction in adherence to appropriate prophylactic antibiotic use prior to surgery. The commenter stated that the prophylactic antibiotic measure (NQF #0527) should be retained to supplement the proposed NHSN measure, since it is the aim of hospitals to minimize antimicrobial use.

Response: We disagree with the commenter that removal of SCIP–Inf–1a, which is topped-out, will result in the unintended reduction in adherence to appropriate prophylactic antibiotic use prior to surgery. Topped-out measures represent care standards that have been widely adopted by hospitals. We believe that hospitals committed to providing quality care will continue to provide good quality care consistent with standard practice. In the past, we have retained the electronic versions of some topped-out measures for reasons such as promoting alignment between programs or to provide an opportunity to monitor topped-out measures for performance decline. In this case, removing SCIP–Inf–1a promotes alignment with the Medicare and Medicaid EHR Incentive Programs. In addition, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we received anecdotal comments about performance level differences between chart-abstracted and eCQM data. We do not have sufficient data to be able to confirm or refute the accuracy of those comments (79 FR 50258), but these comments have prompted us to reconsider our position

that topped-out eCQMs provide an opportunity for CMS to meaningfully monitor topped-out measures for performance decline at this time. In consideration of these factors, we do not believe that the burden of retaining the electronic version to allow the comparison to chart-abstracted data outweighs the benefit. Therefore, we believe that removal of SCIP–Inf–1a in eCQM form is appropriate.

We wish to clarify that we did not propose the NHSN Antimicrobial Use Measure, but rather sought comments regarding potential inclusion of the measure in the future. We do not agree that we should retain SCIP–Inf–1a to supplement the NHSN Antimicrobial Use measure, because if the NHSN measure is adopted into the Program in future years, surgical prophylactic antibiotic use will be captured by the NHSN measure. However, we applaud the commenter's commitment to antibiotic stewardship and refer readers to the NHSN Antibiotic Use and Resistance Module available at: *http://www.cdc.gov/nhsn/acute-care-hospital/aur/*.

Comment: One commenter supported the removal of the AMI–2 and AMI–10 eCQMs because removal would reduce the administrative burden on hospitals. However, the commenter suggested that these measures be kept on reserve for reimplementation if necessary because they are important processes in cardiovascular care.

Response: We thank the commenter for its support of our proposal to remove the AMI–2 and AMI–10 eCQMs because removal will reduce hospital administrative burden. We note that currently we do not have authority to maintain a ''reserve'' status for quality measures in the Hospital IQR Program. If we interpret the commenter to mean that CMS should retain the eCQMs in the program as is, we disagree. We must balance the costs and burden of continued reporting and monitoring of a successful measure with high levels of performance with the adoption of other measures where there are greater opportunities for improvement in clinical quality. As stated above, we also considered other factors such as alignment with other programs, and determined that removal of AMI–2 and AMI–10 promotes alignment with the Medicare and Medicaid EHR Incentive Programs. If we decide to reimplement these measures in the future, as the commenter suggests, we are required to proceed through the pre-rulemaking process for measure selection before they can be considered for adoption in the Hospital IQR Program. For details regarding the pre-rulemaking process we refer readers to: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html*.

Comment: Some commenters did not support the proposal to remove the STK–4 eCQM, and expressed concern that removing this eCQM may lead to poorer performance due to lack of accountability and reporting, as well as send a message that CMS does not consider this an important process of care for patients with ischemic stroke. Two commenters noted that the national averages for the STK–4 measure is only 83 percent, indicating an opportunity for hospitals to improve on this measure. One commenter noted retention of the STK–4 eCQM is necessary because it allows hospitals and CMS to compare the eCQM-reported rates with the historically reported chart-abstracted measure. Another commenter raised concerns with removing the STK–4 measure because it intended to submit this measure as part of the CY 2016 eCQM reporting requirement.

Response: STK–4 meets our topped-out criteria per our analysis of hospitals participating in the Hospital IQR Program. Further, because of the use of structured data fields in eCQMs, eCQM data and chart-abstracted data for the same measure may not always be one hundred percent comparable. We do not believe that removal of STK–4 will lead to poorer performance and accountability. As previously noted, we believe topped-out measures represent care standards that have been widely adopted by hospitals. We believe that hospitals committed to providing quality care will continue to provide quality care consistent with standard practice. In the past, we have retained the electronic versions of some topped-out measures for reasons such as promoting alignment between programs or to provide an opportunity to monitor topped-out measures for performance decline. In this case, removing STK–4 promotes alignment with the Medicare and Medicaid EHR Incentive Programs.

In addition, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we received anecdotal comments about performance level differences between chart-abstracted and eCQM data. We do not have sufficient data to be able to confirm or refute the accuracy of those comments (79 FR 50258), but these comments have prompted us to reconsider our position that topped-out eCQMs provide an opportunity for CMS to meaningfully monitor topped-out measures for performance decline at this time. In consideration of these factors, we do not believe that the burden of retaining the electronic version to allow the comparison to old data outweighs the benefit. Therefore, we believe that removal of STK–4 in eCQM form is appropriate. In regard to the commenter's concern that it will not be able to submit the STK–4 eCQM as part of the CY 2016 reporting period eCQM requirement, we note that the STK–4 eCQM was proposed (and is being finalized) for removal for the FY 2019 payment determination, which affects the CY 2017 reporting period, not the CY 2016 reporting period. The commenter may still submit the STK–4 eCQM for the CY 2016 reporting period for the FY 2018 payment determination.

Comment: One commenter did not support the removal of AMI–10 and AMI–2 because these measures continue to provide useful data to hospitals.

Response: We refer readers to section VIII.A.3.b.(3)(a)(ii) of the preamble of this final rule where we note that measure performance for AMI–10 and AMI–2 is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. Therefore, per the Hospital IQR Program removal factor 1 (80 FR 49641), we have decided to remove these measures from the measure set. In addition to both measures being topped out, we also considered other factors such as alignment with other programs and determined that removing these two measures aligns the Hospital IQR Program measure set with the Medicare and Medicaid EHR Incentive Programs' measure sets. We refer readers to section VIII.E.2.b. of the preamble of this final rule for the Medicare and Medicaid EHR Incentive Programs' measure sets.

Further, these measures have had a change in endorsement designation by NQF (available at: *http://www.qualityforum.org/QPS/QPSTool.aspx*). In addition, as discussed above, we intend to focus on a smaller, more specific subset of eCQMs for the Hospital IQR Program and both the Medicare and Medicaid EHR Incentive Programs.

After consideration of the public comments we received, we are finalizing the removal of the STK–4, AMI–2, AMI–10, SCIP–Inf–1a, and SCIP–Inf–2a eCQMs from the Hospital IQR Program for the FY 2019 payment determination and subsequent years as proposed.

(b) HTN

We proposed to remove the HTN: Healthy Term Newborn (NQF #0716) eCQM, because it is no longer feasible to implement the measure

specifications—removal factor 7 (80 FR 49642). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50249), we added HTN, only as an eCQM, not as a claims-based measure. Although the claims-based version of the HTN measure has never been part of the Hospital IQR Program, the claims-based HTN measure concept was used to develop the HTN eCQM. The measure steward has made substantial revisions to the claims-based version of this measure such that the focus is no longer on the number of healthy term newborns, but the number of unexpected complications in term newborns. The numerator of the revised measure has been restructured to assess the presence of severe or moderate complications after term birth, while the original measure looked for the absence of several types of complications after term birth. For the revised measure specifications, we refer readers to: *https://www.cmqcc.org/focus-areas/quality-metrics/unexpected-complications-term-newborns*. In addition, the measure steward is no longer maintaining the claims-based version of HTN or supporting the maintenance of the original eCQM version of HTN that was developed by CMS and adopted in the Hospital IQR Program. Therefore, it is not feasible to continue to include a measure that is no longer supported by the steward. As a result, we proposed to remove the HTN eCQM from the Program for the FY 2019 payment determination and subsequent years.

Comment: One commenter supported the proposal to remove HTN along with AMI–7a, VTE–3, VTE–4, VTE–5, VTE–6, SCIP–Inf–1a, SCIP–Inf–2a, SCIP–Inf–9, PN–6, and STK–4.

Response: We thank the commenter for its support.

After consideration of the public comment we received, we are finalizing the removal of the HTN: Healthy Term Newborn (NQF #0716) eCQM from the Hospital IQR Program for the FY 2019 payment determination and subsequent years as proposed.

(c) PN–6 and SCIP–Inf–9

We proposed to remove the: (1) PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147) and (2) SCIP–Inf–9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 ((POD2) with Day of Surgery Being Day Zero) eCQMs, because it is no longer feasible to implement the measure specifications—removal factor 7 (80 FR 49642). While the electronic versions were retained, the chart-abstracted versions of PN–6 and SCIP–Inf–9 were determined to be ''topped-out'' and were removed from the Hospital IQR Program measure set in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50204 through 50208).

These two eCQMs have undergone significant changes to their logic expression during the previous annual update.[93] There are a number of data capture requirements that cannot be represented adequately in the eCQM form due to their conceptual complexity. Specifically, for PN–6, hospital feedback has indicated difficulties with interpreting several critical timing requirements, such as for intensive care unit populations, emergency department and inpatient admission transitions, steroid therapy, and pre-admission medications. In addition, hospitals raised concern about the inability to account for variation in recording of the interpretation of laboratory results. For SCIP–Inf–9, feedback from hospitals has indicated that it is difficult to interpret the appropriate timing of elements associated with both the insertion and removal of a catheter. This is particularly problematic, because of the variety of patient locations encountered before and after surgery, as well as transfers among units. While these variations for both PN–6 and SCIP–Inf–9 can be accounted for through chart-based manual abstraction, we have had great difficulties in translating and maintaining these options for electronic reporting. Therefore, we proposed to remove both the PN–6 and SCIP–Inf–9 eCQMs from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

Comment: One commenter supported the removal of SCIP-Inf-9: Urinary Catheter Removed on Postoperative Day 2 (POD2) With Day of Surgery Being Day Zero and PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) because removing these measures from the Hospital IQR Program helps to reduce data collection burden, rid the program of measures that no longer add value, and allow hospitals to focus on measures that demonstrate areas for improvement.

Response: We thank the commenter for its support.

After consideration of the public comment received, we are finalizing the removal of both PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147) and SCIP-Inf-9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 ((POD2) with Day of Surgery Being Day Zero) eCQMs from the Hospital IQR Program for the FY 2019 payment determination and subsequent years as proposed.

(d) VTE–3, VTE–4, VTE–5, and VTE–6

We proposed to remove the four VTE eCQMs: (1) VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373); (2) VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram); (3) VTE–5: Venous Thromboembolism Discharge Instructions; and (4) VTE–6: Incidence of Potentially Preventable Venous Thromboembolism, because it is no longer feasible to implement the measures specifications—removal factor 7 (80 FR 49642). Many of the chart-abstracted versions of these measures were determined to be ''topped-out.'' While the electronic versions of VTE–3 and VTE–4 were retained, the chart-abstracted versions were determined to be ''topped-out'' and were removed from the Hospital IQR Program measure set in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49643) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50205), respectively. In addition, as described above in section VIII.A.3.b.(2) of the preamble of this final rule, we proposed to remove the chart-abstracted version of VTE–5 for the FY 2019 payment determination and subsequent years due to its ''topped-out'' status. The electronic version of VTE–5 was adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50784). Finally, the chart-abstracted version of VTE–6, however, continues to be included in the Hospital IQR Program measure set because chart abstractors can manually find required data elements in clinical notes and not in structured data fields.

Nonetheless, a majority of hospitals do not have the ability to capture required data elements, such as diagnostic study results/reports and location of the specific vein in which deep vein thrombosis was diagnosed, in discrete structured data fields to support these eCQMs, because they are often found as free text in clinical notes instead. It is exceedingly difficult for hospitals to implement the measure specifications in the absence of these functional requirements. Furthermore, as discussed above, we proposed to focus on a smaller, more specific subset of eCQMs in the Hospital IQR Program and both the Medicare and Medicaid

[93] Technical Release Notes: 2015 Annual Update of 2014 Eligible Hospitals and Eligible Professionals Electronic Clinical Quality Measures (eCQMs). Available at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHandEPTRNs.pdf*.

EHR Incentive Programs. Therefore, in light of their ''topped out'' statuses and the infeasibility of implementing the measure specifications, the burden of retaining these measures outweighs the benefits. As a result, we proposed to remove the VTE–3, VTE–4, VTE–5, and VTE–6 eCQMs from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

Comment: One commenter supported the proposal to remove AMI–7a, VTE–3, VTE–4, VTE–5, VTE–6, SCIP-Inf-1a, SCIP-Inf-2a, SCIP-Inf-9, PN–6, STK–04, and HTN. In addition to the reasons articulated by CMS for removing these eCQMs, the commenter expressed concern that AMI–7a and VTE–3, VTE–4, VTE–5, and VTE–6 require data produced and documented in non-certified radiology systems that lack an automated interface necessary to integrate data into certified EHRs for accurate measurement. As a result, the data must be entered manually and this process is very burdensome for providers and could result in great inaccuracies in measure calculations. Another commenter supported the removal of the VTE measures, because these measures have data elements that cannot be captured by electronic reporting.

Response: We thank the commenters for their support.

Comment: One commenter requested that CMS retain the eCQM version of the VTE–6 measure, stating that if CMS sees value in the chart-abstracted form of the measure, then there should also be value in the eCQM format. The commenter also offered that while many other entities have had difficulty implementing this measure in its electronic form, as noted in the proposed rule, it has had success with this measure.

Response: As we state in section VIII.A.3.b.(3)(d) of the preamble of this final rule, the chart-abstracted version of VTE–6 continues to be included in the Hospital IQR Program measure set because chart abstractors can manually find required data elements in clinical notes and not in structured data fields. While we support the commenter's progress with successful data collection for this measure, a majority of hospitals do not have the ability to capture required data elements in discrete structured data fields to support this eCQM. Therefore, in light of their ''topped out'' statuses and the infeasibility of implementing the measure specifications, the burden of retaining these measures outweighs the benefits.

Comment: One commenter suggested that CMS consider future measures for venous thromboembolism, because it is a common condition for hospitalized patients. The commenter expressed concern that with the removal of VTE eCQMs, almost all of the measures related to VTE will be removed from the Hospital IQR Program and given the prevalence and impact of this condition, CMS should consider including more measures that assess VTE to facilitate a renewed focus on improvement in this area. The commenter is developing a comprehensive set of VTE guidelines and plans to reach out to CMS in the future to discuss their implementation in the context of quality measures.

Response: We recognize the importance of assessing VTE in relation to improved patient outcomes for hospital inpatients and will consider the addition of new measures of VTE in future rulemaking. We encourage the commenter to continue their efforts of developing guidelines related to VTE, and welcome future collaboration in this area of clinical quality measurement.

After consideration of the public comments we received, we are finalizing the removal of: (1) VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373), (2) VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram), (3) VTE–5: Venous Thromboembolism Discharge Instructions, and (4) VTE–6: Incidence of Potentially Preventable Venous Thromboembolism eCQMs from the Hospital IQR Program for the FY 2019 payment determination and subsequent years as proposed.

(4) Summary of Measures Finalized for Removal

The table below lists the measures we are finalizing for removal. We invited public comment on our proposals to remove these 15 measures (eCQMs, structural, and chart-abstracted) from the Hospital IQR Program for the FY 2019 payment determination and subsequent years. The comments we received are discussed above.

We note that STK–04 and VTE–5 are listed twice—once as an eCQM and again as a chart-abstracted measure.

MEASURES FINALIZED FOR REMOVAL FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Electronic Clinical Quality Measures:

- AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142).
- AMI–7a: Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
- AMI–10: Statin Prescribed at Discharge.
- HTN: Healthy Term Newborn (NQF #0716).
- PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147).
- SCIP-Inf–1a: Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision (NQF #0527).
- SCIP-Inf–2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528).
- SCIP-Inf–9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero.
- STK–04: Thrombolytic Therapy (NQF #0437).
- VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373).
- VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram).
- VTE–5: Venous Thromboembolism Discharge Instructions.
- VTE–6: Incidence of Potentially Preventable VTE*.

Structural Measures:

- Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care.
- Participation in a Systematic Clinical Database Registry for General Surgery.

Chart-abstracted Measures:

- STK–4: Thrombolytic Therapy (NQF #0437).
- VTE–5: VTE Discharge Instructions.

* Retained in chart-abstracted form.

4. Previously Adopted Hospital IQR Program Measures for the FY 2018 Payment Determination and Subsequent Years

The Hospital IQR Program has previously finalized 65 measures for the FY 2018 payment determination as outlined in the table below:

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF #
	NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
	Chart-abstracted	
ED–1 *	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients	0497
Imm-2	Influenza Immunization	1659
PC–01 *	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
STK–04 *	Thrombolytic Therapy	0437
VTE–5 *	Venous Thromboembolism Discharge Instructions	(+)
VTE–6 *	Incidence of Potentially Preventable Venous Thromboembolism	(+)
	Claims-based Outcome	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468
MORT–30–STK	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke.	N/A
READM–30–AMI	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0505
READM–30–CABG	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2515
READM–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1891
READM–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization.	0330
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
READM–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization.	0506
READM–30–STK	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization	N/A
READM–30–THA/TKA	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1551
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	N/A
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	N/A
Hip/knee complications	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04	Death Rate among Surgical Inpatients with Serious Treatable Complications	0351
PSI 90	Patient Safety for Selected Indicators (Composite Measure)	0531

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
	Claims-based Payment	
AMI payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158
	Electronic Clinical Quality Measures (eCQMs)	
AMI–2	Aspirin Prescribed at Discharge for AMI	0142
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	(+)
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163
AMI–10	Statin Prescribed at Discharge	(+)
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	(+)
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
ED–1 *	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients	0497
HTN	Healthy Term Newborn	0716
PC–01 *	Elective Delivery	0469
PC–05	Exclusive Breast Milk Feeding **	0480
PN–6	Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients.	0147
SCIP-Inf–1a	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0527
SCIP-Inf–2a	Prophylactic Antibiotic Selection for Surgical Patients	0528
SCIP-Inf–9	Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero.	(+)
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–04 *	Thrombolytic Therapy	0437
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
STK–08	Stroke Education	(+)
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism (VTE) Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism (VTE) Prophylaxis	0372
VTE–3	Venous Thromboembolism Patients with Anticoagulation Overlap Therapy	0373
VTE–4	Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol (or Nomogram).	(+)
VTE–5*	Venous Thromboembolism Discharge Instructions	(+)
VTE–6*	Incidence of Potentially Preventable Venous Thromboembolism	(+)
	Patient Survey	
HCAHPS	HCAHPS + 3-Item Care Transition Measure (CTM–3)	0166, 0228
	Structural	
Registry for Nursing Sensitive Care.	Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	N/A
Registry for General Surgery	Participation in a Systematic Clinical Database Registry for General Surgery	N/A
Patient Safety Culture	Hospital Survey on Patient Safety Culture	N/A
Safe Surgery Checklist	Safe Surgery Checklist Use	N/A

* Measure listed twice, as both chart-abstracted and electronic clinical quality measure.
** Measure name has been shortened. Please refer to annually updated measure specifications on the CMS eCQI Resource Center Page for further information: *https://www.healthit.gov/newsroom/ecqi-resource-center*.
+ Endorsement removed.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25180), we did not propose to add or remove any measures for the FY 2018 payment determination.

5. Expansion and Updating of Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the considerations we use to expand and update quality measures under the Hospital IQR Program. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25180), we did not propose any changes to these policies.

6. Refinements to Existing Measures in the Hospital IQR Program for the FY 2018 Payment Determination and Subsequent Years

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25180 through 25185), we proposed refinements to two claims-based measures: (1) PN Payment: Hospital-Level, Risk-Standardized 30-Day Episode-of-Care Payment Measure for Pneumonia; and (2) PSI 90: Patient Safety and Adverse Events Composite (previously known as the Patient Safety for Selected Indicators Composite Measure), beginning with the FY 2018 payment determination and subsequent years. We discuss these refinements in more detail below. In addition, we refer readers to section VIII.A.9.a. of the preamble of this final rule where we discuss public comment on our intent to update the MORT–30–STK measure to include the NIH Stroke Scale as a measure of stroke severity in the risk-adjustment in future rulemaking.

a. Expansion of the Cohort for the PN Payment Measure: Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (NQF #2579)

(1) Background

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25180 through 25182), for the FY 2018 payment determination and subsequent years, we proposed a refinement of the CMS hospital-level, risk-standardized payment associated with a 30-day episode-of-care for pneumonia (NQF #2579) (PN Payment). The proposed refinement expands the measure cohort to align with the following Hospital IQR Program measures: (1) Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) (MORT–30–PN); (2) Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506) (READM–30–PN); and (3) Excess Days in Acute Care After Hospitalization for Pneumonia (an improved measure to the previously developed measure entitled ''30-day Post-Hospital Pneumonia Discharge Care Transition Composite'') (NQF #0707) (PN Excess Days).

The expansion of the measure cohort for the MORT–30–PN and the READM–30–PN was finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660) and is expected to be publicly reported beginning in July 2016. In addition, we refer readers to section VIII.A.7.b. of the preamble of this final rule where we discuss our adoption of the PN Excess Days measure in the Hospital IQR Program for FY 2019 payment determination and subsequent years.

For the purposes of describing the refinement of this measure, we note that ''cohort'' is defined as the hospitalizations, or ''index admissions,'' that are included in the measure and evaluated to ascertain the total payments made on behalf of the Medicare beneficiary for a 30-day episode-of-care. The cohort is the set of hospitalizations that meets all of the inclusion and exclusion criteria. We proposed an expansion to this set of hospitalizations.

The previously adopted PN Payment measure (79 FR 50227 through 50231) includes hospitalizations for patients with a principal discharge diagnosis of pneumonia using the International Classification of Diseases, 9th Edition, Clinical Modification (ICD–9–CM), which includes viral and bacterial pneumonia. For more cohort details on the measure as previously implemented, we refer readers to the measure methodology report, with the measure risk adjustment statistical model, in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

This proposed measure refinement would expand the measure cohort to include hospitalizations for patients with a: (1) Principal discharge diagnosis of pneumonia, including not only viral or bacterial pneumonia, but also aspiration pneumonia; and (2) principal discharge diagnosis of sepsis (but not severe sepsis) with a secondary diagnosis of pneumonia (including viral or bacterial pneumonia and aspiration pneumonia) coded as present on admission (POA). This refinement to the pneumonia cohort was proposed for several reasons, which were previously discussed in the FY 2016 IPPS/LTCH PPS final rule for the MORT–30–PN and READM–30–PN measures (80 FR 49653 through 49660). We believe that refining this measure is appropriate for the following reasons. Recent evidence has shown an increase in the use of sepsis as principal discharge diagnosis codes among patients hospitalized with pneumonia.[94] Pneumonia patients with this principal diagnosis code were not included in the original MORT–30–PN and READM–30–PN measure cohorts, and including them would better capture the complete patient population of a hospital with patients receiving clinical management and treatment for pneumonia. In addition, because patients with a principal diagnosis of sepsis are not included in the original MORT–30–PN and READM–30–PN measure specifications, efforts to evaluate changes over time in pneumonia outcomes could be biased as coding practices change. Lastly, a published article[95] also demonstrated wide variation in the use of sepsis codes as principal discharge diagnosis for pneumonia patients across hospitals, which can potentially bias efforts to compare hospital performance on the MORT–30–PN and READM–30–PN measures.

The proposal to align the PN Payment measure cohort with those of the MORT–30–PN, READM–30–PN, and newly adopted PN Excess Days measures would address the changing coding patterns in which patients with pneumonia are increasingly given a principal discharge diagnosis code of sepsis in combination with a secondary discharge diagnosis of pneumonia that is POA. Moreover, expanding the PN Payment measure cohort would ensure that the measure captures the broader population of patients admitted for pneumonia that may have been excluded from the previously adopted measure. Finally, the expansion of the cohort for the PN Payment measure harmonizes the cohort of this measure with the MORT–30–PN, the READM–30–PN, and the newly adopted PN Excess Days measures.

The proposed PN Payment measure (MUC ID 15–378), which includes this expanded measure cohort was included on a publicly available document entitled ''2015 Measures Under Consideration List'' for December 1, 2015 (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*) and has been reviewed by the NQF MAP Hospital Workgroup. The revised measure was conditionally supported pending the examination of sociodemographic status (SDS) factors and NQF review and endorsement of the measure update, as referenced in the MAP 2016 Final Recommendations

[94] Lindenauer PK, Lagu T, Shieh MS, Pekow PS, Rothberg MB. Association of diagnostic coding with trends in hospitalizations and mortality of patients with pneumonia, 2003–2009. Journal of the American Medical Association. Apr 4 2012;307(13):1405–1413.

[95] Rothberg MB, Pekow PS, Priya A, Lindenauer PK. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. Annals of Internal Medicine. Mar 18 2014;160(6):380–388.

Report (available at: *http://www.qualityforum.org/map/*).[96]

In the proposed rule we stated that with regard to MAP stakeholder concerns that the proposed PN Payment measure may need to be adjusted for SDS, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status, because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

[96] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/*.

The refined PN Payment measure will be submitted to NQF for reendorsement as part of the next Cost and Resource Use project which is expected in the first quarter of 2017. We will work to minimize any potential confusion when publicly reporting the updated measure to ensure that the refined measure would not be confused with the originally adopted measure.

We received general comments related to the efforts underway to determine if risk-adjusting for SDS factors is appropriate for this and other measures in the Hospital IQR Program and would like to address them first.

Comment: Several commenters encouraged CMS to apply SDS factors to quality measures, noting that these factors impact patient outcomes. Further, the commenters stated that SDS factors should be included in quality measures' risk-adjustment models to ensure that hospitals are held accountable only for the factors under their control. In addition, commenters expressed the opinion that accountability programs should include risk adjustment for those SDS factors for which there is a conceptual relationship with outcomes or processes of care and empirical evidence of such an effect, for reasons unrelated to quality of care.

Commenters also indicated that failing to adjust quality measures for SDS factors can result in unintended consequences and can mislead patients, payers, and policymakers who would be otherwise oblivious to community factors that contribute to worsened patient outcomes. Commenters suggested that CMS provide more in depth information related to the current efforts underway to assess the impact of SDS factors on quality measures. Some commenters noted that risk adjustment is of particular importance for measures that are not entirely within the control of the hospital such as resource use, readmissions, and 30-day mortality. However, some commenters stated that measures that are within the control of a hospital stay (that is, process measures) should not be subject to this type of risk adjustment.

One commenter believed that adjusting quality metrics in this way could result in a tiered health care system where consumers could not expect to receive the same quality of care regardless of where they live. A few commenters supported the concept of exploring the implications of risk-adjusting quality measures for SDS factors in the future, but requested that CMS work more readily to account for hospitals that disproportionately treat low-income and more vulnerable patient populations. In addition, the commenters expressed concern about the challenges associated with the feasibility of valid and reliable adjustment for SDS factors and noted that risk adjustment should not be used as an excuse for poor performance or a reason not to improve. The commenters expressed appreciation that CMS is abreast of the efforts underway by NQF and ASPE, but urged CMS to be more proactive with its own efforts to examine SDS factors in quality measures.

Response: With respect to commenters' request that CMS work more readily to account for hospitals that disproportionately treat vulnerable patient populations and concerns about the challenges associated with the feasibility of valid and reliable adjustment for SDS factors, as noted above and in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25208), we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status, because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of SDS on providers' differential performance on our outcome and payment measures.

In response to commenters' suggestion that CMS provide more in depth information related to the current efforts underway to assess the impact of SDS factors on quality measures, as discussed above, the NQF is currently conducting a 2-year trial, in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF is expected to issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. Under the guidance of NQF, we are making every effort to be proactive in examining SDS factors in quality measures by testing SDS factors in the measures' risk models and making recommendations about whether or not to include these factors in the endorsed measure. We are still awaiting final

recommendations from the NQF and intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for SDS factors in our outcome measures. For more detailed information about measures in the NQF SDS trial period, we refer commenters to: *http://www.qualityforum.org/SES_Trial_Period.aspx*. Furthermore, we are awaiting the findings of an ASPE report on SDS factors in risk-adjustment, which is expected to be available in the fall of 2016. We will share the findings of these trials and reports with the public as soon as they become available. Therefore, we are not currently changing our risk-adjustment methodology with respect to SDS factors. We will continue to consider such factors in our ongoing measure development and maintenance activities.

Comment: One commenter expressed concern that the newly proposed measures are not risk-adjusted for SDS factors, noting that they serve a patient population that is affected by these factors, and without risk adjustment, their hospital will be unfairly penalized under the current program. Commenters also encouraged CMS to adjust readmission measures for SDS factors because hospitals that care for vulnerable populations, who are at higher risk for readmissions, are disadvantaged when these factors are not considered for payment updates.

Response: We appreciate the commenter's concern that newly proposed measures are not risk-adjusted for SDS factors, but we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status, because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. Moreover, we do not think it is appropriate to include risk-adjustment for SDS factors at this time until more information is learned from the NQF trial period and ASPE's report. However, we will continue to consider such factors in our ongoing measure development and maintenance activities.

With regard to the commenters' concerns about being unfairly penalized or disadvantaged with regard to payment updates, we note that the Hospital IQR Program is a pay for reporting, not a pay for performance, quality program. This means that its payment determinations are based on hospitals meeting all of the reporting requirements, not performance on the measures, and that claims-based measures, such as the newly proposed measures and the existing readmission measures, have no additional reporting burden for hospitals since the data are derived from administrative data.

Comment: One commenter urged CMS not to add any proposed measure until it is appropriately risk adjusted and should suspend or remove other readmission measures until they incorporate appropriate risk-adjustment methodology because SDS factors can skew performance on certain quality measures, such as those for readmissions. The commenter stated that outcome measures do not accurately reflect hospitals' performance if they do not account for SDS factors outside the hospital's control that can complicate care and influence patients' health care outcomes.

Response: We disagree with the commenter that we should not propose any measure until it is risk adjusted for SDS factors. As we have previously noted, we have not risk-adjusted measures for SDS factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. However, as noted in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25208), while we are monitoring providers' differential performance on our outcome and payment measures, we are not currently changing our risk-adjustment methodology with respect to SDS factors. We will continue to consider such factors in our ongoing measure development and maintenance activities.

(2) Overview of Measure Change

The proposed measure refinement expands the cohort. As the measure is currently specified, the cohort includes hospitalizations for patients with a principal discharge diagnosis of pneumonia using the ICD–9–CM, which includes viral and bacterial pneumonia (79 FR 50227 through 50231). This refinement would expand the cohort to also include hospitalizations for patients with a: (1) Principal discharge diagnosis of pneumonia, including not only viral or bacterial pneumonia, but also aspiration pneumonia; and (2) principal discharge diagnosis of sepsis (but not severe sepsis) with a secondary diagnosis of pneumonia (including viral or bacterial pneumonia and aspiration pneumonia) coded as POA.

For the ICD–9–CM and ICD–10–CM codes that define the expanded PN Payment cohort, we refer readers to the 2016 Reevaluation and Re-specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment Measure- Pneumonia Payment Version 3.1 in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

The data sources, exclusion criteria, assessment of the total payment outcome, and 3 year reporting period all remain unchanged.

(3) Risk Adjustment

The statistical modeling approach as well as the measure calculation remains unchanged from the previously adopted measure. The risk adjustment approach also remains unchanged. However, to maintain model performance, we conducted variable reselection, or reevaluation of the variables used, to ensure the model risk variables are appropriate for the discharge diagnoses included in the expanded cohort.

The previously adopted pneumonia payment risk-adjustment model includes 48 variables.[97] As a result of the variable reselection process, the revised risk-adjustment model includes a total of 57 variables—37 of the same variables that are in the previously adopted model as well as 20 additional variables. There are 11 variables from the previously adopted model that are not included in the revised model. For details on variable reselection and the full measure specifications of the proposed change to the measure, we refer readers to the 2016 Reevaluation and Re-specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment Measure—Pneumonia Payment Version 3.1 in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(4) Estimated Effects of the Cohort Expansion

Using administrative claims data for the FY 2016 payment determination (which included discharges between July 2011 and June 2014), we simulated and analyzed the effects of the proposed cohort refinements on the PN Payment measure (NQF #2579) as if these

[97] Kim N, Ott L, Hsieh A, et al. 2015 Condition-Specific Measure Updates and Specifications Report, Hospital-Level 30-Day Risk-Standardized Payment Measures—Acute Myocardial Infarction (Version 4.0), Heart Failure (Version 2.0), Pneumonia (Version 2.0). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. Accessed Date: March 16, 2016.

changes had been applied for FY 2016 payment determination. We note that these statistics are for illustrative purposes only, and we did not propose to revise measure calculations for the FY 2016 payment determination.

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43881), we established that if a hospital has fewer than 25 eligible cases combined over a measure's reporting period, we would replace the hospital's data with a footnote indicating that the number of cases is too small to reliably determine how well the hospital is performing. These cases are still used to calculate the measure; however, for hospitals with fewer than 25 eligible cases, the hospital's Risk Standardization Payment (RSP) and RSP interval estimates are not publicly reported for the measure. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 24588) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. Expanding the measure cohort to include a broader population of patients as proposed would add a large number of patients, as well as additional hospitals (which would now meet the minimum threshold of 25 eligible cases for public display), to the PN Payment measure (NQF #2579). The increase in the size of the measure cohort as proposed is also estimated to change results for some hospitals as detailed below.

The previously adopted PN Payment measure cohort includes 901,764 patients and 4,685 hospitals for the FY 2016 payment determination (administrative claims from July 2011-June 2014). We noted the following effects for the PN Payment measure if the proposed expanded cohort is applied for FY 2016 payment determinations: (1) The cohort would increase to include an additional 386,143 patients across all hospitals (creating a total measure cohort size of 1,287,907 patients); (2) an additional 81 hospitals would meet the minimum 25 patient case volume threshold over the 3-year reporting period and, as a result, would be publicly reported for the measure; and (3) 31.7 percent of the refined measure cohort would consist of patients who fall into the expanded set of hospitalizations.

The expansion of the cohort leads to an overall increase in the mean national payment of $16,116 when compared to the mean national payment of $14,294 for the previously adopted cohort. This leads to an increase in the RSP outcome of $1,822 or 12.7 percent due to the higher mean payments for patients added to the cohort. An individual hospital's average payment category or reclassification of outlier status of ''higher than the U.S. national payment,'' ''no different than the U.S. national payment,'' or ''less than the U.S. national payment'' may change as demonstrated in the 2016 Reevaluation and Re-specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment measure—Pneumonia Payment Version 3.1, which can be found in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Overall, we estimate that 1.4 percent of hospitals included in the previously adopted measure would change categorization from greater than average to average payment, 9.3 percent would change from average to greater than average payment, and 8.5 percent would change from average to less than average payment. Finally, 1.8 percent of hospitals would change from less than average to average payment. Therefore, there would be an increase in the number of hospitals considered outliers and a shift in some hospitals' outlier status classification. We reiterate that these statistics are for illustrative purposes only, and we did not propose to revise measure calculations for the FY 2016 payment determination; our proposal would affect the FY 2018 payment determination and subsequent years.

A detailed description of the refinements to the PN Payment measure (NQF #2579) and the estimated effects of the change are available in the 2016 Reevaluation and Re-specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment Measure—Pneumonia Payment Version 3.1 in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

We invited public comment on our proposal to refine the Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia (NQF #2579) (PN Payment) measure for the FY 2018 payment determination and subsequent years as described above.

Comment: Some commenters supported the proposed expansion of the cohort definition for the PN Payment measure. Commenters noted the proposed measure refinement accommodates differences in coding patterns and aligns the measure cohort and specifications for the pneumonia population across the payment, readmission, and mortality outcome measures, which will mitigate measurement bias. Further, commenters noted that this measure would align the PN Payment measure with the other pneumonia measures used in CMS hospital quality programs. One commenter mentioned it would align the Hospital IQR Program with the Hospital VBP Program.

Response: We thank the commenters for their support. We note that the PN Payment measure is not currently included in the Hospital VBP Program, but we will take feedback on the PN Payment measure for the Hospital VBP Program into consideration for the future.

Comment: Several commenters urged CMS not to finalize the inclusion of the revised Pneumonia Payment measure in the Hospital IQR Program until the updated version has attained NQF endorsement.

Response: We acknowledge stakeholder concerns that these refinements to the PN Payment measure have not yet been endorsed by NQF, but we refer readers to our earlier discussion in section VIII.A.6.a.(1) of the preamble of this final rule that the MAP conditionally supported this refined measure during the 2016 MAP Hospital Workgroup Meeting pending NQF review of the examination of SDS factors and NQF review and endorsement of the measure update. The refined PN Payment measure will be submitted to NQF as part of the next Cost and Resource Use project which is expected to convene in the first quarter of 2017. The original hospital-level, risk-standardized payment associated with a 30-day episode-of-care for pneumonia (NQF #2579) measure was previously NQF-endorsed, and we do not believe the intent of this measure has changed.

Comment: A commenter encouraged CMS to properly risk adjust this measure for SDS factors so that hospitals that serve complex patients do not perform poorly.

Response: We appreciate the commenter's concern that this measure be risk-adjusted so that hospitals that serve complex populations do not perform poorly, but we continue to have concerns about holding hospitals to different standards for the outcomes of

their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. Moreover, as described above, we do not think it is appropriate to include risk-adjustment for SDS factors at this time until more information is learned from the NQF trial period and ASPE's report. However, we will continue to consider such factors in our ongoing measure development and maintenance activities.

Comment: Several commenters did not support the inclusion of aspiration pneumonia in the cohort. One commenter stated that the expansion of the measure cohort would capture relatively different cohorts of patients (particularly those with aspiration pneumonia), with different baseline factors that influence recovery times and could impact hospitals' performance on this measure. Commenters noted aspiration pneumonia patients overall are a more complex population with higher mortality rates, and aspiration pneumonia could be attributable to a range of potential causes that are clinically distinct despite the coding variation issue.

Response: We appreciate the commenters' concerns about the extent of the refinement of this measure and the inclusion of patients who are more complex (have greater illness severity). In particular, we understand commenters' concerns that aspiration pneumonia can have different causes and associated risks (for example, recurrent aspiration due to other comorbidities). However, while the pathological causes of aspiration pneumonia are slightly different from the causes of community acquired pneumonia, in routine clinical practice, evidence shows it can be very challenging for physicians to differentiate aspiration syndromes including pneumonitis and pneumonia, from other types of pneumonia included in the measure.[98] [99] This is reflected in the tremendous variation across hospitals in the use of aspiration pneumonia diagnosis codes. This variation suggests that hospitals are not consistently distinguishing between these conditions as distinct subtypes regardless of patients' comorbid conditions. Expanding the measure cohort would ensure that the measure is clinically comprehensive.

Moreover, the treatment of patients hospitalized for pneumonia, aspiration pneumonia, or sepsis due to pneumonia is very similar and involves treatment with antibiotics, IV fluids, and symptom management.[100] In addition, although some patients with aspiration pneumonia, such as medically frail patients, have a higher predicted mortality risk (that is, are more complex), many of the associated comorbidities are captured in the PN Payment measure's risk-adjustment methodology. Of note, due to the increased number of patients that are included in the expanded cohort, we reselected risk-adjustment variables to ensure that the measure does not bias hospital performance and it accounts for the differences in risk among the subgroup of patients. For example, the risk model includes clinical history of stroke, as well as conditions associated with frailty, such as neuromuscular disease, and dementia.

Comment: One commenter indicated that the impact of the cohort expansion on the other pneumonia measures remains unknown, as data is not yet publicly available on Hospital Compare.

Response: The expansion of the cohort for the PN Payment measure aligns this measure with the MORT–30–PN measure, READM–30–PN measure, and the newly adopted PN Excess Days measure. The cohort expansion for the CMS Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) and the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization measure were finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660), and are expected to be publicly reported on *Hospital Compare* beginning in 2016.

The 2016 measure results show that the mean RSMR for the MORT–30–PN measure decreased from 16.3 percent for July 2013–June 2014 to 15.9 percent for July 2014–June 2015. The mean RSMR for READ–30–PN measure decreased from 16.5 percent for July 2013–June 2014 to 16.4 percent for July 2014–June 2015.[101] Additional information on the impact of the cohort change on the measures, including measure results, assessments of the revised model, and the impact of the cohort change on the categorization of hospital performance, can be found in the 2015 Reevaluation and Re-Specification Report of the Hospital-Level 30-Day Risk-Standardized Measures Following Hospitalization for Pneumonia—Version 8.2 (readmission) and 9.2 (mortality) (available in the AMI–HF–PN–COPD-and-Stroke-Readmission Updates zip file at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*). In addition, measure specifications can be found in the 2016 Condition-Specific Measures Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Mortality Measures—Pneumonia Mortality Version 10.0 (available in the AMI–HF–PN–COPD-and-Stroke-Mortality Updates zip file) and the 2016 Condition-Specific Measures Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Readmission Measures—Pneumonia Readmission Version 9.0 (available in the AMI–HF–PN–COPD-and-Stroke-Readmission Updates zip file) on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. Finally we note that, as established in the Hospital IQR Program, hospitals have the opportunity to review their data, including their performance on the refined versions of the measures, via their hospital-specific reports (HSRs) during the preview period before public reporting of the measures.

Comment: One commenter expressed concern regarding the significant overlap between the PN Payment measure and Medicare Spending per Beneficiary (MSPB) measure. The commenter acknowledged the potential to create alignment with the physician value-modifier and later merit-based incentive payment system; however, the commenter indicated that there is still a significant need for better alignment between the hospital and physician specifications.

Response: The goal of the PN Payment measure is to complement other quality measures already adopted to provide more holistic and comprehensive information on the value of care provided for the pneumonia condition specifically, while the MSPB measure solely examines total Medicare spending per beneficiary and encompasses all conditions. The PN Payment measure is meant to be considered in conjunction with MORT–30–PN, READM–30–PN, and the newly

[98] Lanspa MJ, Jones BE, Brown SM, Dean NC. Mortality, morbidity, and disease severity of patients with aspiration pneumonia. J Hosp Med. 2013 Feb;8(2):83–90. doi: 10.1002/jhm.1996. Epub 2012 Nov 26.

[99] Marik PE. Aspiration pneumonitis and aspiration pneumonia. N Engl J Med. 2001 Mar 1;344(9):665–71.

[100] Ibid.

[101] Dorsey K, Grady J, et al. *2016 Condition-Specific Measures Updates and Specifications Report, Hospital-Level 30-Day Risk-Standardized Mortality Measures.* 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

adopted PN Excess Days measures in order to gain a better understanding of the value of care for a hospital's patients and the nation as a whole. Moreover, several commenters conveyed support and appreciation for the reporting of the PN Payment measure in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50229), noting that it provided a way to optimally measure care for these patients. Therefore, we believe that the PN Payment measure provides condition-specific feedback to hospitals and can incentivize targeted improvements in care for pneumonia patients.

Lastly, we acknowledge commenters request for better alignment between the hospital and physician specifications. We strive to align specifications across programs when feasible; however, some specifications will remain different to accommodate for the distinctions between quality care programs that focus on hospitals (for example, the Hospital IQR Program) versus eligible professionals (for example, the Physician Value-Based Payment Modifier Program).

After consideration of the public comments we received, we are finalizing the refinement of the Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia (NQF #2579) (PN Payment) measure for the FY 2018 payment determination and subsequent years as proposed.

b. Adoption of Modified PSI 90: Patient Safety and Adverse Events Composite Measure (NQF #0531)

(1) Background

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25182 through 25285), we proposed to adopt refinements to the Agency for Healthcare Research and Quality (AHRQ) Patient Safety and Adverse Events Composite (NQF #0531) for the Hospital IQR Program beginning with the FY 2018 payment determination and subsequent years. In summary, the PSI 90 measure was refined to reflect the relative importance and harm associated with each component indicator to provide a more reliable and valid signal of patient safety events. We believe refining the PSI 90 measure will provide strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, a critical consideration in quality improvement.

In the FY 2009 IPPS/LTCH PPS final rule (73 FR 48607 through 48610), we adopted the Complication/Patient Safety for Selected Indicators Composite Measure (NQF #0531) in the Hospital IQR Program beginning with the FY 2010 payment determination as an important measure of patient safety and adverse events. In the FY 2015 IPPS/LTCH PPS final rule, we updated the title of the measure to Patient Safety for Selected Indicators Composite Measure (NQF #0531), to be consistent with the NQF (79 FR 50211). As previously adopted, the PSI 90 measure consisted of eight component indicators: (1) PSI 03 Pressure Ulcer Rate; (2) PSI 06 Iatrogenic Pneumothorax Rate; (3) PSI 07 Central Venous Catheter-Related Blood Stream Infections Rate; (4) PSI 08 Postoperative Hip Fracture Rate; (5) PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate; (6) PSI 13 Postoperative Sepsis Rate; (7) PSI 14 Postoperative Wound Dehiscence Rate; and (8) PSI 15 Accidental Puncture and Laceration Rate.[102]

The currently adopted eight-indicator version of the measure underwent an extended NQF maintenance reendorsement in the 2014 NQF Patient Safety Committee due to concerns with the underlying component indicators and their composite weights. In the NQF-Endorsed Measures for Patient Safety, Final Report,[103] the NQF Patient Safety Committee deferred their final decision for the PSI 90 measure until the following measure evaluation cycle. In the meantime, AHRQ worked to address many of the NQF stakeholders' concerns about the PSI 90 measure, which subsequently completed NQF maintenance re-review and received reendorsement on December 10, 2015.

The PSI 90 measure's extended NQF reendorsement led to several changes to the measure.[104] First, the name of the PSI 90 measure has changed to ''Patient Safety and Adverse Events Composite'' (NQF #0531) (herein referred to as the ''modified PSI 90''). Second, the modified PSI 90 measure includes the addition of three indicators: (1) PSI 09 Perioperative Hemorrhage or Hematoma Rate ; (2) PSI 10 Postoperative Acute Kidney Injury Requiring Dialysis Rate (formerly titled ''Physiologic and Metabolic Derangement Rate''); and (3) PSI 11 Postoperative Respiratory Failure Rate. Third, PSI 12, Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate, and PSI 15, Unrecognized Abdominopelvic Accidental Puncture/Laceration Rate, have been respecified in the modified PSI 90 measure. Fourth, PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate has been removed in the modified PSI 90 measure. Fifth, the weighting of component indicators in the modified PSI 90 measure is based not only on the volume of each of the patient safety and adverse events, but also the harms associated with the events. We consider these changes to the modified PSI 90 measure to be substantive changes to the measure. Therefore, we proposed to adopt refinements to the PSI 90 measure for the Hospital IQR Program beginning with the FY 2018 payment determination and subsequent years. We explain the modified PSI 90 measure more fully below, and also refer readers to the measure description on the NQF Web site at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3*. We also proposed to modify the reporting periods for FYs 2018 and 2019 payment determinations and subsequent years as detailed further below.

We note that the proposed modified PSI 90 measure (MUC ID 15–604) was included on a publicly available document entitled 2015 Measures Under Consideration for December 1, 2015 [105] in compliance with section 1890A(a)(2) of the Act, and was reviewed by the MAP. The MAP supported this measure stating that, ''the PSI measures were developed to identify harmful healthcare related events that are potentially preventable. Three additional PSIs have been added to this updated version of the measure. PSIs were better linked to important changes in clinical status with 'harm weights' that are based on diagnoses that were assigned after the complication. This is intended to allow the measure to more accurately reflect the impact of the events.'' [106] The measure received support for inclusion in the Hospital IQR Program as referenced in the MAP Final Recommendations Report.[107]

(2) Overview of the Measure Changes

First, the name of the PSI 90 measure has changed from the ''Patient Safety for

[102] NQF-Endorsed Measures for Patient Safety, Final Report. Available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx*.

[103] NQF-Endorsed Measures for Patient Safety, Final Report available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx*.

[104] National Quality Forum QPS Measure Description for ''Patient Safety for Selected Indicators (modified version of PSI90) (Composite measure)'' found at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3*.

[105] 2015 Measures Under Consideration List Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[106] MAP Final Recommendations. Available at: *http://www.qualityforum.org/map/*.

[107] MAP Final Recommendations. Available at: *http://www.qualityforum.org/map/*.

Selected Indicators Composite Measure'' to the ''Patient Safety and Adverse Events Composite'' (NQF #0531) to more accurately capture the indicators included in the measure.

Second, the PSI 90 measure has expanded from eight to 10 component indicators. The modified PSI 90 measure is a weighted average of the following 10 risk-adjusted and reliability-adjusted individual component PSI rates:

- PSI 03 Pressure Ulcer Rate;
- PSI 06 Iatrogenic Pneumothorax Rate;
- PSI 08 In-Hospital Fall With Hip Fracture Rate; [108]
- PSI 09 Perioperative Hemorrhage or Hematoma Rate; *
- PSI 10 Postoperative Acute Kidney Injury Requiring Dialysis Rate; *[109]
- PSI 11 Postoperative Respiratory Failure Rate; *
- PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate;
- PSI 13 Postoperative Sepsis Rate;
- PSI 14 Postoperative Wound Dehiscence Rate; and
- PSI 15 Unrecognized Abdominopelvic Accidental Puncture/ Laceration Rate.[110] [111]

(* Denotes new component for the modified PSI 90 measure)

As stated above, the modified PSI 90 measure also removed PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate, because of potential overlap with the CLABSI measure (NQF #0139), which has been included in the Hospital IQR Program since the FY 2011 IPPS/LTCH PPS final rule (75 FR 50201 through 50202), the HAC Reduction Program since the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), and the Hospital VBP Program since the FY 2013 IPPS/LTCH PPS final rule (77 FR 53597 through 53598).

In response to stakeholder concerns, highlighted in the NQF 2014 Patient Safety Report,[112] the modified PSI 90 measure also respecified two component indicators, PSI 12 and PSI 15. Specifically, for PSI 12 Perioperative PE or DVT Rate, the NQF received public comments concerning the inclusion of: (1) Extracorporeal membrane oxygenation (ECMO) procedures in the denominator; and (2) intra-hospital variability in the documentation of calf vein thrombosis (which has uncertain clinical significance). Therefore, the modified PSI 12 component indicator no longer includes ECMO procedures in the denominator or isolated deep vein thrombosis of the calf veins in the numerator. PSI 15 Unrecognized Abdominopelvic Accidental Puncture/ Laceration Rate, was also respecified to focus on the most serious intraoperative injuries—those that were unrecognized until they required a subsequent reparative procedure. The modified denominator of PSI 15 now is limited to discharges with an abdominal/pelvic operation, rather than including all medical and surgical discharges. In addition, to identify events that are more likely to be clinically significant and preventable, the PSI 15 numerator was modified to require both: (1) A diagnosis of an accidental puncture and/or laceration; and (2) an abdominal/ pelvic reoperation one or more days after the index surgery. Based on these new specifications, the PSI 15 indicator name has been changed as note above.

Finally, the NQF Patient Safety Review Committee raised concerns about the weighting scheme of the component indicators. In prior versions of the measure, the weights of each component PSI were based solely on volume (numerator rates). In the modified PSI 90 measure, the rates of each component PSI are weighted based on statistical and empirical analyses of volume, excess clinical harm associated with the PSI, and disutility (individual preference for a health state linked to a harm, such as death or disability). The final weight for each component indicator is the product of harm weights and volume weights (numerator weights). Harm weights are calculated by multiplying empirical estimates of excess harms associated with the patient safety event by the utility weights linked to each of the harms. Excess harms are estimated using statistical models comparing patients with a safety event to those without a safety event in a Medicare fee-for-service sample. Volume weights are calculated based on the number of safety events for the component indicators in an all-payer reference population. For more information on the modified PSI 90 measure and component indicators, we refer readers to Quality Indicator Empirical Methods available online at: *www.qualityindicators.ahrq.gov*.

(3) Risk Adjustment

The risk adjustment and statistical modeling approaches of the models remain unchanged in the modified PSI 90 measure. In summary, the predicted value for each case is computed using a modeling approach that includes, but is not limited to, applying a Generalized Estimating Equation (GEE) hierarchical model (logistic regression with hospital random effect) and covariates for gender, age, Modified MS–DRG (MDRG), Major Diagnostic Category, transfer in, point of origin not available, procedure days not available, and AHRQ comorbidity (COMORB).

The expected rate for each of the indicators is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (that is, the hospital). The risk-adjusted rate for each of the indicators is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate. For more details about risk adjustment, we refer readers to: *http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf*. As stated above, we did not propose any changes to the risk adjustment for this measure.

(4) Reporting Periods

The PSI 90 measure is a claims-based measure that has been calculated using 24-months of data. For the FY 2018 and FY 2019 payment determinations, measure rates would be calculated using reporting periods of July 1, 2014 through June 30, 2016 and July 1, 2015 through June 30, 2017, respectively. However, because hospitals began ICD–10–CM/PCS implementation on October 1, 2015, these reporting periods for the FY 2018 and FY 2019 payment determinations would require using both ICD–9 and ICD–10 claims data to calculate measure performance.

Since the ICD–10 transition was implemented on October 1, 2015, we have been monitoring our systems, and claims continue to be processed normally. The measure steward, AHRQ, has been reviewing the measure for any potential issues related to the conversion of approximately 70,000 ICD–10 coded operating room procedures [113] (*https://www.cms.gov/icd10manual/fullcode_cms/P1616.html*), which could directly affect the modified PSI 90 component

[108] Previously titled ''Postoperative Hip Fracture'' prior to v6.0.

[109] Previously titled ''Postoperative Physiologic and Metabolic Derangement'' prior to v6.0.

[110] Previously titled ''Accidental Puncture or Laceration Rate'' prior to v6.0.

[111] *http://www.qualityforum.org/QPS/0531*.

[112] NQF Endorsed Measures for Patient Safety, Final Report. Available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx*.

[113] International Classification of Diseases, (ICD–10–CM/PCS) Transition—Background. Available at: *http://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm*.

indicators. In addition, to meet program requirements and implementation schedules, our system would require an ICD–10 risk-adjusted version of the AHRQ QI PSI software [114] by December 2016 for the FY 2018 payment determination year. At this time, a risk adjusted ICD–10 version of the modified PSI 90 Patient Safety and Adverse Events Composite software is not expected to be available until late CY 2017.

To address the above issues, we proposed to modify the reporting periods for the FYs 2018 and 2019 payment determinations. For the FY 2018 payment determination, we proposed to use a 15-month reporting period spanning July 1, 2014 through September 30, 2015. The 15-month reporting period would only apply to the FY 2018 payment determination and would only use ICD–9 data. For the FY 2019 payment determination, we proposed to use a 21-month reporting period spanning October 1, 2015 through June 30, 2017. The 21-month reporting period would only apply to the FY 2019 payment determination and would only use ICD–10 data. For all subsequent payment determinations after FY 2019, we proposed to use the standard 24-month reporting period, which would only use ICD–10 data. In order to align the modified PSI 90 measure and the use of ICD–9 and ICD–10 data across CMS hospital quality programs, we proposed similar modifications for FYs 2018 and 2019 payment determinations in the HAC Reduction Program, as discussed in section IV.I.3.b. of the preamble of this final rule, and similar modifications to the performance period for the Hospital VBP Program FY 2018 program year, as discussed in section IV.H.2. of the preamble of this final rule.

Prior to deciding to propose abbreviated reporting periods for the FY 2018 and FY 2019 payment determinations, we took several factors into consideration, including the recommendations of the measure steward, the feasibility of using a combination of ICD–9 and ICD–10 data without the availability of the appropriate measure software, minimizing provider burden, program implementation timelines, and the reliability of using shortened reporting periods, as well as the importance of continuing to publicly report this measure. We believe that using a 15-month reporting period for the FY 2018 payment determination and a 21-month reporting period for the FY 2019 payment determination best serves the need to provide important information on hospital patient safety and adverse events by allowing sufficient time to process the claims data and calculate the measures, while minimizing reporting burden and program disruption. We will continue to test ICD–10 data that are submitted in order to ensure the accuracy of measure calculations, to monitor and assess the translation of measure specifications to ICD–10 as well as potential coding variation, and to assess any impacts on measure performance.

We note that a prior reliability analysis of the PSI 90 measure (not the modified PSI 90 measure) showed that the majority of hospitals attain a moderate or high level of reliability after a 12-month reporting period.[115] Although the modified PSI 90 measure has undergone substantial changes since this analysis, we believe that measure scores would continue to be reliable for the above proposed reporting periods, because the NQF, which reendorsed the modified version, found it to be reliable using 12 months of data.[116] In establishing the revised reporting periods for the modified PSI 90 measure, we also relied upon an analysis by Mathematica Policy Research (MPR), a CMS contractor, which found that the measure was most reliable with a 24-month reporting period and unreliable with a reporting period of less than 12 months.[117] While not discussed in the proposed rule, we would like to elaborate on the reliability of the shortened reporting period. We took into account that the findings in the MPR analysis are based on older data (7 months of data from March 2010–September 2010), which do not reflect changes to current inter-hospital variation over time due to quality improvements. The findings also simulate results over a 2 year period based on 7 months of data; and use an older version of the PSIs (analysis uses v4.2; NQF-endorsed uses v6.0) that does not include improvements in POA coding, a composite with 10 component indicators with a revised weighting scheme or refinements to the component indicators. Therefore, we believe that the proposed abbreviated reporting periods for the modified PSI 90 measure would produce reliable data because the reporting periods are still greater than 12 months.

(5) Adoption of the Modified PSI 90 Measure

In summary, the PSI 90 measure was revised to reflect the relative importance and harm associated with each component indicator to provide a more reliable and valid signal of patient safety events. We believe that adopting the modified PSI 90 measure would continue to provide strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, which is a critical consideration in quality improvement.

We invited public comment on our proposal to adopt the modified PSI 90 measure (NQF #0531) for the Hospital IQR Program beginning with the FY 2018 payment determination. We will continue to use the currently adopted eight-indicator version of the PSI 90 measure in the Hospital IQR Program for the FY 2017 payment determination. We also invited public comment on the proposals to revise the reporting periods for this measure as described above: (1) A 15-month reporting period using only ICD–9 data for the FY 2018 payment determination; (2) a 21-month reporting period using only ICD–10 data for the FY 2019 payment determination; and (3) a 24-month reporting period using only ICD–10 data for the FY 2020 payment determination and subsequent years.

Comment: Several commenters supported the proposed adoption of the modified PSI 90, including the additional PSI components, the removal of PSI components, and the updated weighting convention. Specifically, commenters expressed support for the removal of PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate from the measure because the removal of this indicator eliminates potential overlap with the CLABSI measure (NQF #0139). Commenters also specifically supported the inclusion of PSI 09 Perioperative Hemorrhage or Hematoma Rate and the refinements to the definition of PSI 15 Unrecognized Abdominopelvic Accidental Puncture/ Laceration Rate. Commenters believed that changing the weighting factors that assess harm adds value to the measure. In addition, commenters agreed that mixing ICD–9 and ICD–10 data would

[114] The AHRQ QI Software is the software used to calculate PSIs and the composite measure. More information is available at: *http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf.*

[115] Mathematica Policy Research (November 2011). Reporting period and reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf.*

[116] ''Patient Safety 2015 Final Report'' is available at: *http://www.qualityforum.org/Publications/2016/02/Patient_Safety_2015_Final_Report.aspx.*

[117] Mathematica Policy Research (November 2011). Reporting period and reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised. Available at: *http://www.cms.gov/Medicare/*Quality-Initiatives-Patient-Assessment Instruments/hospital-value-based purchasing/Downloads/HVBP_Measure_Reliability-.pdf.

not be favorable for this measure. One commenter supported the proposal to shorten the PSI 90 measure reporting period to account for the transition from ICD–9–CM to ICD–10–CM/PCS. Finally, commenters noted that the inclusion of this modified measure would help align with other hospital quality programs.

Response: We appreciate the commenters' support of the adoption of the modified PSI 90.

Comment: Some commenters suggested adding an exclusion criterion for PSI 12 Perioperative PE or DVT Rate for any patient who has a tracheostomy because it is not the surgery that places the patient at risk for PE or DVT, rather it is the medical problem that leads to tracheostomy that places the patient at increased risk for PE or DVT.

Response: We agree that some medical conditions, which lead to a tracheostomy,[118] may also increase patients' risk for PE or DVT. However, we do not believe that just because a patient has a tracheostomy they are at increased risk for PE or DVT and should be excluded. We note that most of the medical conditions that can lead to tracheostomy are already captured by the extensive set of risk factor variables used in the risk adjustment for PSI 12. For more information on the PSI 12 risk model, we refer readers to: *http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V50/Parameter_Estimates_PSI_50.pdf*. Further suggestions regarding potential PSI measure revisions can be made directly to: *QIsupport@ahrq.hhs.gov*.

Comment: A few commenters encouraged CMS to work with AHRQ to update the software required for monitoring PSI 90 measure performance to account for the conversion to ICD–10–CM/PCS coding. Commenters also expressed concern that the transition to ICD–10–CM/PCS codes has caused inaccuracies in PSI reporting and evaluation. The commenters also noted that some minor procedures are now being categorized as surgical and some organizations are not reporting these minor procedures. Commenters noted that PSI 90 is critical in pay-for-performance programs, thus it is imperative that hospitals are able to monitor performance in an ongoing manner.

Response: We applaud the commenters' commitment to continuous monitoring of performance. We understand that it is imperative for hospitals to monitor performance in an ongoing manner and are working with AHRQ to have the risk-adjusted software available as soon as possible. We note that one of the factors in our decision to delay the use of ICD–10 claims data until FY 2019 was to allow for the necessary one year of ICD–10 data collection required for AHRQ to create a risk adjusted software version. For more information on the release plan for ICD–10 risk adjusted software, we refer commenters to the AHRQ Quality Indicators Software page available at: *http://www.qualityindicators.ahrq.gov/Software/Default.aspx*.

While we acknowledge commenters concerns that the transition to ICD–10–CM/PCS codes has caused inaccuracies in PSI reporting and evaluation, there is no evidence of which we are aware that supports this assertion. However, we are actively monitoring for any potential issues related to ICD–10 conversion. We note that all measure specifications have been translated to and updated for corresponding ICD–10 code specifications. AHRQ's changes for ICD–10–CM/PCS conversion of its patient safety indicators are available at: *http://www.qualityindicators.ahrq.gov/Modules/PSI_TechSpec_ICD10.aspx*.

Lastly, we interpret commenters' concerns regarding ''minor procedures'' to refer to non-operating room (OR) procedures. As noted in the Frequently Asked Questions about using AHRQ Quality Indicators (QIs), *www.qualityindicators.ahrq.gov/FAQs_Support/FAQ_QI.aspx*#, the denominators of the AHRQ Patient Safety Indicators (PSIs) use the list of major OR procedures that is developed and maintained by CMS (see draft ICD–10 MS–DRG v32 definitions, Appendix E, at: *https://www.cms.gov/ICD10Manual/version32-fullcode-cms/fullcode_cms/P0001.html*). We acknowledge that some procedures that were previously classified as a non-OR procedure in the ICD–9–CM MS–DRG list are currently classified as an OR procedure in the draft ICD–10 MS–DRG v28. AHRQ has addressed these discrepancies as they relate to the PSIs going forward. Further, in the mid-July 2016 release of v6.0 ICD–10–CM/PCS software, AHRQ refined the list of major OR procedures. We believe this refined list of major OR procedures provides clear guidance regarding classifying OR procedures and non-OR procedures to ensure accurate reporting by all organizations. AHRQ welcomes input from the user community on AHRQ QI ICD–10–CM/PCS v6.0. Please provide suggestions/comments directly to: *QISupport@ahrq.hhs.gov*.

Comment: Several commenters did not support the proposed adoption of the modified PSI 90 because of the susceptibility of PSI 12 Perioperative PE or DVT Rate to surveillance bias and lack of appropriate measure exclusions.

Response: CMS and AHRQ recognize the commenters' concerns about surveillance bias for PSI 12 Perioperative PE or DVT Rate and the issue was addressed in the NQF Patient Safety Steering Committee in 2015. Surveillance bias is a non-random type of systemic bias where a diagnosis is more likely to be observed the more vigilant one is in looking for it.[119] In the case of DVT or PE, hospitals may underdiagnose or over diagnose DVT or PE depending upon how often they screen or perform diagnostic testing to look for these diagnoses. Several research teams have examined DVT and PE rates and surveillance bias.[120] However, studies have not specifically examined whether the observed rates reflect underdiagnosis of DVT or PE at low-testing hospitals, over diagnosis of DVT or PE at high-testing hospitals, or the underlying true incidence of symptomatic DVT or PE. While some hospitals might hypothesize that increased surveillance is desirable, there is no evidence to support the hypothesis that ''increased vigilance in DVT or PE detection'' is desirable, from the perspective of patients and their families. Over diagnosis of DVT or PE among patients may lead to overtreatment, and overtreatment is not inconsequential as there are known adverse effects associated with treatment of DVT and PE. Thus, while we acknowledge commenter's concerns regarding surveillance bias, we believe that PSI 12 is an important component indicator of the modified PSI 90

[118] A tracheotomy or a tracheostomy is an opening surgically created through the neck into the trachea (windpipe) to allow direct access to the breathing tube and is commonly done in an operating room under general anesthesia. Definition obtained from *http://www.hopkinsmedicine.org/tracheostomy/about/what.html*.

[119] Haut ER, Pronovost PJ. Surveillance bias in outcomes reporting. JAMA. 2011 Jun 15;305(23):2462–3.

[120] Bilimoria KY, Chung J, Ju MH, et al. Evaluation of surveillance bias and the validity of the venous thromboembolism quality measure. JAMA. 2013;310(14):1482–1489; Holcomb CN, DeRussy A, Richman JS, Hawn MT. Association Between Inpatient Surveillance and Venous Thromboembolism Rates After Hospital Discharge. JAMA Surg. 2015;150(6):520–527; Ju MH, Chung JW, Kinnier CV, et al. Association between hospital imaging use and venous thromboembolism events rates based on clinical data. Ann Surg. 2014;260(3):558–566 and Pierce CA, Haut ER, Kardooni S, et al. Surveillance bias and deep vein thrombosis in the national trauma data bank: the more we look, the more we find. The Journal of Trauma. 2008;64(4):932–936; discussion 936–937. Haut ER, Chang DC, Pierce CA, et al. Predictors of posttraumatic deep vein thrombosis (DVT): hospital practice versus patient factors—an analysis of the National Trauma Data Bank (NTDB). The Journal of trauma. 2009;66(4):994–9.

measure, because it encourages hospitals not only to prevent DVT or PE, but also to appropriately assess a patient's risk for DVT and PE to prevent over diagnosis and underdiagnosis. Given the negative economic and health consequences associated with DVT or PE diagnosis, we believe that preventing underdiagnosis and over diagnosis is critical to improving patient safety.

Lastly, we disagree with commenter that PSI 12 Perioperative PE or DVT Rate lacks appropriate exclusions. Measure exclusions were reviewed by the NQF Patient Safety Steering Committee in 2015 and the measure was re-endorsed as reliable and valid. We note that AHRQ removed isolated thrombosis of calf veins (ICD–9–CM 453.42) from the version 6.0 specification reviewed by the NQF Patient Safety Steering Committee in 2015 in order to minimize the impact of clinically unimportant distal thromboses on hospital-specific PSI 12 rates. However, suggestions regarding potential PSI measure revisions can be made directly to: *QIsupport@ahrq.hhs.gov*.

Comment: Several commenters noted that the modifications to the PSI 90 measure do not address the many, well-documented concerns about the reliability of individual claims data elements or the validity of the PSIs. Commenters expressed the opinion that claims-based measures in general, and PSIs in particular, have not demonstrated that they are accurate, reliable, and valid indicators of quality and safety of care. Other commenters cautioned against the measure's use of claims data due to the composite structure because the composite lacks specific direction for prevention strategy focus. Commenters also expressed concern about the utility of the modified measure and its ability to provide actionable information to providers. Lastly, commenters expressed concern that the shortened reporting period will not produce reliable data on hospital performance. Due to the modifications made to the component PSIs and the new weighting scheme, commenters believed that the previous reliability results do not provide sufficient information on the reliability of the modified measure when a shortened 15-month reporting period is used.

Response: We disagree with commenters that claims-based measures in general, and PSIs in particular, have not demonstrated that they are accurate, reliable, and valid indicators of quality and safety of care. Regarding the administrative data elements of PSI 90, we note that there are previously conducted studies that validate the relationship between administrative claims data and medical records.[121] These studies demonstrate that administrative claims data can provide sufficient clinical information to assess patient safety. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50091) for a further discussion of this issue in the context of the HAC Reduction Program. Further, over the past decade, AHRQ has supported a series of validation studies based on detailed abstraction of medical records.[122] These studies informed AHRQ's PSI development process, including further refinements to indicators, working with others to improve coding practices, and retirement of a few indicators.

Furthermore, many of these claims-based indicators have been endorsed by the NQF, which includes a review process that assesses reliability and validity.[123] We note that NQF endorsed the modified PSI 90, including the risk-adjustment methodology of the component indicators, as reliable and valid (NQF #0531).[124] Further, we believe the modified PSI 90 does provide actionable information and specific direction for prevention of patient safety events, because hospitals can track and monitor individual PSI rates and develop targeted improvements to improve patient safety. For further guidance on PSI monitoring and strategies for applying quality improvements to PSI data, we refer readers to the Toolkit for Using the AHRQ quality indicators available at: *http://www.ahrq.gov/professionals/systems/hospital/qitoolkit/index.html*.

Lastly, while we acknowledge commenters' concerns that the previous reliability results may not provide sufficient information on the reliability of the modified measure for a shortened 15-month reporting period, we note that this reliability analysis does not include the modifications to the PSI 90, such as improvements in POA coding, refinements to the component indicators, or a composite with 10 component indicators with a revised weighting scheme. We believe these refinements and improvements enhance the reliability of the measure. Moreover, we note that the NQF found the modified PSI 90 to be reliable using specifically 12 months of data.[125] We continue to believe the modified PSI 90 measure is a scientifically rigorous measure that provides actionable feedback to hospitals to improve patient safety and quality of care.

Comment: One commenter expressed concern that PSI 09 Perioperative Hemorrhage or Hematoma Rate may apply to a number of transplant patients and recommended that transplantation should be added to the exclusion list a priori and requested that that liver transplant patients be excluded from the PSI 09 denominator. The commenter indicated that perioperative hemorrhage or hematoma is normal after liver transplant, and is frequent after kidney transplant, and the repercussions of these and other transplantation procedures are not indicative of poor quality care. The commenter further noted that liver transplants result in significant blood loss in nearly every case, and poor performance on this measure can be driven by the number of liver transplants performed.

One commenter expressed concern with the PSI 11 Postoperative Respiratory Failure Rate because acute respiratory failure, mechanical ventilation, and reintubation are fairly common for both liver and kidney procedures and do not suggest poor quality of care. This commenter stated that transplant surgeries have a high incidence of acute respiratory failure, mechanical ventilation, and reintubation meeting the specifications set forth in this measure, due to fluid shifts, medications, neurological status, and potential for infection involved in this complex surgery. Another commenter expressed concern that PSI

[121] (1) Zrelak PA, Romano PS, Tancredi DJ, Geppert JJ, Utter GH. Validity of the AHRQ Patient Safety Indicator for Postoperative Physiologic and Metabolic Derangement based on a national sample of medical records. Medical Care 2013; 51(9):806–11. (2) Utter GH, Zrelak PA, Baron R, Tancredi DJ, Sadeghi B, Geppert JJ, Romano PS. Detecting postoperative hemorrhage or hematoma from administrative data: The performance of the AHRQ Patient Safety Indicator. Surgery 2013; 154(5):1117–25. (3) Borzecki AM, Cevasco M, Chen Q, Shin M, Itani KM, Rosen AK. How valid is the AHRQ Patient Safety Indicator ''postoperative physiologic and metabolic derangement''? J Am Coll Surg. 2011 Jun;212(6):968–976. (4) Borzecki AM, Kaafarani H, Cevasco M, Hickson K, Macdonald S, Shin M, Itani KM, Rosen AK. How valid is the AHRQ Patient Safety Indicator ''postoperative hemorrhage or hematoma''? J Am Coll Surg. 2011 Jun;212(6):946–953.

[122] A list of all AHRQ validation studies is available at: *http://www.qualityindicators.ahrq.gov/Resources/Publications.aspx*.

[123] More information on the NQF endorsement process is available in the NQF Review and Update of Guidance for Evaluating Evidence and Measure Testing—Technical Report available at: *http://www.qualityforum.org/Publications/2013/10/Review_and_Update_of_Guidance_for_Evaluating_Evidence_and_Measure_Testing_-_Technical_Report.aspx*.

[124] Measure information is available at: *http://www.qualityforum.org/QPS/0531*.

[125] Modified_Version_of_PSI90_NQF0531_Composite_Measure_Testing_151022.pdf available in the Patient Safety for Selected Indicators (modified version of PSI90) zip file at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=77836*.

10 Postoperative Acute Kidney Injury Requiring Dialysis Rate is inappropriate for liver transplantation. The commenter stated that while the measure excludes patients with preoperative renal failure, many liver transplant patients with relatively normal baseline renal function get acute renal failure after transplant despite high quality care, due to hemodynamic factors and the nature of the drugs involved in the performance of the procedure and its aftermath. These commenters recommended that liver and kidney transplantation should be added to the exclusion list for this measure.

Response: We do not agree with the commenters that liver transplant patients should be excluded from the PSI 09, PSI 10, and PSI 11 denominators. While we appreciate one commenter's observation that transplant patients may have an elevated risk of hemorrhage or hematoma, we note that the risk-adjustment model for PSI 09 explicitly accounts for the increased risk associated with solid organ transplantation. For more information on the PSI 09 risk model, we refer readers to: *http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V50/Parameter_Estimates_PSI_50.pdf*.

Similarly, the risk-adjustment models for PSI 10 and PSI 11 explicitly account for the increased risk associated with hepatic failure and solid organ transplantation, respectively. For more information on the PSI 10 risk model, we refer readers to: *http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V50/Parameter_Estimates_PSI_50.pdf*.

Comment: One commenter expressed concern that changes in coagulation in the early postoperative period may lead to increased incidence of clotting disorders including Deep Vein Thrombosis (DVT) after transplant procedures and also may be caused by large bore IVs.[126] In addition, transplant patients often get products that promote clotting due to inherent coagulopathy, and some patients have clotting disorders that cause hypercoagulability. The commenter noted that this measure excludes surgeries involving interruption of the vena cava, and stated that all liver transplants involve such interruption. This commenter recommended that liver and kidney transplant be added to the exclusion list because DVT is not indicative of poor quality care for these procedures due to the frequency of DVT in transplantation.

Response: We appreciate commenter's observation that PSI 12 Perioperative PE or DVT Rate excludes cases where a procedure for interruption of the vena cava occurs before or on the same day of the first operating room procedure. Cases meeting this criterion should be excluded, because inferior vena cava (IVC) filter placement (which is by far the most common example of surgical interruption of the vena cava) is appropriate only for patients who cannot tolerate, or have already failed, conventional pharmacologic prophylaxis. IVC filters are placed in high-risk patients with the knowledge that they increase the risk of deep vein thrombosis distal to the device while decreasing the risk of embolization to the pulmonary circulation.

However, we disagree with commenter that liver and/or kidney transplants must be placed on the exclusion list, just because these patients may have clotting disorders that cause hypercoagulability, get products that promote clotting, or may have large bore IVs. We note that the risk-adjustment model for PSI 12 Perioperative PE or DVT Rate explicitly accounts for the increased risk of thrombosis (clotting) associated with solid organ transplantation. Risk adjustment accounts for differences in patient populations (transplant patients, etc.) to allow for comparisons across providers. For example, liver transplantation (MDRG 7702) is associated with an adjusted odds ratio of 3.2 in AHRQ's v5.0 risk model for PSI 12. PSI 12 is designed to improve surveillance prevention and awareness of perioperative DVT and pulmonary embolism. Because of the morbidity and mortality associated with these conditions, we continue to believe that PSI 12 is important to improving perioperative quality of care and patient safety. For more information on the PSI 12 risk model, we refer readers to: *http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V50/Parameter_Estimates_PSI_50.pdf*.

The measure steward, AHRQ, carefully considers all suggestions of this type, and will consult with clinical experts as the Patient Safety Indicators are updated in the future. Suggestions regarding potential PSI measure revisions can be made directly to: *QISupport@ahrq.hhs.gov*.

After consideration of the public comments we received, we are finalizing the adoption of the modified PSI 90 measure (NQF #0531) for the Hospital IQR Program for the FY 2018 payment determination and subsequent years as proposed. To summarize, we will use: (1) A 15-month reporting period using only ICD–9 data for the FY 2018 payment determination; (2) a 21-month reporting period using only ICD–10 data for the FY 2019 payment determination and; (3) a 24-month reporting period using only ICD–10 data for the FY 2020 payment determination and subsequent years. We will continue to use the previously adopted eight-indicator version of the PSI 90 measure in the Hospital IQR Program for the FY 2017 payment determination.

7. Additional Hospital IQR Program Measures for the FY 2019 Payment Determination and Subsequent Years

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25185 through 25193), we proposed to add four new measures to the Hospital IQR Program for the FY 2019 payment determination and subsequent years. We proposed to adopt three clinical episode-based payment measures:

- Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) Measure;
- Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) Measure; and
- Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) Measure.

In addition, we proposed to adopt one required outcome measure: Excess Days in Acute Care after Hospitalization for Pneumonia.

The proposed measures were included on a publicly available document entitled ''2015 Measures Under Consideration'' [127] in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP as discussed in its MAP Pre-Rulemaking Report and Spreadsheet of MAP 2016 Final Recommendations.[128]

Below, we discuss each of the above measures in more detail.

a. Adoption of Three Clinical Episode-Based Payment Measures

(1) Background

Clinical episode-based payment measures are clinically coherent groupings of healthcare services that can be used to assess providers' resource use. Combined with other clinical quality measures, they contribute to the overall picture of providers' clinical

[126] Bore refers to the size of a needle used for an IV.

[127] Measure Applications Partnership: List of Measures Under Consideration (MUC) for December 1, 2015. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[128] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/*.

effectiveness and efficiency. Episode-based performance measurement allows meaningful comparisons between providers based on resource use for certain clinical conditions or procedures, as noted in the NQF report for the ''Episode Grouper Evaluation Criteria'' project available at: *http://www.qualityforum.org/Publications/2014/09/Evaluating_Episode_Groupers__A_Report_from_the_National_Quality_Forum.aspx* and in various peer-reviewed articles.[129] We proposed three clinical episode-based payment measures for inclusion in the Hospital IQR Program beginning with the FY 2019 payment determination: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) measure; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) measure; and (3) Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) measure. The proposed measures capture Medicare payment for services related to the episode procedure and take into account beneficiaries' clinical complexity as well as geographic payment differences.

We proposed these clinical episode-based measures to supplement the Hospital IQR Program's Medicare Spending per Beneficiary (MSPB) measure. The proposed measures also support our mission to provide better healthcare for individuals, better health for populations, and lower costs for healthcare. We note that these measures were reviewed by the MAP and did not receive support for adoption into the Hospital IQR Program, as discussed in its MAP Pre-Rulemaking Report and Spreadsheet of MAP 2016 Final Recommendations.[130] The result of the MAP vote for the proposed measures was as follows: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment measure: 8 percent support, 32 percent conditional support, and 60 percent do not support; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment measure: 20 percent support, 28 percent conditional support, and 52 percent do not support; and (3) Spinal Fusion Clinical Episode-Based Payment measure: 16 percent support, 36 percent conditional support, and 48 percent do not support. MAP stakeholders expressed concerns that the proposed measures: (1) Overlap with the Medicare Spending per Beneficiary (MSPB) measure;[131] (2) are not NQF-endorsed; (3) may need to be adjusted for SDS; and (4) fail to link outcomes to quality because they do not reflect appropriateness of care.

In response to MAP stakeholder concerns that the clinical episode-based payment measures overlap with the MSPB measure, we note that unlike the overall MSPB measure, the clinical episode-based payment measures assess payment variation at the procedure level and only include services that are clinically related to the named episode procedure (for example, the spinal fusion measure includes inpatient admissions for ''medical back problems'' that occur following the initial spinal fusion procedure since the admission is likely a result of complications from the initial procedure).

With respect to MAP stakeholder concerns that the clinical episode-based payment measures are not NQF-endorsed, section 1886(b)(3)(B)(IX)(bb) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We considered other existing measures related to payment that have been endorsed by the NQF and other consensus organizations, but we were unable to identify any NQF-endorsed (or other consensus organization endorsed) payment measures that assess the aortic aneurysm procedure, cholecystectomy and common duct exploration, or spinal fusion. However, these proposed clinical episode-based payment measures will be submitted to NQF for endorsement as part of the next Cost and Resource Use project.

In regard to MAP stakeholder concerns that the clinical episode-based payment measures may need to be adjusted for SDS, we refer readers to section VIII.A.6.a.(1) of the preamble of this final rule for a discussion of our policy on SDS factor risk adjustment. Finally, regarding MAP stakeholder concerns that the clinical episode-based payment measures fail to link outcomes to quality because they do not reflect appropriateness of care, we believe that the proposed measures cover topics of critical importance to quality in the inpatient hospital setting. Hospitals have a significant influence on Medicare spending during the episode surrounding a hospitalization, through the provision of appropriate, high-quality care before and during inpatient hospitalization, and through proper hospital discharge planning, care coordination, and care transitions. While we recognize that high or low payments to hospitals are difficult to interpret in isolation, high payments for services may implicitly be associated with poor quality of care (for example, preventable readmissions, procedure complications, or emergency room usage).

Although the MAP did not support inclusion of these clinical episode-based payment measures in the Hospital IQR Program,[132] stakeholders have requested to have more condition-specific and procedure-specific measures, similar to the MSPB measure included in the Hospital IQR Program, as described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51623). We believe that including condition- and procedure-specific payment measures will provide hospitals with actionable feedback that will better equip them to implement targeted improvements in comparison to an overall payment measure alone. Further, we believe that supplementing the MSPB measure with condition-specific and procedure-specific measures will provide both overall hospital-level and detailed information on high-cost and high-prevalence conditions and procedures to better inform their future spending plans. Moreover, the payment measures will help consumers and other payers and providers identify hospitals involved in the provision of efficient care for certain procedures.

The three procedures selected for the clinical episode-based payment measures were chosen based on the following criteria: (1) The condition constitutes a significant share of Medicare payments and potential savings for hospitalized patients during and surrounding a hospital stay; (2) there was a high degree of agreement among clinical experts consulted for this project that standardized Medicare payments for services provided during this episode can be linked to the care provided during the hospitalization; (3)

[129] For example: Hussey, P. S., Sorbero, M. E., Mehrotra, A., Liu, H., & Damberg, S. L.: (2009). Episode-Based Performance Measurement and Payment: Making It a Reality. Health Affairs, 28(5), 1406–1417. Doi:10.1377/hlthaff.28.5.1406.

[130] Spreadsheet of MAP 2016 Final Recommendations. Available at: *http://www.qualityforum.org/map/*.

[131] MSPB measure specifications can be found in the ''Medicare Spending Per Beneficiary (MSPB) Measure Overview,'' available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*.

[132] Spreadsheet of MAP 2016 Final Recommendations. Available at: *http://www.qualityforum.org/map/*.

episodes of care for the condition are comprised of a substantial proportion of payments and potential savings for postacute care, indicating episode payment differences are driven by utilization outside of the MS–DRG payment; (4) episodes of care for the condition reflect high variation in postdischarge payments, enabling differentiation among hospitals; and (5) the medical condition is managed by general medicine physicians or hospitalists and the surgical conditions are managed by surgical subspecialists, enabling comparison between similar practitioners. These selection criteria were also used for the three clinical episode-based payment measures finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49664 through 49665).

The measures follow the general construction of episode-based measures previously adopted in the Hospital IQR Program: The NQF-endorsed MSPB measure finalized in the FY 2012 IPPS/LTCH PPS final rule for the Hospital IQR Program (76 FR 51626 through 74529); and the three clinical episode-based payment measures for kidney/UTI, cellulitis, and gastrointestinal hemorrhage finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49674). Similar to these previously adopted measures, the proposed measures include standardized payments for Medicare Part A and Part B services and are risk adjusted for individual patient characteristics and other factors (for example, the MS–DRG of the index inpatient stay). However, unlike the MSPB measure, the clinical episode-based payment measures only include Medicare Part A and Part B services that are clinically related to the named episode procedure. The clinical episode-based payment measures are price-standardized, risk-adjusted ratios that compare a provider's resource use against the resource use of other providers within a reporting period (that is, the measure calculation includes eligible episodes occurring within a 1-year timeframe). Similar to the MSPB measure though, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation.

Each clinical episode-based payment measure is calculated as the ratio of the Episode Amount for each provider divided by the episode-weighted median Episode Amount across all providers. To calculate the Episode Amount for each provider, one calculates the average of the ratio of the observed episode payment over the expected episode payment (as predicted in risk adjustment), and then multiplies this quantity by the average observed episode payment level across all providers nationally. The denominator for a provider's measure is the episode weighted national median [133] of Episode Amounts across all providers. A clinical episode-based payment measure of less than 1 indicates that a given provider's resource use is less than that of the national median provider during a reporting period. Mathematically, this is represented in equation (A) below.

$$\text{(A)}\ \textit{Episode Measure}_j = \frac{\textit{Episode Amount}_j}{\substack{\textit{Episode-Weighted}\\ \textit{Median of All Providers'}\\ \textit{Episode Amounts}}} = \frac{\frac{\Sigma_{i\in j}(\frac{O_{ij}}{E_{ij}})}{n_j} * \bar{O}_{i\in I}}{\substack{\textit{Episode-Weighted}\\ \textit{Median of All Providers'}\\ \textit{Episode Amounts}}}$$

where

O_{ij} =observed episode payment for episode i in provider j,

E_{ij} =epected episode payment for episode i in provider j,

O_{iEI} =average observed episode payment across all episodes i nationally, and

n_j =total number of episodes for provider j.

Each of the three measures we proposed is described further below, followed by explanations of payment standardization and risk adjustment. For detailed measure specifications, we refer readers to the clinical episode-based payment measures report entitled, ''Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion'' available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228775614447*.

We invited public comment on our proposals to add three clinical episode-based payment measures for the FY 2019 payment determination and subsequent years. General comments related to all three measures are discussed below. Specific comments for each measure are discussed even further below.

Comment: Several commenters supported the adoption of the proposed clinical episode-based payment measures.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern that hospitals would not be able to report statistically reliable information on such a small number of hospital-specific observations, recommending instead that CMS use condition-specific cost measures broadly and not base financial incentives on them.

Commenters were also concerned that the majority of performance variation reflects differences in services used by patients, but the measures do not provide insight on whether the services were necessary and appropriate, arguing that cost is not indicative of quality of care. Some commenters believed that consumers are likely to associate higher cost with better quality.

Response: We disagree with the commenters that a hospital will not be able to report statistically reliable information on the condition-specific, clinical episode-based payment measures. We note that the conditions for these measures were selected specifically because these conditions are high volume and constitute a significant share of Medicare payments and potential savings, as detailed in the Background sections corresponding to each measure in sections VIII.A.7.a.(2)(a), VIII.A.7.a.(3)(a), and VIII.A.7.a.(4)(a) of the preamble of this final rule. In addition, analysis of 2014 administrative claims data shows that the majority of hospitals achieved moderate reliability (above 0.4) when using 20-episode case minimums for Aortic Aneurysm Procedure and Spinal Fusion Clinical Episode-Based Payment Measure, and a 30-episode case minimum for the Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure. For more details, we refer readers to the measure methodology report available at: *https://www.qualitynet.org/dcs/*

[133] Example of episode weighted median: if there are 2 hospitals and one hospital had an measure score of 1.5 and another had one of 0.5, but the first had 4 episodes and the second only 1, then the episode-weighted median would be 1.5 (that is, 0.5, 1.5, 1.5, 1.5, 1.5).

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We appreciate the commenter's recommendation not to use episode-based cost measures for financial incentives, but note that the payment incentive in the Hospital IQR Program is for reporting only, therefore, there is no financial incentive associated with performance on these specific measures. We agree with commenters that some consumers may associate higher cost with better quality, and we will continue to explore options to improve the manner in which data is presented on *Hospital Compare* to enable consumers to make informed decisions about their healthcare.

Comment: One commenter noted that the Hospital IQR Program does not currently include appropriate outcome measures for many of these conditions, nor has CMS proposed inclusion of new outcome measures. This commenter urged CMS to identify and employ relevant health outcome measures to provide context for these cost measures, so that the function of the cost measures is not to simply reduce spending, even when the spending is appropriate. Some commenters stated that there are no concurrent outcome measures in the Hospital IQR Program and thus the measures do not offer meaningful insight on whether or not outcomes are better in places where more or fewer services are used.

Response: We interpret the commenters' reference to places where more or fewer services are used to refer to hospital resource use. While we agree that observation of cost alongside quality (outcome measures) is an important concept, we believe that resource use information, even in the absence of a corresponding (concurrent) quality measure, provides useful and valuable information for consumers and other stakeholders as they seek to make informed decisions about facilities involved in the provision of their care. Furthermore, the clinical episode-based payment measures only include costs from services/procedures related to the condition, which would include readmissions that are clinically related to the hospitalization. In that sense, certain outcomes would be captured in these measures through higher resource use. However, we appreciate the commenter's suggestion and will consider it in future measure development.

Comment: One commenter observed that the proposed clinical episode-based payment measures would help supplement the MSBP measure by tracking resource use within these particular episodes of care, but several commenters echoed the MAP's concern that these measures overlap with the MSPB measure. One commenter expressed concern that these measures overlap with other efficiency measures. One commenter requested clarification about whether or not the proposed clinical episode-based payment measures will be used as part of the MSPB measure for the Hospital VBP Program in future payment years, stating that it is important for all stakeholders to be fully aware how cost collection under these measures may impact future quality scores and payment adjustments.

Response: We interpret ''other efficiency measures'' to mean the MSPB measure, and acknowledge that there may be some overlap between the MSPB measure and these three episode-based payment measures. However, unlike the overall MSPB measure, the clinical episode-based payment measures assess payment variation at the procedure level and only include services that are clinically related to the named episode procedure (for example, the spinal fusion measure includes inpatient admissions for ''medical back problems'' that occur following the initial spinal fusion procedure since the admission is likely a result of complications from the initial procedure). We believe that the episode-based measures are of critical importance to improving efficiency of care. Including episode-based measures alongside the MSPB measure provides hospitals with actionable feedback that will better equip them to implement targeted improvements, in comparison to an overall payment measure alone. Moreover, these episode-based measures will allow consumers, providers, and payers to make a more fully informed assessment of value of care. In addition, any proposal to adopt the clinical episode-based payment measures into the Hospital VBP Program would be subject to future rulemaking.

Comment: One commenter expressed concern that claims do not accurately reflect the provider performance across the entire patient population that includes non-Traditional Medicare patients, while some commenters specifically recommended including Medicare Advantage (MA) patients in the measure population since fee-for-service is only a small portion of the total patient population. To that end, some commenters encouraged CMS to validate MA data and to supplement claims data with MA data to assure valid and reliable reports of quality provided to Medicare beneficiaries.

Response: We interpret the commenter's reference to ''non-Traditional Medicare patients'' to refer to beneficiaries enrolled in MA plans. We note that we do not receive claims data for beneficiaries who are enrolled in the MA plans because Medicare pays these plans a fixed amount. Therefore, we cannot include or supplement MA claims data for measure calculation.

Comment: Some commenters did not support the measures because they are not NQF-endorsed, noting that the MAP also recommended that the measures be NQF-endorsed prior to being included in the Hospital IQR Program because the endorsement process identifies needed refinements or problems with measures which should be considered prior to program adoption. Some commenters suggested that the measures have full support of the clinical community prior to being included in the measure set.

Response: We believe the MAP provides valuable insights and we consider and carefully weigh all of their recommendations. When we disagree with these recommendations, we take care to explain our rationale when proposing such measures. We refer readers to section VIII.A.7.a.(1) of the preamble of this final rule for a discussion of our rationale for including the Clinical Episode-Based Payment measures in the Hospital IQR Program measure set. Likewise, we attempt to engage stakeholders in the measure development process as much in possible, including by working with them on TEPs and Environmental Working Groups (EWGs).

Finally, whenever feasible, we adopt measures that are NQF-endorsed, but note that sometimes there are important areas of clinical concern for which NQF-endorsed measures do not exist. Section 1886(b)(3)(B)(IX)(bb) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We considered other existing measures related to payment that have been endorsed by the NQF and other consensus organizations, but we were unable to identify any NQF-endorsed (or other consensus organization endorsed) payment measures that assess the aortic aneurysm procedure, cholecystectomy and common duct exploration, or spinal fusion. However, these proposed clinical episode-based payment

measures will be submitted to NQF for endorsement as part of the next Cost and Resource Use project.

Comment: Some commenters noted that the measures reflect the actions of a group of healthcare providers, rather than just hospitals. Other commenters also noted that the measures do not account for national variation in the mix of services and degree of integration in health care markets beyond the hospital's control. Some commenters recommended that inclusion of these measures be delayed in the Hospital IQR Program until all settings of postacute care have similar measures.

Response: We believe these measures reflect the actions of hospitals and the care their patients receive postdischarge. Hospitals providing quality inpatient care, conducting appropriate discharge planning, and working with providers and suppliers on appropriate follow-up care will likely perform well, because the Medicare beneficiaries they serve will have a reduced need for excessive postdischarge services. The risk adjustment methodology used for these measures acknowledge the differences in a given hospital's patient case mix, so that their performance can be compared to a national average. We recognize that the structure of health care markets and practice patterns vary geographically, beyond the variation in patient case mix. However, as mentioned above, we believe that the aforementioned opportunities for hospitals to exert control over postdischarge services exist, regardless of the degree of integration of a health system. In cases where systems are not well-integrated, there may be an even greater opportunity for redesign of care processes to achieve high performance on these measures. We are collaborating with our postacute care quality programs and we will take the commenters' suggestions that similar measures should be incorporated into those programs under consideration. However, we do not believe that it would be appropriate to delay adoption of this measure and the public reporting of this valuable and actionable payment information until such time as any similar, postacute care measures are implemented.

Comment: Some commenters did not believe claims data were adequate to calculate measure scores for these measures. Another commenter stated that the measure should be based on clinical data rather than claims data.

Response: Because all measures in the Hospital IQR Program require clinical data, we interpret the commenter's request that the measure should be based on clinical data rather than claims data to refer to the risk adjustment methodology since payment information must come from a filed claim. We believe that using administrative claims data is a valid approach to risk adjustment that adequately assesses the difference in case-mix among hospitals. However, we also are continuing to explore the use of patient clinical data (core clinical data elements) derived from EHRs for risk adjustment in future measure development (80 FR 49698 through 49704).

Comment: Some commenters cited concerns about the risk adjustment and scoring of these measures. One commenter noted that it is imperative to assess for risk-adjustment factors to ensure that facilities are not financially penalized for serving vulnerable populations and/or worsening care disparities. Another commenter specifically suggested that the measures be SDS risk-adjusted to account for the effects of poverty on the use of healthcare services.

Response: Because the Hospital IQR Program is a quality reporting program and does not score measures for performance, we interpret commenters' concerns regarding scoring to refer to measure calculation. In response to concerns regarding risk adjustment and measure calculation, we note that the steps used to calculate risk-adjusted payments align with the NQF-endorsed MSPB measure (NQF #2158) method as specified in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51624 through 51626). The risk adjustment model adjusts for age, severity of illness, and the MS–DRG of the hospitalization that triggers the episode. The risk adjustment model also includes clinical subtypes that distinguish relatively homogeneous subpopulations of patients whose health conditions significantly influence the form of treatment and the expected postdischarge outcomes and risks.

For each clinical subtype, the risk adjustment model is estimated separately such that the measure compares observed spending for an episode of a given clinical subtype only to expected spending among episodes of that subtype. The Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure includes two clinical subtypes: (1) Abdominal Aortic Aneurysm Procedure; and (2) Thoracic Aortic Aneurysm Procedure. The Spinal Fusion Clinical Episode-Based Payment measure includes five clinical subtypes: (1) Anterior Fusion—Single; (2) Anterior Fusion—2 Levels; (3) Posterior/Posterior-Lateral Approach Fusion—Single; (4) Posterior/Posterior-Lateral Approach Fusion—2 or 3 Levels; and (5) Combined Fusions. In addition, postdischarge episode payment is limited to services that are clinically related to the reason for the initial hospitalization, which removes sources of variation in episode spending that are out of the hospital's control.

The specifications for clinical subtypes and grouping rules for postdischarge services were based on consensus decisions by a team of clinical experts, which included CMS and non-CMS physicians. For a complete list of the clinical experts whose input considered, we refer readers to the report detailing the specifications of the episode-based payment measures, entitled, ''Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion'' available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228775614447*.

In response to the comments about risk-adjustment factors that account for serving vulnerable populations and/or worsening care disparities, as stated in section VIII.A.6.a.(1) of the preamble of this final rule, several measures developed by CMS have been brought to NQF since the beginning of the SDS trial. CMS, in compliance with NQF's guidance, has tested SDS factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for SDS factors in our outcome measures.

Furthermore, ASPE is conducting research to examine the impact of SDS on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Comment: Despite concerns about these measures, some commenters noted the potential benefit of sharing confidential cost reports to providers, specifically those interested in bundled payments, so that these providers can assess the drivers of high-cost payment episodes and explore interventions. These commenters suggested that CMS provide these cost reports while the measures undergo NQF review. Some commenters suggested conducting a ''dry run'' of the measures in which CMS would provide hospitals with

confidential reports, soliciting feedback on the usefulness of the information. Another commenter requested that CMS publish supplementary data demonstrating cost variations to better inform stakeholders of the appropriateness of tracking these costs and to evaluate whether the data show any evidence that higher quality hospital treatment may yield lower postdischarge payment.

Response: In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49672), we finalized a dry run for similar clinical episode-based payment measures, which will be conducted in the summer of 2017 using CY 2016 data. The purpose of this dry run is to allow hospitals to gain experience with clinical episode-based payment measures through confidential feedback reports. We believe this dry run will enable hospitals to gain experience with clinical episode-based payment measures, including the three payment measures being adopted in this final rule, and therefore another similar dry run is unnecessary.

We thank commenters for their support of the confidential hospital-specific feedback reports. We currently provide confidential hospital-specific feedback reports and supplemental files for the MSPB measure, and we intend to create similar reports and supplemental files for these clinical episode-based payment measures. We will coordinate with measure stewards to try to develop a process for making these reports available while measures are undergoing NQF review. We appreciate the commenter's suggestion that we publish supplementary data of cost variations and will take it into future consideration.

Comment: One commenter encouraged CMS to work collaboratively with stakeholders to ensure that policies allow hospitals to provide the best care for patients in the most appropriate setting as determined by the physician.

Response: We thank the commenter for this suggestion and we will continue to seek and consider stakeholder input as we improve the Hospital IQR Program.

(2) Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) Measure

(a) Background

Inpatient hospital stays and associated services assessed by the proposed Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) measure have high payments with substantial variation. In CY 2014, Medicare FFS beneficiaries experienced more than 22,000 aortic aneurysm procedure episodes triggered by related inpatient stays. Payment-standardized, risk-adjusted episode payment for these episodes (payment for the hospitalization plus payment for clinically related services in the episode window) totaled nearly $760 million in CY 2014, with a mean episode payment of over $33,000. There is substantial variation in aortic aneurysm procedure episode payment—ranging from approximately $21,000 at the 5th percentile to approximately $62,000 at the 95th percentile—that is partially driven by variation in postdischarge payment clinically-related to the inpatient hospitalization.[134] These clinically-related postdischarge payments may be an indicator of the quality of care provided during the hospitalization. Specifically, higher quality hospital treatment may yield lower postdischarge payment.

(b) Overview of Measure

The proposed AA Payment measure includes the set of medical services related to a hospital admission for an aortic aneurysm procedure, including treatment, follow-up, and postacute care. The measure includes two clinical subtypes: (1) Abdominal Aortic Aneurysm Procedure; and (2) Thoracic Aortic Aneurysm Procedure. Clinical subtypes are included in the measure construction to distinguish relatively homogeneous subpopulations of patients whose health conditions significantly influence the form of treatment and the expected postdischarge outcomes and risks. The risk adjustment model is estimated separately for each clinical subtype, such that the measure compares observed spending for an episode of a given clinical subtype only to expected spending among episodes of that subtype. This measure, like the NQF-endorsed MSPB measure (NQF #2158), assesses the payment for services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the ''episode window,'' discussed in more detail below). In contrast to the MSPB measure, however, this proposed measure includes Medicare payments for services during the episode window only if they are clinically related to the aortic aneurysm procedure that was performed during the index hospital stay.

[134] Statistics based on Acumen's testing of episode definition on Medicare FFS population using Medicare Parts A and B claims.

(c) Data Sources

The proposed AA Payment measure is a claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for an aortic aneurysm procedure. The reporting period for the measure is 1 year (that is, the measure calculation includes eligible episodes occurring within a 1-year timeframe). For example, for the FY 2019 payment determination, the reporting period would be CY 2017.

(d) Measure Calculation

The proposed AA Payment measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without the need to adjust for inflation. The numerator is the Episode Amount, calculated as the average of the ratios of the observed episode payment over the expected episode payment (as predicted in risk adjustment), multiplied by the average observed episode payment level across all providers nationally. The denominator for a provider's measure is the episode weighted national median of Episode Amounts across all providers. An aortic aneurysm procedure episode begins 3 days prior to the initial (index) admission and extends 30 days following the discharge from the index hospital stay. For detailed measure specifications, we refer readers to the clinical episode-based payment measures report entitled, ''Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion'' and available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228775614447*.

(e) Cohort

The proposed AA Payment measure cohort includes Medicare FFS beneficiaries hospitalized for an aortic aneurysm procedure. Measure exclusions are discussed in more detail in section VIII.A.7.a.(5) of the preamble of this final rule.

We invited public comment on our proposal to adopt the Aortic Aneurysm

Procedure Clinical Episode-Based Payment (AA Payment) measure to the Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years as discussed in this section.

Comment: One commenter specifically opposed the proposed inclusion of the AA Payment measure, noting that the measure is not NQF-endorsed or supported by the MAP.

Response: We refer readers to our response in the section above in which we respond to general comments on the clinical episode-based payment measures.

Comment: One commenter recommended that the measure should be subdivided into several different measures by: Location of the Aortic Aneurysm; Type of Surgery that is performed; and Emergent or Non Emergent Aortic Aneurysm.

Response: We disagree that the measure should be subdivided into several different measures. The measure already risk adjusts for the factors listed by the commenter, including through two clinical subtypes based on the location of the procedure: (1) Abdominal Aortic Aneurysm Procedure, and (2) Thoracic Aortic Aneurysm Procedure. Creating separate measures would substantially reduce hospitals' sample size and limit the number of hospitals included in the measure after an episode case minimum is imposed.

After consideration of the public comments we received, we are finalizing the adoption of the Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) measure to the Hospital IQR Program for the FY 2019 payment determination and subsequent years as proposed.

(3) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) Measure

(a) Background

Inpatient hospital stays and associated services assessed by the proposed Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) measure have high payments with substantial variation. In CY 2014, Medicare FFS beneficiaries experienced more than 48,000 cholecystectomy and common duct exploration episodes triggered by related inpatient stays. Payment-standardized, risk-adjusted episode payment for these episodes (payment for the hospitalization plus the payment for clinically related services in the episode window) totaled nearly $690 million in CY 2014, with a mean episode payment of over $14,000. There is substantial variation in cholecystectomy and common duct exploration episode payment—ranging from approximately $11,000 at the 5th percentile to approximately $22,000 at the 95th percentile—that is partially driven by variation in postdischarge payment clinically-related to the inpatient hospitalization.[135] These clinically-related postdischarge payments may be an indicator of the quality of care provided during the hospitalization. Specifically, higher quality hospital treatment may yield lower postdischarge payment.

(b) Overview of Measure

The proposed Chole and CDE Payment measure includes the set of medical services related to a hospital admission for a cholecystectomy and common duct exploration, including treatment, follow-up, and postacute care. This measure, like the NQF-endorsed MSPB measure (NQF #2158), assesses the payment for services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the ''episode window,'' discussed in more detail below). In contrast to the MSPB measure, however, this measure includes Medicare payments for services during the episode window only if they are clinically related to the cholecystectomy and common duct exploration that was performed during the index hospital stay.

(c) Data Sources

The proposed Chole and CDE Payment measure is a claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for a cholecystectomy and common duct exploration. The reporting period for the measure is 1 year (that is, the measure calculation includes eligible episodes occurring within a 1-year timeframe). For example, for the FY 2019 payment determination, the reporting period would be CY 2017.

(d) Measure Calculation

The proposed Chole and CDE Payment measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation. The numerator is the Episode Amount, calculated as the average of the ratios of the observed episode payment over the expected episode payment (as predicted in risk adjustment), multiplied by the average observed episode payment level across all providers nationally. The denominator for a provider's measure is the episode weighted national median of Episode Amounts across all providers. A cholecystectomy and common duct exploration episode begins 3 days prior to the initial (index) admission and extends 30 days following the discharge from the index hospital stay. For detailed measure specifications, we refer readers to the clinical episode-based payment measures report entitled, ''Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion'' and available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228775614447*.

(e) Cohort

The proposed Chole and CDE Payment measure cohort includes Medicare FFS beneficiaries hospitalized for cholecystectomy and common duct exploration. Measure exclusions are discussed in more detail in section VIII.A.7.a.(5) of the preamble of this final rule below.

We invited public comment on our proposal to adopt the Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) measure to the Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years as discussed in this section.

Comment: One commenter recommended that CMS modify the Chole and CDE Payment measure to only include Cholecystectomy procedures without CDE because of the low volume of these procedures in hospitals. The commenter cautioned that inclusion of CDE will diminish the measure's reliability because hospitals will be accountable for payments on procedures they rarely perform.

Response: We thank the commenter, but believe it is important to incentivize cost efficient care for cholecystectomies whether performed with or without CDE. Reliability calculations on the Chole and CDE Payment measure show

[135] Statistics based on Acumen's testing of episode definition on Medicare FFS population using Medicare Parts A and B claims.

that a majority of hospitals have at or above moderate reliability (above 0.4) when using a 30-episode case minimum.

We recognize that reliability may be limited for hospitals that perform a small number of procedures; however, we select appropriate case minimums for reporting before these measures are publicly reported on *Hospital Compare.*

After consideration of the public comment we received, we are finalizing the adoption of the Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) measure to the Hospital IQR Program for the FY 2019 payment determination and subsequent years as proposed.

(4) Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) Measure

(a) Background

Inpatient hospital stays and associated services assessed by the proposed Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) measure have high payments with substantial variation. In CY 2014, Medicare FFS beneficiaries experienced nearly 60,000 spinal fusion episodes triggered by related inpatient stays. Payment-standardized, risk-adjusted episode payment for these episodes (payment for the hospitalization plus the payment for clinically related services in the episode window) totaled over $2 billion in CY 2014, with a mean episode payment of over $35,000. There is substantial variation in spinal fusion episode payment—ranging from approximately $27,000 at the 5th percentile to approximately $56,000 at the 95th percentile—that is partially driven by variation in postdischarge payment clinically-related to the inpatient hospitalization.[136] These clinically-related postdischarge payments may be an indicator of the quality of care provided during the hospitalization. Specifically, higher quality hospital treatment may yield lower postdischarge payment.

(b) Overview of Measure

The SFusion Payment measure includes the set of medical services related to a hospital admission for a spinal fusion, including treatment, follow-up, and postacute care. The measure includes five clinical subtypes: (1) Anterior Fusion—Single; (2) Anterior Fusion—2 Levels; (3) Posterior/Posterior-Lateral Approach Fusion—Single; (4) Posterior/Posterior-Lateral Approach Fusion—2 or 3 Levels; and (5) Combined Fusions. The clinical subtypes are included in the measure construction to distinguish relatively homogeneous subpopulations of patients whose health conditions significantly influence the form of treatment and the expected outcomes and risks. The risk adjustment model is estimated separately for each clinical subtype, such that the measure compares observed spending for an episode of a given clinical subtype only to expected spending among episodes of that subtype. A similar measure, the Lumbar Spinal Fusion/Refusion Clinical Episode-Based Payment Measure, was proposed for inclusion in the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24570 through 24571). Based on public comments regarding the heterogeneity of the spinal fusion patient population, we decided not to finalize the measure for the Hospital IQR Program at that time (80 FR 49668 through 49674). We have since refined the measure by including more granular subtypes of fusions of the lumbar spine to create more homogenous patient cohorts.

This proposed measure, like the NQF-endorsed MSPB measure (NQF #2158), assesses the payment for services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the ''episode window,'' discussed in more detail below). In contrast to the MSPB measure, however, this measure includes Medicare payments for services during the episode window only if they are clinically related to the spinal fusion procedure that was performed during the index hospital stay.

(c) Data Sources

The proposed SFusion Payment measure is a claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for spinal fusion. The reporting period for the measure is 1 year (that is, the measure calculation includes eligible episodes occurring within a 1-year timeframe). For example, for the FY 2019 payment determination, the reporting period would be CY 2017.

(d) Measure Calculation

The proposed SFusion Payment measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation. The numerator is the Episode Amount, calculated as the average of the ratios of the observed episode payment over the expected episode payment (as predicted in risk adjustment), multiplied by the average observed episode payment level across all providers nationally. The denominator for a provider's measure is the episode weighted national median of Episode Amounts across all providers. A spinal fusion episode begins 3 days prior to the initial (index) admission and extends 30 days following the discharge from the index hospital stay.

For detailed measure specifications, we refer readers to the clinical episode-based payment measures report entitled, ''Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion'' available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228775614447*.

(e) Cohort

The proposed SFusion Payment measure cohort includes Medicare FFS beneficiaries hospitalized for spinal fusion. Measure exclusions are discussed in more detail in section VIII.A.7.a.(5) of the preamble of this final rule below.

We invited public comment on our proposal to adopt the Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) measure to the Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years as discussed in this section.

Comment: Several commenters supported the proposed inclusion of the SFusion Payment measure, noting the measure aligns with the NQS and can help incentivize improved care coordination between hospitals and postacute providers since the cost for these episodes is largely driven by variation in postacute care utilization. One commenter stated that inclusion of such a measure will provide CMS and providers with the information necessary to narrow the growing variation in payment rates associated with spinal fusion procedures, and bring quality to the forefront in this important field. This commenter also

[136] Statistics based on Acumen's testing of episode definition on Medicare FFS population using Medicare Parts A and B claims.

noted that studies conducted on the utility of ACTIFUSE (a bone void filler) indicate that surgical adjunct technologies exist that can help facilitate cost effectiveness while preserving positive patient outcomes. Another commenter noted that the updated version makes the lumbar fusion cohort more homogeneous.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS only include subtypes 1, 2 and 3 in the proposed Spinal Fusion Clinical Episode-Based Payment Measure, noting that measuring subtypes 4 and 5 (posterior/posterior-lateral approach fusion—2 or 3 levels and combined fusions, respectively) would compromise validity because those subtypes include a wide breadth of procedures and heterogeneous patient population that would make comparisons potentially unreliable.

Response: We thank the commenter for the suggestion on the SFusion Payment measure. We believe that the Posterior/Posterior-lateral Approach Fusion—2 or 3 Levels and Combined Fusions subtypes do not include a wide breadth of procedures or heterogeneous populations. To create homogenous cohorts of patients for which we can reasonably compare resource use, the subtypes focus on patients hospitalized for fusions of the lumbar spine and elective cases of degenerative disease and do not include procedures that might indicate treatment for other clinical conditions such as trauma, congenital, neoplastic, or infectious processes. In addition, the measure uses risk adjustment to account for various levels of clinical complexity in the patient population that are beyond the influence of the attributed provider. The risk adjustment model aligns with the NQF-endorsed MSPB measure (NQF #2158) method as specified in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51624 through 51626).

In response to concerns about reliability, testing on the SFusion Payment measure shows that a majority of hospitals have at or above moderate reliability (above 0.4) when using a 20-episode case minimum.

Comment: One commenter expressed concern that CMS has released the grouping rules based on ICD–9 codes whereas implementation will be evaluating claims with ICD–10 codes for specific items included in the Spinal Fusion Grouping Rules.

Response: We thank the commenter for its concern regarding the ICD–10 transition. We plan to update the measure for ICD–10–CM/PCS diagnosis and procedure codes prior to implementation of the measures.

Comment: A few commenters specifically did not support the proposal to include the SFusion Payment measure. One commenter stated that the measure does not account for the patient's diagnosis and does not appear to account for other important patient complexity variables such as SDS factors, obesity, tobacco use, and population health variables. This commenter noted that these factors are outside of the provider's control, add to the complexity of the case, and clearly impact patient outcomes and therefore should be accounted for within the risk adjustment of the measure.

Response: We thank the commenters for their input and note that the measure does account for the patient's procedure and diagnosis to limit the cohort of patients to those with high frequency elective cases of degenerative disease. To create homogenous patient cohorts, MS–DRGs indicating spinal fusions performed to treat other clinical conditions such as malignancy or infection were not included in the list of episode triggers. Of note, risk adjustment methodology also incorporates diagnostic information and is discussed further below. Furthermore, in developing the episodes, we separated more complex cases (multi-level fusions) from less complex cases (single-level fusions) into clinical subtypes. We also separated anterior, posterior, and combined approach fusions and limited our number of levels involved in fusion. These characteristics were related to the indication for the fusion, and were a reasonable way to infer more diagnostic information. We removed procedures and DRGs that were mostly used in trauma, congenital, neoplastic, or infectious cases, and concentrated on cases that mostly occurred with degenerative disease.

In response to the comments about risk adjusting for SDS factors, we refer readers to section VIII.A.6.a.(1) in the preamble of this final rule where we respond to similar comments.

In regard to the concern about not including population health variables, these measures rely on Medicare administrative data and therefore are limited to variables found in this data source. Codes for obesity and tobacco are also not included in the risk adjustment model, as the clinical experts who specified the measure determined that these codes were unlikely to be uniformly coded on Medicare claims. We believe that the other risk adjustment variables adequately adjust for patient case mix by accounting for Hierarchical Condition Categories (HCCs), clinical case mix categories, and prior inpatient and ICU length of stay. The measure's risk adjustment methodology does account for a range of diagnoses reflecting comorbidities that could impact spinal fusion episode spending, including diabetes and other organ system disease. We refer readers to the measure's risk adjustment methodology available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228775614447*.

Comment: One commenter noted that stakeholders have no information on the conditions and services being grouped into the episode and counted in the overall cost of the episode. To be transparent, the commenter suggested that CMS should specify a list of services it is proposing for inclusion in each grouping option for the SFusion Payment measure.

Response: We refer readers to the detailed specifications for all of the clinical episode-based payment measures, which we referred readers to in the proposed rule (81 FR 25189), in the Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion file posted on the QualityNet Web page at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228775614447*. These specifications provide details on the conditions and services being grouped into the episode and counted in the overall cost of the episode for the SFusion Payment measure.

Comment: Another commenter noted that the North American Spine Society (NASS) expressed concern about the measure. This commenter encouraged CMS to work with applicable parties to select and develop a more accurate and useful measure.

Response: The SFusion Payment measure was developed in collaboration with a team of clinicians with a range of expertise including neurosurgery. For a complete list of the clinical experts whose input considered for these clinical episode-based payment measures, we refer readers to the report available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228775614447*. In addition, all three measures were reviewed by the MAP and will be submitted to NQF for endorsement as part of the next Cost and Resource Use project. We will continue to engage with stakeholders in

soliciting input on ways to refine these measures.

After consideration of the public comments we received, we are finalizing the adoption of the Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) measure to the Hospital IQR Program for the FY 2019 payment determination and subsequent years as proposed.

(5) Exclusion Criteria

For a full list of the MS–DRG, procedure, and diagnosis codes used to identify beneficiaries included in the final cohort for each of the proposed episode-based payment measures, we refer readers to the report entitled, ''Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion'' available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228775614447.*

Episodes for beneficiaries that meet any of the following criteria are excluded from all three measures: (1) Lack of continuous enrollment in Medicare Part A and Part B from 90 days prior to the episode through the end of the episode with traditional Medicare fee-for-service as the primary payer; (2) Death date during episode window; or (3) Enrollment in Medicare Advantage anytime from 90 days prior to the episode through the end of the episode.

In addition, claims that meet any of the following criteria do not trigger, or open, an episode for all three measures: (1) Claims with data coding errors, including missing date of birth or death dates preceding the date of the trigger event; (2) Claims with standardized payment ≤0; (3) Admissions to hospitals that Medicare does not reimburse through the IPPS system (for example, cancer hospitals, critical access hospitals, hospitals in Maryland); or (4) Transfers (by which a transfer is defined based on the claim discharge code) are not considered index admissions. In other words, these cases do not generate new episodes; neither the hospital that transfers a patient to another hospital, nor the receiving hospital will have an index admission or associated admission attributed to them.

(6) Standardization

Standardization, or payment standardization, is the process of adjusting the allowed charge for a Medicare service to facilitate comparisons of resource use across geographic areas. Medicare payments included in these proposed episode-based measures would be standardized according to the standardization methodology previously finalized for the MSPB measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51627). The methodology removes geographic payment differences, such as wage index and geographic practice cost index, incentive payment adjustments, and other add-on payments that support broader Medicare program goals, such as add-on payments for indirect graduate medical education (IME) and add-ons for serving a disproportionate share of uninsured patients.[137]

(7) Risk Adjustment

Risk adjustment uses patient claims history to account for case-mix variation and other factors. The steps used to calculate risk-adjusted payments align with the NQF-endorsed MSPB measure (NQF #2158) method as specified in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51624 through 51626). For more details on the specifications for the risk adjustment employed in the proposed episode-based payment measures, we refer readers to the report entitled, ''Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion'' available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228775614447.*

We did not receive any comments regarding the exclusion criteria for the three clinical episode-based payment measures. We refer readers to our discussions above, where we finalize the three clinical episode-based payment measures as proposed.

b. Adoption of Excess Days in Acute Care After Hospitalization for Pneumonia (PN Excess Days) Measure

(1) Background

Pneumonia is a priority area for outcomes measurement because it is a common condition associated with considerable morbidity, mortality, and healthcare spending. Pneumonia was the third most common principal discharge diagnosis among patients with Medicare in 2011.[138] Pneumonia also accounts for a large fraction of hospitalization costs, and it was the seventh most expensive condition billed to Medicare, accounting for 3.7 percent of the total national costs for all Medicare hospitalizations in 2011.[139]

Some of the costs for pneumonia can be attributed to high acute care utilization for postdischarge pneumonia patients in the form of readmissions, observation stays, and emergency department (ED) visits. Patients admitted for pneumonia have disproportionately high readmission rates, and that readmission rates following discharge for pneumonia are highly variable across hospitals in the United States.[140] [141]

For the previously adopted Hospital IQR Program measure, Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (NQF #0506) (hereinafter referred to as READM–30–PN) (80 FR 49654 through 49660), publicly reported 30-day risk-standardized readmission rates for pneumonia ranged from 12.9 percent to 24.8 percent for the time period between July 2012 and June 2015.[142] However, during the postdischarge period, patients are not only at risk of requiring readmission. ED visits represent a significant proportion of postdischarge acute care utilization. Two recent studies conducted in patients of all ages have shown that 9.5 percent of patients return to the ED within 30 days of hospital discharge and approximately 12 percent of these patients are discharged from the ED, and thus are not captured by the READM–30–PN Measure.[143] [144]

[137] An overview of payment standardization can be found in the ''CMS Price (Payment) Standardization—Basics'' document available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPages%2FQnetTier4&cid=1228772057350.*

[138] Agency for Healthcare Research and Quality (AHRQ). *Healthcare Cost and Utilization Project (HCUP) http://hcupnet.ahrq.gov/.*

[139] Torio CM, Andrews RM. National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011. HCUP Statistical Brief #160. 2013; *http://hcup-us.ahrq.gov/reports/statbriefs/sb160.jsp.*

[140] Lindenauer PK, Bernheim SM, Grady JN, et al. The performance of US hospitals as reflected in risk-standardized 30-day mortality and readmission rates for medicare beneficiaries with pneumonia. *J Hosp Med.* 2010;5(6):E12–18.

[141] Dharmarajan K, Hsieh AF, Lin Z, et al. Hospital readmission performance and patterns of readmission: retrospective cohort study of Medicare admissions. *BMJ.* 2013;347:f6571.

[142] Dorsey K, Grady J, Desai N, Lindenauer P, et al. 2016 Condition-Specific Measures Updates and Specifications Report: Hospital-Level Risk-Standardized Readmission Measures for Acute Myocardial Infarction, Heart Failure, and Pneumonia. 2016.

[143] Rising KL, White LF, Fernandez WG, Boutwell AE.: Emergency Department Visits After Hospital Discharge: A Missing Part of the Equation. *Annals of Emergency Medicine.* 2013(0).

[144] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently

In addition, over the past decade, the use of observation stays has rapidly increased. Specifically, between 2001 and 2008, the use of observation services increased nearly three-fold,[145] and significant variation has been demonstrated in the use of observation services.

Thus, in the context of the previously adopted and publicly reported READM–30–PN measure, the increasing use of ED visits and observation stays has raised concerns that the READM–30–PN measure does not capture the full range of unplanned acute care in the postdischarge period. In particular, some policymakers and stakeholders have expressed concern that high use of observation stays in some cases could replace readmissions, and hospitals with high rates of observation stays in the postdischarge period may therefore have low readmission rates that do not more fully reflect the quality of care.[146]

In response to these concerns, we improved on a previously developed measure, which is not currently part of the Hospital IQR Program measure set, titled, ''30-Day Post-Hospital Pneumonia Discharge Care Transition Composite'' (NQF #0707—NQF endorsement removed). The improved measure entitled Excess Days in Acute Care after Hospitalization for Pneumonia (PN Excess Days) is a risk-adjusted outcome measure for pneumonia that incorporates the full range of acute care use that patients may experience postdischarge: hospital readmissions, observation stays, and ED visits. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25190 through 25192), we proposed this PN Excess Days measure for inclusion in the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

The proposed PN Excess Days measure assesses all-cause acute care utilization for postdischarge pneumonia patients for several reasons. First, from the patient perspective, acute care utilization for any cause is undesirable. It is costly, exposes patients to additional risks of medical care, interferes with work and family care, and imposes significant burden on caregivers. Second, limiting the measure to inpatient utilization may make it susceptible to gaming. Finally, this measure includes all-cause acute care utilization because it is often hard to exclude quality concerns and accountability based on the documented cause of a hospital visit.

Although the original measure was NQF-endorsed, this improved measure has not yet been NQF-endorsed. Section 1886(b)(3)(B)(IX)(bb) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. While we considered other existing measures related to care transitions and postdischarge acute care utilization that have been endorsed by NQF or other consensus organizations, we were unable to identify any NQF-endorsed (or other consensus organization endorsed) measures that assess the full range of postdischarge acute care use that patients may experience. Existing process measures capture many important domains of care transitions such as education, medication reconciliation, and follow-up, but all require chart review and manual abstraction. Existing outcome measures are focused entirely on readmissions or complications and do not include observation stays or ED visits. We are not aware of any other measures that assess the quality of transitional care by measuring 30-day risk-standardized days in acute care (hospital readmissions, observation stays, and ED visits) following hospitalization for pneumonia that have been endorsed or adopted by a consensus organization, and we have not found any other feasible and practical measures on this topic. However, we note that this measure has been submitted to NQF for endorsement proceedings as part of the All-Cause Admissions and Readmissions project in January 2016.

The proposed PN Excess Days measure was developed in conjunction with the previously adopted Hospital IQR Program measures, Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI Excess Days) (80 FR 49690) and Hospital 30-Day Excess Days in Acute Care after Hospitalization for Heart Failure (HF Excess Days) (80 FR 49690). All three measures assess the same outcome and use the same risk-adjustment methodology. They differ only in the target population and the specific risk variables included.

When we finalized the AMI Excess Days and HF Excess Days measures for the FY 2018 payment determination and subsequent years, stakeholders expressed concern about the interaction between Medicare payment policy regarding admissions spanning two midnights and the AMI Excess Days and HF Excess Days measures (80 FR 49686 through 49687). We continue to believe that the ''2-midnight'' policy or any changes to such policy will not influence the outcome of Excess Days in Acute Care measures, as all postdischarge days in acute care are captured whether they are billed as inpatient or outpatient days (80 FR 49686 through 49687).

The proposed PN Excess Days measure (MUC ID 15–391) was included on a publicly available document entitled ''2015 Measures Under Consideration List'' for December 1, 2015 (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*) and has been reviewed by the NQF MAP Hospital Workgroup. The measure was conditionally supported pending the examination of SDS factors and NQF review and endorsement of the measure update, as referenced in the MAP 2016 Final Recommendations Report (available at: *http://www.qualityforum.org/map/*).[147] We refer readers to section VIII.A.6.a.(1) of the preamble of this final rule for a discussion of our policy on SDS factors. As stated above, we note that this measure has been submitted to NQF for endorsement proceedings as part of the All-Cause Admissions and Readmissions project in January 2016.

(2) Overview of Measure

The proposed PN Excess Days measure is a risk-standardized outcome measure that compares the number of days that patients, discharged from a hospital for pneumonia, are predicted to spend in acute care across the full spectrum of possible events (hospital readmissions, observation stays, and ED visits) to the days that patients are expected to spend based on their degree of illness as defined using principal diagnosis and comorbidity data from administrative claims.

(3) Data Sources

The proposed PN Excess Days measure is claims-based. It uses Part A and Part B Medicare administrative

discharged from the hospital. *JAMA: the journal of the American Medical Association.* Jan 23 2013;309(4):364–371.

[145] Venkatesh AK GB, Gibson Chambers JJ, Baugh CW, Bohan JS, Schuur JD. Use of Observation Care in US Emergency Departments, 2001 to 2008. *PLoS One.* September 2011;6(9):e24326.

[146] Carlson J. Readmissions are down, but observational-status patients are up and that could skew Medicare numbers. Modern Healthcare. 2013.

[147] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/.*

claims data from Medicare FFS beneficiaries hospitalized for pneumonia. To determine eligibility for inclusion in the measure, we also use Medicare enrollment data. As proposed, the measure would use 3 years of data. For example, for the FY 2019 payment determination, the reporting period would be July 2014 through June 2017.

(4) Outcome

The outcome of the proposed PN Excess Days measure is the excess number of days patients spend in acute care (hospital readmissions, observation stays, and ED visits) per 100 discharges during the first 30 days after discharge from the hospital, relative to the number spent by the same patients discharged from an average hospital. The measure defines days in acute care as days spent: (1) In an ED; (2) admitted to observation status; or (3) admitted as an unplanned readmission for any cause within 30 days from the date of discharge from the index pneumonia hospitalization. Readmission days are calculated as the discharge date minus the admission date. Admissions that extend beyond the 30-day follow-up period are truncated on day 30. Observation days are calculated by the hours in observation, rounded up to the nearest half day. Based on the recommendation of our TEP convened as part of developing this measure, an ED treat-and-release visit is counted as one half day. ED visits are not counted as a full day because the majority of treat-and-release visits last fewer than 12 hours.

''Planned'' readmissions are those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. This measure excludes planned readmissions using the planned readmission algorithm previously developed for the READM–30–PN measure (78 FR 50786 through 50787). The planned readmission algorithm is a set of criteria for classifying admissions as planned among the general Medicare population using Medicare administrative claims data. The algorithm identifies admissions that are typically planned and may occur within 30 days of discharge from the hospital. The planned readmission algorithm has three fundamental principles: (1) A few specific, limited types of care are always considered planned (transplant surgery, maintenance chemotherapy/immunotherapy, rehabilitation); (2) otherwise, a planned readmission is defined as a non-acute readmission for a scheduled procedure; and (3) admissions for acute illness or for complications of care are never planned. A more detailed discussion of exclusions follows in section VIII.A.7.b.(6) of the preamble of this final rule.

The measure counts all use of acute care occurring in the 30-day postdischarge period. For example, if a patient returns to the ED three times, the measure counts each ED visit as a half-day. Similarly, if a patient has two hospitalizations within 30 days, the days spent in each are counted. We take this approach to capture the full patient experience of need for acute care in the postdischarge period.

(5) Cohort

We defined the eligible cohort using the same criteria as the previously adopted Hospital IQR Program measure, READM–30–PN (80 FR 49654 through 49660). The READM–30–PN cohort criteria are included in a report posted on our Measure Methodology Web page, under the ''Downloads'' section in the ''AMI, HF, PN, COPD, and Stroke Readmission Updates'' zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

The cohort includes Medicare FFS patients aged 65 years or older: (1) With a principal discharge diagnosis of pneumonia, a principal discharge diagnosis of aspiration pneumonia, or a principal discharge diagnosis of sepsis (not including severe sepsis) who also have a secondary diagnosis of pneumonia present on admission; (2) enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission, and enrolled in Part A during the index admission; (3) who were discharged from a non-Federal acute care hospital; (4) who were not transferred to another acute care facility; and (5) who were alive at discharge.

The measure cohort is also harmonized with the previously adopted Hospital IQR Program measure, the MORT–30–PN measure (80 FR 49837), and the newly adopted refined cohort for the PN Payment measure discussed in section VIII.A.6.a. of the preamble of this final rule.

For the ICD–9–CM and ICD–10–CM codes that define the measure development cohort, we refer readers to the ''Excess Days in Acute Care after Hospitalization for Pneumonia Version 1.0'' in the Pneumonia Excess Days in Acute Care zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

(6) Exclusion Criteria

The proposed PN Excess Days measure excludes the following admissions from the measure cohort: (1) Hospitalizations without at least 30 days of postdischarge enrollment in Part A and Part B FFS Medicare, because the 30-day outcome cannot be assessed in this group since claims data are used to determine whether a patient was readmitted, was placed under observation, or visited the ED; (2) discharged against medical advice, because providers did not have the opportunity to deliver full care and prepare the patient for discharge; and (3) hospitalizations for patients with an index admission within 30 days of a previous index admission, because additional pneumonia admissions within 30 days are part of the outcome, and we choose not to count a single admission both as an index admission and a readmission for another index admission.

(7) Risk-Adjustment

The proposed PN Excess Days measure adjusts for variables that are clinically relevant and have strong relationships with the outcome. The measure seeks to adjust for case-mix differences among hospitals based on the clinical status of the patient at the time of the index admission. Accordingly, only comorbidities that convey information about the patient at that time or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk adjustment. The measure does not adjust for patients' admission source or their discharge disposition (for example, skilled nursing facility) because these factors are associated with the structure of the healthcare system, not solely patients' clinical comorbidities. Patients' admission source and discharge disposition may be influenced by regional differences in the availability of postacute care providers and practice patterns. These regional differences might exert undue influence on results. In addition, patients' admission source and discharge disposition are not audited and are not as reliable as diagnosis codes. The proposed PN Excess Days measure uses the same risk-adjustment variables as the READM–30–PN measure (73 FR 48614).

The outcome is risk adjusted using a two-part random effects model. This statistical model, often referred to as a ''hurdle'' model, accounts for the structure of the data (patients clustered within hospitals) and the observed distribution of the outcome.

Specifically, it models the number of acute care days for each patient as: (1) A probability that they have a non-zero number of days; and (2) a number of days, given that this number is non-zero. The first part is specified as a logit model, and the second part is specified as a Poisson model, with both parts having the same risk-adjustment variables and each part having a random effect. This is an accepted statistical method that explicitly estimates how much of the variation in acute care days is accounted for by patient risk factors, how much by the hospital where the patient is treated, and how much is explained by neither. This model is used to calculate the predicted (including random effects) and expected (assuming random effects are zero) number of days for each patient. The average difference between the predicted and expected number of days for each patient for each hospital is used to construct the risk-standardized Excess Days in Acute Care. For more details about risk-adjustment for this proposed measure, we refer readers to the ''Pneumonia Excess Days in Acute Care'' zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

(8) Calculating Excess Acute Care Days

The proposed PN Excess Days measure is calculated as the difference between the average of the predicted number of days spent in acute care for patients discharged from each hospital and the average number of days that would have been expected if those patients had been cared for at an average hospital, and then the difference is multiplied by 100 so that the measure result represents PN Excess Days per 100 discharges. We multiply the final measure by 100 to be consistent with the reporting of the previously adopted READM–30–PN measure that is reported as a rate (that is, a 25 percent rate is equivalent to 25 out of 100 discharges) (80 FR 49654 through 49660), as well as the AMI Excess Days (80 FR 49690) and HF Excess Days (80 FR 49685) measures. A positive result indicates that patients spend more days in acute care postdischarge than expected if admitted to an average performing hospital with a similar case mix; a negative result indicates that patients spend fewer days in acute care than expected if admitted to an average performing hospital with a similar case mix. A negative PN Excess Days measure score reflects better quality.

We invited public comment on our proposal to adopt the PN Excess Days measure for the FY 2019 payment determination and subsequent years as described above.

Comment: Several commenters supported the proposed adoption of the PN Excess Days measure. Commenters noted adoption of this measure demonstrates a movement away from the use of clinical process measures and toward outcome measures in quality measurement. Commenters believed that the proposed measure addresses the unintended consequence of shifting patients outside of inpatient care. In addition, one commenter indicated that this measure aligns with the NQS and addresses a condition that is a significant driver of cost for the Medicare program. Lastly, one commenter noted that variation in measure performance resulting in excess days in acute care for pneumonia patients will likely be driven by exacerbation of pneumonia leading to more critical, and potentially preventable conditions, such as sepsis.

Response: We thank the commenters for their support.

Comment: Several commenters did not support the proposed inclusion of the PN Excess Days measure, stating that only measures that have been endorsed by the NQF should be considered for inclusion in the Hospital IQR Program measure set. Commenters encouraged CMS to work collaboratively with stakeholders to ensure that policies allow hospitals to provide the best care for patients in the most appropriate setting as determined by the physician.

Response: As we noted above, section 1886(b)(3)(B)(IX)(bb) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. While we considered other existing measures related to care transitions and postdischarge acute care utilization that have been endorsed by NQF or other consensus organizations, we were unable to identify any NQF-endorsed (or other consensus organization endorsed) measures that assess the full range of postdischarge acute care use that patients may experience.

Existing process measures capture many important domains of care transitions such as education, medication reconciliation, and follow-up, but all require chart review and manual abstraction. Existing outcome measures are focused entirely on readmissions or complications and do not include observation stays or ED visits. We are not aware of any other measures that assess the quality of transitional care by measuring 30-day risk-standardized days in acute care (hospital readmissions, observation stays, and ED visits) following hospitalization for pneumonia that have been endorsed or adopted by a consensus organization, and we have not found any other feasible and practical measures on this topic. However, we note that this measure has been submitted to NQF for endorsement proceedings as part of the All-Cause Admissions and Readmissions project in January 2016.

Furthermore, the PN Excess Days measure's cohort was reviewed by clinical experts and a TEP and was subject to separate public input prior to being proposed for the Hospital IQR Program. This measure was also included on a publicly available document entitled ''2015 Measures Under Consideration List'' for December 1, 2015 (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*) and has been reviewed by the NQF MAP Hospital Workgroup. The measure was conditionally supported pending the examination of SDS factors and NQF review and endorsement of the measure update, as referenced in the MAP 2016 Final Recommendations Report (available at: *http://www.qualityforum.org/map/*).[148] We will continue to work collaboratively with stakeholders in soliciting input on ways to refine this measure in the future.

Comment: Several commenters did not support the inclusion of the proposed measure, noting that the risk-adjustment mechanism does not take SDS factors into consideration.

Response: We refer readers to section VIII.A.6.a.(1) of the preamble of this final rule where we have previously responded to similar comments.

Comment: Some commenters did not support the proposal to adopt the PN Excess Days measure because they believe that the measure addresses outcomes already captured by the current readmission and MSPB measures. One commenter requested more information about how the impact and performance differs from the current readmission measure.

Response: Although the MSPB measure may include similar events, it

[148] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/.*

specifically examines resource use through Medicare payment for all Medicare beneficiaries, whereas the PN Excess Days measure examines excess days in acute care following discharge after hospitalization for pneumonia. The PN Excess Days measure is intended to provide patients and providers a perspective on variation among hospitals in the number of days spent in acute care during the 30-day postdischarge period as compared to what would be expected at an average hospital, in contrast to the MSPB measure which assesses total spending per beneficiary. The MSPB measure also includes spending in non-acute settings such as SNFs, which are not part of the Excess Days outcome. Thus, the Excess Days measure captures a range of specific postdischarge outcomes that are important to patients, such as readmissions, observation stays, and ED visits. The cohort includes Medicare FFS patients aged 65 years or older: (1) With a principal discharge diagnosis of pneumonia, a principal discharge diagnosis of aspiration pneumonia, or a principal discharge diagnosis of sepsis (not including severe sepsis) who also have a secondary diagnosis of pneumonia present on admission; (2) enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission, and enrolled in Part A during the index admission; (3) who were discharged from a non-Federal acute care hospital; (4) who were not transferred to another acute care facility; and (5) who were alive at discharge.

In response to the commenter's request about how performance for the PN Excess Days measure differs from the current readmission measure, we interpret the commenter to be referring to the READM–30–PN measure. That measure and the PN Excess Days measure assess different outcomes. Although both measures count readmission, the READM–30–PN measure only informs a hospital if a patient had a readmission, and does not include all postdischarge outcomes that matter to patients, such as having to return to the ED or spending time in the hospital under observation, like the PN Excess Days measure does. The PN Excess Days measure provides patients a more comprehensive and patient-centered perspective on the 30-day postdischarge experience because it includes not only readmissions, but also ED visits and observation stays and captures the numbers of days in these settings.

Comment: One commenter believed that the proposed PN Excess Days measure would not add additional value and does not address the effects of the ''2-midnight'' policy.

Response: We understand that commenters have concerns about the interaction between Medicare payment policy regarding admissions spanning two midnights and the PN Excess Days measure. The ''2-midnight'' policy provides guidance as to when an inpatient admission is appropriate for payment under Medicare Part A, but does not help beneficiaries to select providers or to understand postdischarge acute care use. The proposed PN Excess Days measure aims to capture all postdischarge acute care days, regardless of whether they are considered outpatient or inpatient. Therefore, the ''2-midnight'' policy or any changes to such policy will not influence the outcome of these measures, as all postdischarge days in acute care are captured whether they are billed as outpatient or inpatient days. When we finalized the AMI Excess Days and HF Excess Days measures for the FY 2018 payment determination and subsequent years, stakeholders expressed concern about the interaction between Medicare payment policy regarding admissions spanning two midnights and the AMI Excess Days and HF Excess Days measures (80 FR 49686 through 49687). We continue to believe that the ''2-midnight'' policy or any changes to such policy will not influence the outcome of Excess Days in Acute Care measures, as all postdischarge days in acute care are captured whether they are billed as inpatient or outpatient days (80 FR 49686 through 49687).

Comment: Several commenters expressed concern that hospitals might be penalized twice for the same readmission, once through the existing readmission measure in Hospital Readmissions Reduction Program and again through the ''excess days'' measure in Hospital VBP Program (if and when the ''excess days'' measures are incorporated into the Hospital VBP Program).

Response: The Hospital VBP Program cannot adopt this measure, as section 1886 (o)(2)(A) of the Act prohibits readmission measures under the Hospital VBP Program. With respect to commenters' expressed concern that hospitals might be penalized twice for the same readmission, since readmission measures cannot be adopted into the Hospital VBP Program, hospitals cannot be penalized through the existing readmission measure in Hospital Readmissions Reduction Program and through the ''excess days'' measure for the same condition in Hospital VBP Program.

For the Hospital IQR Program, the Excess Days measures are calculated using Medicare administrative claims data, and regardless of hospitals' performance on the measures, hospitals would receive credit for submitting the information under the Hospital IQR Program. Therefore, we do not believe hospitals would be penalized twice because they are not being asked to submit additional information and payment will not be adjusted based on performance of this measure. The PN Excess Days measure is not being proposed for use in a pay-for-performance program (such as the Hospital VBP Program), only for use in the pay-for-reporting Hospital IQR Program.

Comment: Some commenters had reservations about the interpretability of the measure score and providers' ability to take meaningful actions that would have an impact on patient outcomes.

Response: We disagree that providers do not have the ability to take meaningful actions that would have an impact on patient outcomes as a result of adopting the PN Excess Days measure. The measure spotlights the excess number of days patients spend in acute care (hospital readmissions, observation stays, and ED visits) per 100 discharges during the first 30 days after discharge from the hospital, relative to the number spent by the same patients discharged from an average hospital. We believe the information provided to hospitals through this measure will help inpatient and outpatient providers better understand the trajectory of care for patients that have been discharged from their facility. Specifically, hospitals will be able to assess whether patients discharged from their facility have readmissions, observation stays, and/or ED visits during the first 30 days after discharge from the hospital. Because the measure provides more granular information regarding patient discharge outcomes, this will assist hospitals in developing targeted quality improvement activities aimed at improving transitions of care. We believe that the measure will reduce readmissions, observation stays, and/or ED visits by encouraging hospitals to further invest in interventions to improve hospital care by better assessing the readiness of patients for discharge and facilitating quality transitions to outpatient status.

Comment: Some commenters suggested that CMS provide hospital-specific, confidential reports to hospitals to allow them to undertake quality improvement efforts, without including the measure in the Hospital

IQR Program or publicly reporting measure data.

Response: We disagree that the measure should not be included in the program or publicly reported as this is an important aspect of quality that addresses the NQS and CMS Quality Strategy priority to promote effective communication and coordination of care that should be measured. Hospitals will have the opportunity to review their data via their hospital-specific reports (HSRs) during the preview period before public reporting of this measure.

Comment: Several commenters did not support the proposal to adopt the PN Excess Days measure due to a lack of clear or consistent evidence to suggest hospitals are using observation stays and ED visits to avoid being penalized for readmissions. Commenters also noted that recent research from ASPE suggests that hospitals are not using observation status as a way to avoid triggering a readmission or to decrease readmission rates.

Response: We understand the commenters' concern regarding the uncertainty of hospitals' use of observation stays in place of readmissions. The development of this measure was not primarily motivated by a concern that hospitals are using ED visits or observation stays to avoid readmission, but rather to provide a more comprehensive perspective on postdischarge events that are important to patients.

Comment: One commenter noted that the PN Excess Days measure does not account for situations when it may be appropriate for a patient to return to the hospital for care. The commenter stated that there are factors beyond the hospitals' control that may contribute to higher excess days. A few commenters did not support the adoption of the proposed PN Excess Days measure because the measure combines readmissions, observation stays, and ED visits into a single number of days, but each of these episodes reflect widely different approaches to patient-centered care and cannot be interpreted from a single number. One commenter expressed concern with the decision to equate the costs and intensity in observation and ED care with that of inpatient care when they are treated differently for payment purposes.

Response: We do not dismiss the importance of hospital-level care and support hospitals using the level of care most appropriate for each particular patient's condition. We agree with the commenter that some returns to the acute care setting are necessary. The goal is not to avoid all postdischarge acute care service utilization, but to identify excess use of acute care postdischarge. Acute care utilization after discharge (that is, return to the ED, observation stay, and readmission), for any reason, is disruptive to patients and caregivers, costly to the healthcare system, and puts patients at additional risk of hospital-acquired infections and complications. Although some factors are outside hospitals' control, when appropriate care transition processes are in place (for example, a patient is discharged to a suitable location, communication occurs between clinicians, medications are correctly reconciled, timely follow-up is arranged), fewer patients return to an acute care setting, whether for an ED visit, observation stay, or hospital readmission during the 30 days postdischarge. Numerous studies have found an association between quality of inpatient or transitional care and early (typically 30-day) readmission rates and ED visits for a wide range of conditions including PN.[149] [150] [151] [152] [153] [154]

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49688), similar concerns were raised for two related measures, AMI and HF Excess Days, around combining readmissions, observations stays, and ED visits into a single number. We believe from a patient perspective, it is the count of total days that is most meaningful and representative of the disruption, which is why we combine day counts for each type of event and do not separately report rates of each type of event. This day count is also valuable for hospitals, because a hospital with a high number of ED visits may still be able to achieve a low number of total days in acute care by actively coordinating care from the ED and avoiding rehospitalizations. The measure combines these three visit types based on the concept that the rate of each type of event is not as relevant to patients as the total days that they spend in acute care settings. Therefore, the PN Excess Days measure provides a broader perspective on postdischarge events than the current READM–30–PN measure and is intended to incentivize improvements in care transitions from the hospital so that patients are less likely to return to the acute setting.

Regarding the commenter's concern with the decision to equate the costs and intensity in observation and ED care with that of inpatient care, we agree that all acute care utilization is not equal in its disruption, cost, or risk to patients. In the PN Excess Days measure, the weight of events (such as observation or ED care) is determined by the intensity of care delivered to patients. Prolonged acute care is more costly and worse from a patient perspective than a brief ED visit. That is why we elected to report the PN Excess Days measure as a count of days: Events lasting longer with more cost and disruption (such as readmissions), therefore, naturally weigh more than brief events (such as ED visits) in the overall day count.

Comment: One commenter specifically disagreed with counting ED visits as half days, because the majority of ED visits last much less time than that.

Response: We appreciate the commenter's concern on considering ED treat-and-release visits as half a day. The average length of stay for a treat-and-release patient from the ED is approximately four hours.[155] [156] Furthermore, based on this information, we received feedback from the TEP advising that we consider a treat-and-release ED visit to be equivalent to one half day. A shorter length of stay may not capture the full burden on the patient to return to the hospital (for example, travel time and lost work time).

Comment: Some commenters expressed concern that ''excess days'' do not represent an actionable or meaningful measure of quality for the provider because more complex patients with comorbidities may require more days in an acute care setting.

Response: We disagree with the commenters' concern that ''excess days'' do not represent an actionable or meaningful measure of quality for the

[149] Dean NC, Bateman KA, Donnelly SM, Silver MP, Snow GL, Hale D. Improved clinical outcomes with utilization of a community-acquired pneumonia guideline. Chest. 2006;130(3):794–799.

[150] Coleman EA, Parry C, Chalmers S, et al. 2006. The care transitions intervention: results of a randomized controlled trial. Arch Intern Med 166:1822–1828.

[151] Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. J Am Geriatr Soc 2004;52(11):1817–25.

[152] Mistiaen P, Francke AL, Poot E. Interventions aimed at reducing problems in adult patients discharged from hospital to home: a systematic metareview. BMC Health Serv Res 2007;7:47.

[153] Leppin AL, Gionfriddo MR, Kessler M, et al. Preventing 30-day hospital readmissions: a systematic review and meta-analysis of randomized trials. JAMA Internal Med. 2014; 174(7):1095–107.

[154] Hansen LO, Young RS, Hinami K, et al. Interventions to reduce 30-day rehospitalization: a systematic review. 2011; 155(8):520–8.

[155] Horwitz LI, Green J, Bradley EH. United States emergency department performance on wait time and length of visit. Annals of emergency medicine. 2010;55(2):133–141.

[156] Karaca Z, Wong HS, Mutter RL. Duration of patients' visits to the hospital emergency department. BMC Emergency Medicine. 2012;12(1):1–14.

provider. We have developed the PN Excess Days measure to try to provide important patient-centered information to providers. The measure supports existing hospital incentives to further invest in interventions and tools to improve hospital care, better respond to individual patient preferences, better assess patient readiness for discharge, and facilitate transitions to outpatient status. Such interventions and tools will reduce the likelihood of patients having any return to the hospital and make it more likely that patients who do return have less severe illnesses which may require fewer days of care.

Comment: Some commenters opposed the addition of the PN Excess Days measure, noting that the measure includes a cohort of patients with multiple risk levels and is not a clear indicator of quality.

Response: We understand that hospitals have complex patients with varying comorbidities. Although the cohort may contain patients with different disease severity, and therefore, different levels of risk, the measure accounts for this range of severity and risk because it is risk-adjusted for 41 factors that are clinically relevant and have strong relationships with the outcome of acute care utilization. Furthermore, the measure is intended to help patients and providers understand variations among hospitals in the days that are spent by patients in acute care settings following a discharge for pneumonia. The cohort for the PN Excess Days measure is aligned with the cohort for the READ–30–PN measure. For more details about the risk-adjustment methodology, we refer readers to the ''Excess Days in Acute Care after Hospitalization for Pneumonia Version 1.0'' methodology report in the Pneumonia Excess Days in Acute Care zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

The measure's cohort was reviewed by clinical experts and a TEP and was subject to a separate period for public input that was publicly posted on CMS' Public Comment Web site for measures under development, prior to being proposed for the Hospital IQR Program. During measure development, public comment is sought via several avenues of communication. These include: (1) Posting the call for public comment to the CMS Measures Management System (MMS) Web site (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html*); (2) sending emails to stakeholders, including via CMS listservs; and (3) conducting outreach through the Electronic Clinical Quality Improvement (eCQI) Resource Center. These stakeholders agreed with harmonizing the cohort and risk-adjustment model of the PN Excess Days measure with those of the READM–30–PN measure. As a result, we believe this is a clinically coherent cohort. As it is our practice, we will continue to monitor how hospital performance may be influenced by hospital type.

Comment: Commenters expressed concern that no link to measure specifications was provided in the proposed rule.

Response: As noted in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25192), for measure specifications, we refer readers to the ''Excess Days in Acute Care after Hospitalization for Pneumonia Version 1.0'' methodology report in the Pneumonia Excess Days in Acute Care zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

After consideration of the public comments we received, we are finalizing the adoption of Excess Days in Acute Care after Hospitalization for Pneumonia (PN Excess Days) measure for the FY 2019 payment determination and subsequent years as proposed.

c. Summary of Previously Adopted and Newly Finalized Hospital IQR Program Measures for the FY 2019 Payment Determination and Subsequent Years

The table below outlines the Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years, and includes both previously adopted measures and measures newly finalized in this final rule. Measures finalized for removal in section VIII.A.3.b. of the preamble of this final rule are not included in this chart.

HOSPITAL IQR PROGRAM MEASURE SET FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF #
	NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
	Chart-abstracted	
ED–1 *	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients	0497
Imm-2	Influenza Immunization	1659
PC–01 *	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
VTE–6	Incidence of Potentially Preventable Venous Thromboembolism	(+)

HOSPITAL IQR PROGRAM MEASURE SET FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
	Claims-based Outcome	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–STK	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke.	N/A
READM–30–AMI	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0505
READM–30–CABG	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2515
READM–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1891
READM–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization.	0330
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
READM–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization.	0506
READM–30–STK	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization	N/A
READM–30–THA/TKA	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1551
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	N/A
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	N/A
PN Excess Days**	Excess Days in Acute Care after Hospitalization for Pneumonia	N/A
Hip/knee complications	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04	Death Rate among Surgical Inpatients with Serious Treatable Complications	0351
PSI 90	Patient Safety for Selected Indicators Composite Measure, Modified PSI 90 (Updated Title: Patient Safety and Adverse Events Composite).	0531
	Claims-based Payment	
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158
Cellulitis Payment	Cellulitis Clinical Episode-Based Payment Measure	N/A
GI Payment	Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure	N/A
Kidney/UTI Payment	Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure	N/A
AA Payment**	Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure	N/A
Chole and CDE Payment**	Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure	N/A
SFusion Payment**	Spinal Fusion Clinical Episode-Based Payment Measure	N/A
	Electronic Clinical Quality Measures (eCQMs)	
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	(+)
ED–1*	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2*	Admit Decision Time to ED Departure Time for Admitted Patients	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
PC–01*	Elective Delivery	0469
PC–05	Exclusive Breast Milk Feeding***	0480
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
STK–08	Stroke Education	(+)
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371

HOSPITAL IQR PROGRAM MEASURE SET FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Survey		
HCAHPS	HCAHPS + 3-Item Care Transition Measure (CTM-3)	0166, 0228
Structural Measures		
Patient Safety Culture	Hospital Survey on Patient Safety Culture	N/A
Safe Surgery Checklist	Safe Surgery Checklist Use	N/A

* Measure listed twice, as both chart-abstracted and electronic clinical quality measure.
** Newly finalized measures for the FY 2019 payment determination and for subsequent years.
*** Measure name has been shortened. Please refer to annually updated electronically clinical quality measure specifications on the CMS eCQI Resource Center Page for further information: *https://www.healthit.gov/newsroom/ecqi-resource-center*.
+ NQF endorsement has been removed.

8. Changes to Policies on Reporting of eCQMs

For a discussion of our previously finalized eCQMs and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709).

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25194 through 25196), we proposed two changes to our policies with respect to eCQMs reporting to require that hospitals: (1) Submit data for an increased number of eCQMs as further detailed below; and (2) report a full year of data. These proposals were made in conjunction with our proposals discussed in section VIII.A.3.b.(3) of the preamble of this final rule to remove 13 eCQMs from the Hospital IQR Program and proposals discussed in sections VIII.A.10.d. and VIII.E.2.b. of the preamble of this final rule to align requirements for the Hospital IQR and the Medicare and Medicaid EHR Incentive Programs.

In addition, we are clarifying that for three measures (ED–1, ED–2, and PC–01), our previously finalized policy that hospitals must submit a full year of chart-abstracted data on a quarterly basis, regardless of whether data also are submitted electronically, continues to apply.

a. Requirement That Hospitals Report on an Increased Number of eCQMs in the Hospital IQR Program Measure Set for the CY 2017 Reporting Period/FY 2019 Payment Determination and Subsequent Years

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698), we finalized our policy to require hospitals to submit one quarter of data (either Q3 or Q4) for 4 self-selected eCQMs for the CY 2016 reporting period/FY 2018 payment determination by February 28, 2017. Furthermore, in that final rule (80 FR 49694), we signaled our intent to propose increasing the reporting requirement to 16 eCQMs in future rulemaking. In the proposed rule, we proposed to require reporting of a full calendar year of data for all available eCQMs in the Hospital IQR Program measure set for the CY 2017 reporting period/FY 2019 payment determination and subsequent years.

Requiring hospitals to electronically report a greater number of eCQMs furthers our goal of expanding electronic reporting in the Hospital IQR Program, which we believe will improve patient outcomes by providing more robust data to support quality improvement efforts. As stated above, this proposal is made in conjunction with our proposals discussed in section VIII.A.3.b.(3) of the preamble of this final rule to remove 13 eCQMs from the Hospital IQR Program and proposals discussed in sections VIII.A.10.d. and VIII.E.2.b. of the preamble of this final rule to align requirements for the Hospital IQR and the Medicare and Medicaid EHR Incentive Programs. In addition, as discussed in section VIII.A.3.b.(3) of the preamble of this final rule, we believe that removing certain eCQMs for which the chart-abstracted versions have been determined to be ''topped-out'' will reduce certification burden and implementation hurdles, enabling hospitals to focus efforts on successfully implementing a smaller subset of eCQMs. In the proposed rule, we stated that if our proposals to remove 13 eCQMs in section VIII.A.3.b.(3) of the preamble of the proposed rule were finalized as proposed, hospitals would be required to report on a total 15 eCQMs for the CY 2017 reporting period/FY 2019 payment determination. While the number of required eCQMs would increase as compared to that required for the CY 2016 reporting period/FY 2018 payment determination (that is, from 4 to 15 eCQMs), we believe that a coordinated reduction in the overall number of eCQMs (from 28 to 15 eCQMs) in both the Hospital IQR and Medicare and Medicaid EHR Incentive Programs will reduce certification burden on hospitals and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of eCQMs.

In crafting this proposal, we also considered proposing to require a lesser number of eCQMs—that hospitals submit 8 of the available eCQMs (that is, in other words, 8 of the proposed 15 eCQMs as discussed above) for the CY 2017 reporting period/FY 2019 payment determination. Specifically, hospitals would submit a full calendar year of data on an annual basis for 8 of the available eCQMs whether reporting only for the Hospital IQR Program or if reporting for both the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program for the CY 2017 reporting period/FY 2019 payment determination. Reporting on all eCQMs in the Hospital IQR Program measure set would begin with the CY 2018 reporting period/FY 2020 payment determination and subsequent years.

Ultimately, we chose to propose to require reporting on all the proposed eCQMs for the CY 2017 reporting period/FY 2019 payment determination, because we believe that requiring hospitals to report measures electronically is consistent with our goals to move towards eCQM reporting and to align with the Medicare and

Medicaid EHR Incentive Programs. We believe that the FY 2019 payment determination is the appropriate time to require eCQM reporting because hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and Hospital IQR Program (3 years of voluntary reporting and 3 years of reporting as part of a pilot). Based upon data collected by CMS, currently, 95 percent of hospitals attest to successful eCQM reporting under the Medicare and Medicaid EHR Incentive Programs.

We invited public comment on our proposal to require hospitals to report on all eCQMs in the Hospital IQR Program measure set beginning with the CY 2017 reporting period/FY 2019 payment determination.

Comment: A few commenters supported the proposed requirement that hospitals report on all eCQMs in the Hospital IQR Program measure set because: (1) The majority of hospitals have attested to having implemented these eCQMs in the Meaningful Use program and many have now had five years of experience; (2) almost all performance related issues in these measures stem from difficulty aligning data sources, which in turn causes clinical workflow and data mapping as the main problems, but fixing these almost always improves the performance scores; (3) CMS will not use these data for payment adjustments and public reporting, which should give eligible hospitals and CAHs some level of comfort; (4) eligible hospitals and their vendors are unlikely to submit any eCQM data electronically on a volunteer basis; (5) CMS needs to have these data for the type of analysis necessary for improvement; and (6) the proposal aligns with the EHR Incentive Program and continues to tie hospital payment to submission of quality data.

Response: We thank the commenters for their support of our original proposal.

Comment: Many commenters supported the concept of electronic reporting but did not support the proposed requirement that hospitals report on all eCQMs in the Hospital IQR Program measure set beginning with the CY 2017 reporting period because they believed the significant increase in number of required eCQMs with such an aggressive timeline would pose an undue burden on hospitals. Commenters raised specific issues such as difficulty making required changes to health IT systems, documentation or utilization of EHRs in much more granular detail than is often necessary for clinical care, and workflow process changes in the short period of time between the publication of this final rule and the beginning of the CY 2017 reporting period. Commenters expressed concern about the significant expenditure of resources that additional required eCQM reporting imposes on hospitals in terms of both staff time and finances. Several commenters did not support the proposed requirement that hospitals report on all eCQMs in the Hospital IQR Program because of concerns about general feasibility, accuracy, validity, and reliability of electronically-submitted measures.

Commenters also expressed concern that the rush to implement the changes necessary to satisfy reporting requirements for an additional nine eCQMs by CY 2017 would result in errors and unreliable, inaccurate data submissions. One commenter noted that the dramatic increase in number of required eCQMs over such a short period of time could cause delays in coding the files and therefore, cause delays in submitting the eCQMs by the established deadline. In addition, the proposed timeline fails to allow sufficient time if problems arise with the Quality Reporting Document Architecture Category I (QRDA I) files and/or pre-submission validation efforts. The commenter requested that CMS consider moving the deadline to a more feasible date such as March 31, 2018 or later. Another commenter expressed concern that hospitals currently are struggling with the degree of technical difficulty involved in extracting the measures from their EHRs and noted that hospitals have had limited experience with eCQM submission (the first required transmission of four measures is not until the third or fourth quarter of CY 2016). The commenter urged CMS to reconsider expansion of this requirement until a review of the CY 2016 transmission results has been completed and hospitals have received feedback.

Several commenters suggested that CMS consider amending the proposal to require an addition of 2 to 4 eCQMs required for a total of 6 to 8, for the CY 2017 reporting period. One commenter recommended that CMS reduce the proposed requirement to report on 8 eCQMs. Other commenters requested that CMS retain the current requirement of 4 eCQMs until hospitals have successfully operationalized reporting complete and accurate data on existing required eCQMs before adding new measures.

Response: We appreciate commenters sharing their concerns about the challenges associated with eCQM reporting, including the significant expenditure of resources required to make necessary changes to health IT systems, documentation or utilization of EHRs, and workflow process changes and acknowledge commenters' feedback that many hospitals may not be ready to successfully report on all of the available eCQMs beginning with the CY 2017 reporting period/FY 2019 payment determination. In response to commenter concerns that the proposed timeline fails to allow sufficient time if problems arise with the QRDA I files and/or pre-submission validation efforts, that we should push back the deadline, and that hospitals have had limited experience with eCQM submission, we disagree. Hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and Hospital IQR Program (3 years of voluntary reporting and 3 years of reporting as part of a pilot).

More specifically, previously we have requested electronic QRDA I submission. As described in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50905), electronic reporting pilots for the EHR Incentive Program from 2012 and 2013 included electronic reporting using the QRDA I file format. Further, in that same rule, we encouraged the use of QRDA I files since we finalized a proposal that would allow hospitals to begin voluntarily reporting eCQMs (78 FR 50817 through 50818). Therefore, we believe that hospitals have had adequate time to understand and correct any processing issues that may arise during data submission and we believe that the CY 2017 reporting period/FY 2019 payment determination is the appropriate time to require additional eCQM reporting. Delaying the implementation of electronic reporting would hinder our efforts to validate, and thereby improve the reliability and validity of electronic data.

We believe that increasing the requirements for hospitals to report measures electronically is consistent with our goal to make progress towards eventual reporting on all eCQMs in the Hospital IQR Program, but we also appreciate commenters' feedback to continue to do so in a stepwise manner. We believe that retaining the reporting requirements previously established for the CY 2016 reporting period/FY 2018 payment determination (that is, require reporting on 4 eCQMs) would not help in this improvement approach.

We believe that increasing the number of required eCQMs to be reported from 4, as currently required, but requiring a lesser number of eCQMs than originally proposed (that is, all available eCQMs)

would continue to allow hospitals flexibility and choice in reporting eCQMs, while still furthering our goal of moving towards full implementation of reporting on all eCQMs in a stepwise manner while being responsive to hospitals' concerns about timing, readiness, and burden associated with the increased number of measures required to be reported. However, we note that it is still our intent to require reporting on all eCQMs in the Hospital IQR Program in the near future. We believe that reducing the required number of eCQMs from all, as proposed, to 8 for the CY 2017 and CY 2018 reporting periods balances hospitals' request to have more time to improve and refine their eCQM reporting capabilities, including to address challenges such as data mapping issues, while still furthering CMS' goals to expand electronic data reporting and validation.

In determining the number 8, we considered that reporting of 8 eCQMs is about midway between the current required reporting of 4 eCQMs and the proposed required reporting of all 15 eCQMs. We note that hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program (3 prior years of pilot reporting and 3 prior years of voluntary reporting). In addition, because 95 percent of hospitals currently attest to successful eCQM reporting under the EHR Incentive Program, we believe that the majority of hospitals should be ready to successfully report on more than 4 eCQMs beginning with the CY 2017 reporting period/FY 2019 payment determination. We believe that only requiring 6 eCQMs (only 2 more than already required) as suggested by some commenters, does not adequately advance our goal of moving toward requiring all eCQMs in the near future. We must balance the importance of keeping pace with evolving electronic standards and the timing cycle for the regulatory adoption of standards when adopting policies for the Hospital IQR Program.

As described in section VIII.A.11.b.(3) of the preamble of this final rule, we intend to address concerns about the reliability of electronic data through validation. In order to be able to effectively validate eCQM data, we need to continuously assess more data. Moreover, we believe that it is appropriate to require reporting and validation of eCQMs given that measures available now and those being developed for the future are increasingly based on electronic standards (80 FR 49696). Lastly, requiring 8 eCQMs promotes alignment between the Hospital IQR Program measure set and the Medicare and Medicaid EHR Incentive Programs.

Therefore, after consideration of the public comments we received, we are finalizing a modified version of our proposal. Instead of requiring hospitals to report on all eCQMs in the Hospital IQR Program measure set beginning with the CY 2017 reporting period/FY 2019 payment determination, we are finalizing a policy to require submission of 8 self-selected eCQMs out of the available eCQMs in the Hospital IQR Program for the CY 2017 reporting period/FY 2019 payment determination and CY 2018 reporting period/FY 2020 payment determination. In other words, hospitals would submit a full calendar year (that is, 4 quarters) of data by an annual submission deadline for 8 of the available eCQMs whether reporting only for the Hospital IQR Program or if reporting for both the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs for both the FY 2019 and 2020 payment determinations. We intend to determine requirements for beyond the FY 2020 payment determination in future rulemaking.

Although we are not finalizing our original proposal to require reporting on all eCQMs, we encourage hospitals to continue refining their electronic reporting implementation activities to successfully achieve electronic data capture and reporting despite mapping and integration issues or to work with their vendors to do so. In addition, we encourage early testing and the use of presubmission testing tools to reduce errors and inaccurate data submissions in eCQM reporting. As time passes, we expect that hospitals will continue to build and refine their EHR systems and gain more familiarity with reporting eCQM data, resulting in more accurate data submissions with fewer errors. We believe that the best way to encourage hospitals to invest in improving their EHR systems is by requiring reporting of additional eCQMs.

Comment: Some commenters recommended that CMS increase its education and outreach efforts to help hospitals better prepare for eCQM reporting. Other commenters recommended that CMS continue outreach to EHR vendors, hospital quality staff, and other affected stakeholders to identify and address structural problems prior to increasing the number of required eCQMs. Further, the commenter requested that CMS take into consideration the factors associated with difficulties in eCQM reporting, such as new software, changes to workflows, training staff, and testing, that may require additional time to vet as a means of ensuring hospital readiness.

Response: As we move forward with advancing electronic submission of quality measures and eCQM validation, we will bolster our education and outreach efforts and ensure that all affected stakeholders have the opportunity to provide feedback on the implementation of eCQM reporting. We will continue to share these results in education and outreach to hospitals. We will also consider the issues associated with new software, workflow changes, training, et cetera as we continue to improve our education and outreach efforts for eCQM submission and validation.

Comment: A few commenters did not support required reporting of any eCQMs in the Hospital IQR Program measure set because of challenges associated with eCQM reporting. Some commenters noted that the infrastructure and reporting functionality for eCQMs are not mature enough to facilitate mandatory electronic reporting for hospitals. Other commenters indicated that EHR vendors are not prepared for the functional and operational demands of an increase in eCQM reporting. A few commenters urged CMS to reach out to EHR vendors and other stakeholders to identify underlying structural problems and barriers to successful reporting on these measures. One commenter stated that the increase in required eCQMs may jeopardize hospitals' efforts to meet the current requirements, as vendors are not prepared to handle providers' requests to augment their eCQMs on an annual basis. Further, this commenter urged CMS to align vendors and providers requiring vendors to support all eCQMs in certified EHR products that are required by CMS. A few commenters expressed concern about the role of the EHR vendors, not the hospitals, in using the correct version of specifications.

Another commenter expressed the opinion that although eCQMs are supposed to reduce provider burden for quality reporting, in reality they increase provider burden by disrupting workflow and requiring providers to document detailed information in structured fields which may not appropriately reflect the clinical situation, while negatively impacting the quality of the data being reported. The commenter urged CMS to set standards for EHR vendors to ensure the EHR is structured in a way that fits in with the clinical work flow to restore focus to patient-centered care that

promotes high quality outcomes and lower costs. One commenter also noted that the eCQM specifications have serious flaws that prove challenging with current clinical workflows, given how EHRs track orders and documentation and in some cases the measure specifications do not accurately measure the quality of care delivered, absent the development of manual workarounds that divert time and resources from patient care. These commenters recommended delaying any mandatory reporting of eCQMs until these concerns are resolved.

Response: We thank the commenters for their recommendations but note that we believe requiring electronic reporting aligns with CMS and HHS policy goals to promote quality through performance measurement and that in the intermediate- to long-term, electronic reporting will both improve the accuracy of the data and reduce reporting burden for providers. Our focus is to improve hospital quality. However, we encourage hospitals that retain vendors to work closely together to ensure that a contract is in place which supports the hospital's quality reporting requirements and the annual update of quality measures. We believe that vendor retention would help to alleviate some of the concerns associated with the infrastructure and reporting functionality for eCQMs as expressed by some commenters.

When hospitals work with their vendors to ensure that EHRs are appropriately structured in a way that fits in with the clinical work flow to yield reliable data through eCQMs, we believe that eCQMs promote high quality outcomes and lower costs while ultimately decrease reporting burden on hospitals.

In response to commenters' concerns that EHR vendors are not prepared for the functional and operational demands of an increase in eCQM reporting, we note that hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program (3 years of pilot reporting and 3 years of voluntary reporting). As stated previously, 95 percent of hospitals attest to successful electronic clinical reporting under the Medicare EHR Incentive program. We thank commenters for their suggestion to reach out to EHR vendors and other stakeholders to identify underlying structural problems and barriers to successful reporting on these measures, and we will continue to work with stakeholders to overcome barriers to successful eCQM reporting.

We appreciate the commenter's concern that an increase in required eCQMs may jeopardize hospitals' efforts to meet the current requirements, as vendors are not prepared to handle providers' requests to augment their eCQMs on an annual basis, but we believe that our finalized policy requiring a lesser number of eCQMs than originally proposed (that is, all available eCQMs) provides hospitals with sufficient time to augment their eCQMs and satisfy electronic reporting requirements. We will take the commenter's note about the alignment of vendors and their concern about the role of the EHR vendors, not the hospitals, in using the correct version of specifications, into account as we work to improve our education and outreach efforts.

In response to concerns about the burden and difficulty with technical mapping, we recognize that technical mapping may initially be burdensome for some hospitals, however, we believe that the efforts to properly map data elements to structured data fields will be beneficial in both improved accuracy of the data reported and reduced reporting burden in the intermediate- to long-term. In addition, we believe that if hospitals and EHR vendors and health IT developers continue to refine EHR systems to appropriately structure them commensurate with the clinical work flow, this will lead to improved accuracy, reliability, and completeness of the eCQM data, which will promote high quality outcomes and lower costs while ultimately decreasing reporting burden on hospitals as compared with chart-abstraction of quality measure data.

Finally, we refer readers to our modified final policy to only require 8 eCQMs as discussed above. We believe this policy balances the burden on hospitals and vendors with our policy goal to move towards increased electronic reporting. In addition, as we describe in section VIII.A.11.b.(3) of the preamble of this final rule, we are modifying our validation process to include electronic clinical quality measures. The implementation of eCQM data validation will be able to better reconcile the observed measure specification issues.

Comment: A few commenters expressed concern that requiring reporting on all available eCQMs would require facilities to provide data for measures that reflect services they do not provide. Commenters acknowledged the ''zero denominator'' reporting option, but maintained that reporting a zero denominator would still place undue burden on facilities. One commenter stated that the increase in reporting would force facilities to implement new builds, new workflows, and could potentially have to do substantial rework with the Clinical Quality Language (CQL) [157] implementation for measures not previously reported. A few commenters asked for clarification about whether they would be required to submit eCQM data for PC–05 and CAC–3 since they have not previously submitted data on these measures.

One commenter requested that CMS increase the minimum case exemption threshold for eCQMs because it is difficult to implement eCQMs when there are low benefits to the hospital due to small patient populations. Another commenter expressed the opinion that reporting on an increased number of eCQMs has no direct correlation to improvement in quality because there are instances where a facility would be required to report on an eCQM that refers to care that is not provided at that hospital. Some commenters suggested that reporting for all of the available eCQMs should not be mandatory and that hospitals should be allowed to select which specific eCQMs to report on to ensure the information captured would prove meaningful.

Response: We acknowledge the commenters' concern with small patient populations and will explore the minimum case exemption threshold for eCQMs as we continue to evolve our electronic reporting requirements in future rulemaking. We currently allow hospitals to enter a value of zero to demonstrate that they had no clinical cases. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50323 through 50324) where we discuss the details of our requirements for the minimum exemption threshold. As previously stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49695), for the CY 2017 reporting period/FY 2019 payment determination and CY 2018 reporting period/FY 2020 payment determination, utilization of the zero denominator declaration and case threshold exemptions are considered as part of the criteria for successful submissions when reporting eCQMs for the to the Hospital IQR and Medicare and Medicaid EHR Incentive Programs. Therefore, we do not believe any undue

[157] Clinical Quality Language (CQL) is an HL7 draft standard that is part of the effort to harmonize standards between electronic clinical quality measures (eCQMs) and clinical decision support (CDS). CQL provides the ability to express computer logic that is human readable yet structured enough for processing a query electronically. More information is available at the eCQI Resource Center at: *https://ecqi.healthit.gov/cql.*

burden will be placed on hospitals that elect to utilize this declaration, as it is a policy that has been in place for 2 calendar years of reporting. The submission of zero denominator declarations and case threshold exemptions for the CY 2016 reporting period continues to be completed through the QualityNet Secure Portal.

Further, as we learn more through eCQM validation, we intend to publicly report the eCQM data results so that hospitals that do not provide care for certain populations will be able to benchmark (evaluate by comparison with results provided by hospitals that do provide care for those populations) data. We understand the importance of having accurate measure data, however, the only way to readily identify issues is to review more data. We believe that our finalized policy to require submission of only 8 eCQMs serves to incrementally increase electronic reporting, as suggested by commenters, while also allowing us to collect data derived from EHRs to further our plans for electronic data collection and validation. In addition, the finalized policy to require submission of 8 eCQMs allows hospitals the flexibility to select the eCQMs that are least burdensome and do not require new builds, new workflows, or rework with the CQL implementation for measures not previously reported. Implementation of any new measure not previously reported will impose some additional burden, but our finalized policy enables hospitals to choose and prioritize which eCQMs to build into their systems in the order most convenient for their particular circumstances and case mix. Moreover, allowing hospitals to select 8 eCQMs addresses the commenter's concern that reporting on an increased number of eCQMs has no direct correlation to improvement in quality because there would not be instances where a facility would be required to report on an eCQM that refers to care that is not provided at that hospital; hospitals have the option of reporting those eCQMs that are most relevant to their patient population to ensure that information captured proves meaningful. We refer readers to section VIII.A.8.a. of the preamble of this final rule for details about our finalized policy to require submission of only 8 eCQMs.

Comment: Some commenters stated that requiring hospitals to collect electronic data for measures that still have flawed specifications is inefficient and burdensome.

Response: We disagree that specifications are flawed and encourage hospitals to work with vendors to gain experience with the eCQM specifications and how to fully integrate them into their EHRs. We believe that our modified policy to require submission of 8 self-selected eCQMs out of the available eCQMs in the Hospital IQR Program provides hospitals flexibility to select eCQMs for which they have familiarity with the technical specifications and for services they do provide.

Comment: One commenter cited difficulty manipulating the reporting Structured Query Language (SQL), obscure or unnecessary measure data points, the redundancy of the measure data points, and the bottleneck created by the role of EHR vendors and developers in the reporting workflow. Specifically, the commenter stated that modifications of the SQL require the acquisition of professionals with specialized skills in the functionality and utility of CEHRT, a strong working knowledge of programming and an understanding of the eCQM process. The commenter asserted that highly-skilled professionals are expensive to acquire and difficult to retain within hospitals.

Response: In response to the commenter that cited difficulty manipulating the reporting SQL, obscure or unnecessary measure data points, the redundancy of the measure data points, and the bottleneck created by the role of CEHRT vendors in the reporting workflow, we believe that increased reporting would help to mature workflows, and over time, mitigate some, if not all, of these additional concerns. We acknowledge the commenter's assertion that highly-skilled professionals are expensive to acquire and difficult to retain within hospitals, however, we believe that as more professionals gain knowledge, training, and experience with electronic standards and reporting and fill this need in the labor market, this challenge will be reduced. In addition, we encourage hospitals to work with and retain their vendors to fulfill their EHR system needs. When hospitals work more closely with their vendors to ensure that EHRs are appropriately structured in a way that fits in with the clinical work flow to yield reliable data through eCQMs, we believe that eCQMs promote high quality outcomes and lower costs while ultimately decrease reporting burden on hospitals. We encourage hospitals to be educated about the existing practices, while still reserving the right to establish protocols that most accurately and efficiently support their clinical workflow.

Comment: One commenter stated that the best practice guidelines released by the EHR vendor or developer often require use of EHR functions or physician documentation in a much more granular detail than is often necessary for clinical care.

Response: We disagree that the best practice guidelines released by the CEHRT vendor require physician documentation or utilization of EHR sections in a much more detailed manner than is necessary for clinical care. We believe that detailed documentation of care provided in EHRs will help bolster the clinical care that is offered and will provide information that is invaluable for quality reporting programs to facilitate better patient outcomes.

Comment: One commenter recommended that CMS develop a system or strategy for notification of eCQMs likely to be retired in the next 12 to 24 months as well as a system or strategy that alerts hospitals about eCQMs that are being considered for addition to the Hospital IQR Program in the next 2 years. Another commenter requested that CMS provide a 2-year lead time prior to eCQM requirements because it takes significant time to implement these measures.

Response: We appreciate the commenter's recommendation to notify hospitals of eCQMs likely to be retired as well as eCQMs that are being considered for addition to the Hospital IQR Program in the next 2 years. We intend to continue using the rulemaking process with notice and comment period to establish and communicate timelines for implementation, as well as to remove and adopt new measures. In response to commenters' request for more advance notice as to eCQM reporting requirements, in this final rule we are finalizing a modification from our proposal with requirements for both the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination. We note that in the FY 2016 IPPS/LTCH PPS final rule, we signaled our intent to increase the number of eCQMs required for reporting (80 FR 49693 through 49698) and to remove 13 eCQMs (80 FR 49644 through 49645) in future rulemaking. We also noted in that rule (80 FR 49698 through 49704) that we would consider alternative measure types (hybrid measures) in future rulemaking.

Further, in section VIII.A.9.c. of the preamble of this final rule, we discuss future considerations of behavioral health measures, some of which could potentially be developed as eCQMs in the future. We also refer readers to the Hospital OQR Program discussion in the FY 2017 OPPS/ASC PPS proposed rule

(81 FR 45721) for additional discussion of possible future eCQMs that are under development for the outpatient hospital setting. In addition to using the rulemaking process, we will continue to provide ongoing education and outreach to stakeholders through Special Open Door Forums (information available at: *https://www.cms.gov/outreach-and-education/outreach/opendoorforums/ODFspecialODF.html*) and periodic training sessions. In addition, stakeholders may learn about and provide feedback on newly developed eCQMs during the measure development process, the NQF public comment period, and/or the MAP's pre-rulemaking public comment period.

Comment: One commenter suggested that AMI–8a not be included among the required eCQMs because it is not discrete data.

Response: While we acknowledge that there may be challenges associated with electronic reporting of AMI–8a due to the non-discrete data which could pose collection issues because the values are spread over a range of data points, we do not believe these challenges warrant removal of the measure from the Hospital IQR Program at this time. As stated in section VIII.10.d.(2) of the preamble of this final rule, hospitals may continue to either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I. We recognize and support the use of third-party vendors to assist in data submission in required formats as needed to reduce burden on hospitals.

Comment: One commenter recommended that CMS launch an effort to develop a clinical quality measurement infrastructure necessary to transition federal pay-for-performance programs into utilizing both process improvement measurement and outcomes measurement derived from CEHRT to alleviate the reporting burden associated with collecting data from different parts of the EHR enterprise. Another commenter recommended that CMS include measures for which critical data elements are entered directly into the CEHRT or can be obtained through provider financial systems flowing to the CEHRT to minimize the need for data abstracted from non-certified systems which necessitates double data entry by providers. Further, one commenter believed that redundant structured data points require a duplication of work efforts.

Response: We thank the commenters for their suggestions. As we have previously stated, we believe that reporting measures as eCQMs is valuable and we are working to refine the eCQM measure set in the Hospital IQR and Medicare and Medicaid EHR Incentive Programs, as well as to develop and adopt eCQMs for other quality reporting programs, with the longer-term goal of using eCQMs for value-based purchasing programs. We continuously strive to develop strategies and systems to facilitate fully transitioning to eCQMs across providers and programs in a way that minimizes reporting burdens for hospitals and increases the validity of the data.

Comment: One commenter expressed concern that the proposed list of eCQMs does not allow for comparison with chart-abstracted measures and suggested that there should be greater overlap between eCQMs and chart-abstracted measures. Other commenters expressed concern that eCQM data submission to CMS has not been fully tested at this point and recommended that expanding the required number of eCQMs should be delayed until there has been successful transmission of data. Until EHR standards are better structured to yield reliable data through eCQMs, one commenter urged CMS to defer to chart abstraction so that the clinical team can focus on quality care and the abstractors can abstract and report high quality data without diverting the attention of the clinical team from patient care to documentation and quality reporting.

Response: As described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we have received anecdotal comments about performance level differences between chart-abstracted and eCQM data. We do not have sufficient data to be able to confirm or refute the accuracy of those comments (79 FR 50258). In order to substantiate or refute the existence of performance-level differences between eCQM data and chart-abstracted measure data, we believe that we must collect more eCQM data and develop a process for validating the accuracy of that data. We believe that adopting an eCQM validation process in the Hospital IQR Program, as discussed in section VIII.11.b. of the preamble of this final rule and analyzing the results from eCQM data validation, beginning with an analysis of CY 2016 reported data, will allow us to examine concerns about the accuracy of eCQM data so that we may begin publicly reporting eCQM data in future years.

Comment: One commenter requested clarification about when eCQM data will be made publicly available. Several commenters explicitly supported CMS' decision to continue to not publicly report eCQM data until the data are verified and reliable, noting that one quarter's worth of data would not provide a statistically valid sample from which to assess a hospital's performance and that it would be premature to report these data due to challenges associated with reliability and validity. Another commenter specifically recommended that the data collected by eCQMs not be publicly reported on *Hospital Compare* until electronic reporting improves and benchmarks are freely available.

One commenter made the following recommendations with respect to future public reporting of eCQM data: (1) One year prior to the proposed inclusion year, the eCQM should be announced in the proposed rule for the following year, with the opportunity for public comments; (2) in the first year, data should be reported to CMS to assure validity and plausibility, but not publicly reported; and (3) assuming that year one results are demonstrated to be valid and plausible, the data should be collected and reported publicly in year two and subsequent years. In addition, this commenter recommended that CMS provide additional education about how to interpret the publicly reported data because publicly reported scores can be confusing to consumers.

Response: We thank the commenters for their support. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50815 through 50818), we adopted a policy under which we would only publicly report eCQM data in the Hospital IQR Program if we deem that the data are accurate enough to be publicly reported (78 FR 50816). We believe that our current policy to delay public reporting of eCQM data submitted by hospitals for the CY 2017 reporting period/FY 2019 payment determination in conjunction with the adoption of an eCQM validation process in this final rule is consistent with our stated policy on eCQM public reporting.

We agree with the commenters that suggested we implement a quality process to ensure that eCQMs are accurate, which is why we are finalizing our proposal to examine electronic measures through our validation process and refer readers to section VIII.A.11.b.(3) of the preamble of this final rule for more details. We believe that implementing an eCQM validation process in the Hospital IQR Program and analyzing the results from eCQM data validation, beginning with an analysis of CY 2017 reported data, will allow us to examine concerns about the accuracy of eCQM data so that we may begin publicly reporting eCQM data in the future.

With respect to the commenter's suggestions about future public reporting of eCQM data, we will take

these recommendations into account as we continue to develop and refine our electronic reporting policies.

Comment: One commenter requested clarification on the meaning of ''all available eCQMs.'' The commenter asked if the term refers to submitting all the 2017 eCQMs in 2017, submitting all the 2017 eCQMs applicable to their patient populations, or only submitting the 2017 eCQMs currently built in their CEHRT systems. The commenter noted that if ''all available eCQMs'' means all available for 2017 (and not what is available in the current EHR build), hospitals will be required to reengage their vendors to allocate valuable HIT resources currently focused on complying with the new 2016 IPPS electronic submission requirements and timeline.

Response: We define the term ''all available eCQMs'' to mean all of the eCQMs included in the Hospital IQR Program measure set at the beginning of CY 2017 for the FY 2019 payment determination. We recognize the challenges associated with eCQM reporting and encourage hospitals to continue refining their electronic reporting implementation activities to successfully achieve electronic data capture and reporting despite mapping and integration issues or work with their vendors to do so. However, instead of requiring all available eCQMs as proposed, we are only requiring 8 eCQMs and refer readers to our final policy for eCQMs as discussed above.

Comment: Several commenters expressed concern that hospitals unable to submit eCQMs would be penalized under the Medicare EHR Incentive Program in addition to the Hospital IQR Program. The commenters believed that a provider that is unable to submit eCQM data should only be penalized under the Medicare EHR Incentive Program and not by both programs.

Response: We disagree that the requirements for electronic reporting in the Hospital IQR Program duplicates penalties. In an effort to align with the Medicare and Medicaid EHR Incentive Programs, we have specified that hospitals meeting electronic reporting requirements for the Hospital IQR Program will be considered to have successfully reported the eCQM requirement to the Medicare and Medicaid EHR Incentive Programs as well. In addition, we note that our data show that 95 percent of hospitals already attest to successful eCQM reporting under the EHR Incentive Program and, accordingly, we believe that the majority of hospitals will be able to successfully report eCQMs, meeting both the Medicare and Medicaid EHR Incentive Programs' CQM reporting requirements and the Hospital IQR Program requirements. Finally, for hospitals that find they are unable to meet the eCQM submission deadline and meet our criteria for an eCQM-related Extraordinary Circumstances Extension/Exemption (ECE), we note that we are adopting our proposal to extend the deadline for requesting an eCQM-related ECE to April 1 following the end of the reporting calendar year, as discussed in section VIII.A.15.b. of the preamble of this final rule.

Comment: One commenter supported CMS' efforts to align the Hospital IQR Program with the EHR Incentive Programs but did not support the proposed requirement that hospitals report on all eCQMs in the Hospital IQR Program measure set because providers invest considerable resources to revise and validate the eCQMs and face the following challenges: (1) Consistent with findings of CMS' eCQM validation pilot, significant discrepancies between manually abstracted measures and eCQMs; (2) eCQM vendor tools are not able to generate accurate measure results because EHRs were not designed to capture data elements required for eCQM reporting during the course of care requiring clinical staff to enter data in multiple places to ensure the data are available for eCQM reporting; and (3) hospitals with multiple vendor systems across clinical departments have encountered difficulty ensuring these disparate systems are interfacing appropriately with quality measure systems and appropriately mapping data fields in order to generate the required QRDA I files for submission to CMS. The commenter observed that as a result of these challenges, hospitals have not had an opportunity to strategically refine their systems to capture the necessary data elements and conduct the requisite testing. The commenter urged CMS to continue the 2016 reporting requirements in 2017 to give hospitals time to thoughtfully modify their internal processes in concert with their vendors to improve eCQM reporting.

Response: We thank the commenter for this support. As described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we have received anecdotal comments about performance level differences between chart-abstracted and eCQM data. We stated that we did not have sufficient data to be able to confirm or refute the accuracy of those comments (79 FR 50258). In order to substantiate or refute the existence of performance-level differences between eCQM data and chart-abstracted measure data, we believe that we must collect more eCQM data and develop a process for validating the accuracy of that data. Further, the 2015 eCQM Validation Pilot did not compare manual chart-abstracted data to eCQM data, rather, the data elements for validation were derived from the hospitals' EHR. We received many comments that suggested we implement a quality process to ensure that eCQMs are accurate, which is why we are finalizing our proposal to implement an eCQM validation process in section VIII.A.11.b of the preamble of this final rule. We believe analysis of results from eCQM data validation will serve to alleviate concerns about the accuracy of eCQM data so that we may begin publicly reporting eCQM data in future years. We recognize the challenges associated with electronic reporting and encourage hospitals to work with their vendors to achieve electronic capture and reporting despite mapping and integration issues.

As stated above, we believe that the best way to encourage hospitals to invest in improving their EHR systems is by requiring reporting of additional eCQMs. Consequently, we believe that retaining the reporting requirements from FY 2016 would not help in this improvement approach. However, as previously stated, we are modifying our proposal to finalize requirement of 8 eCQMs in direct response to commenters' suggestions that we incrementally increasing the reporting requirements. Lastly, we believe that our finalized policy to require the submission of only 8 eCQMs for the CY 2017 and CY 2018 reporting periods, which provides an additional full year for refining reporting capabilities on 8 eCQMs, will provide hospitals adequate time to address mapping issues.

Comment: Some commenters questioned whether the proposal to increase the number of required eCQMs for reporting functions to promote better quality care. The commenters expressed the opinion that this proposal seems to drive a particular data collection mechanism, and while they supported the continued use of EHRs to collect meaningful data, they are concerned about the feasibility and accuracy of eCQMs.

Response: While we appreciate the commenter's concern about whether an increase in the number of eCQMs will promote better quality of care, we believe that if hospitals and EHR vendors continue to refine EHR systems to appropriately structure them commensurate with the clinical work flow, this will lead to improved accuracy, reliability, and completeness

of the eCQM data, which will promote higher quality outcomes and lower costs while ultimately decreasing reporting burden on hospitals as compared with chart-abstraction for quality measure data. We note that 2015 is not the first year CMS has requested eCQM data submission. As described in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50905), electronic reporting pilots for the EHR Incentive Program from 2012 and 2013 included eCQM reporting. We understand the importance of having feasible and accurate measure data, however, the only way that we will be able to readily identify issues is to assess more data. We believe that our policy to only require submission of 8 eCQMs serves to incrementally increase electronic reporting, as suggested by commenters, while also allowing us to collect data derived from EHRs to further our plans for electronic data collection and validation. Moreover, we believe that it is appropriate to require reporting and validation of eCQMs because measures available now and those being developed for the future are increasingly based on electronic standards (80 FR 49696).

Comment: A few commenters recommended that CMS maintain the current eCQM reporting requirement and allow hospitals to voluntarily report on additional eCQMs. The commenter stated that this approach would allow more time for the reconciliation and upgrading of the resources necessary (that is, EHRs) to handle additional measure specifications. One commenter suggested requiring a smaller number of eCQMs, specifically, the following six measures: CAC–3—Pediatric Asthma—Home Management Plan of Care Given to Patient/Caregiver; ED–1—Median Time from ED Arrival to ED Departure for Admitted ED Patients; ED–2—Admit Decision time to ED departure Time for Admitted Patients; EHDI–1a—Newborn Hearing Screening Prior to Discharge; PC–01—Early Elective Delivery; PC–05—Exclusive Breastfeeding.

Response: We appreciate the commenters' recommendation to maintain the current eCQM reporting requirement and allow hospitals to voluntarily report on additional eCQMs, however hospitals have already had 3 years to voluntarily report on eCQMs. As stated above, we believe that mandatory reporting is necessary to advance our policy goal to move facilities towards reporting electronic measures. In response to overwhelming concern about the issues related to the proposal to require reporting on all available eCQMs, we direct the commenter to our finalized policy to require submission of 8 eCQMs, described in section VIII.A.8.a. of the preamble to this final rule. Rather than requiring hospitals to report on particular eCQMs, as suggested by one commenter, we hope that allowing hospitals to self-select 8 eCQMs based upon their own patient mix and consistent with internal quality improvement efforts will increase flexibility and reduce burden.

After consideration of the public comments we received, we are finalizing a modified version of our proposal. Specifically, instead of requiring hospitals to report on all available eCQMs for the CY 2017 reporting period/FY 2019 payment determination and subsequent years as proposed, we are finalizing a policy that hospitals must report on at least 8 self-selected eCQMs from the available eCQMs in the Hospital IQR Program for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination. We intend to propose to increase the number of required eCQMs for reporting in the Hospital IQR Program for the CY 2019 reporting period/FY 2021 payment determination and future years through rulemaking.

b. Requirement That Hospitals Report a Full Year of eCQM Data

In the FY 2016 IPPS/LTCH PPS final rule, we finalized our policy to require hospitals to submit one quarter of data (either Q3 or Q4) for 4 self-selected eCQMs for the CY 2016 reporting period/FY 2018 payment determination by February 28, 2017 (80 FR 49698). As previously stated, we believe that the CY 2017 reporting period/FY 2019 payment determination is the appropriate time to require increased eCQM reporting because hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and for the Hospital IQR Program. Therefore, we proposed that for the CY 2017 reporting period/FY 2019 payment determination and subsequent years, hospitals must submit one year's worth (that is, four quarters) of eCQM data for each required eCQM. For example, for the ED–1 eCQM, hospitals would be required to submit one year of data (covering Q1, Q2, Q3, and Q4), instead of just one quarter of data (either Q3 or Q4) as previously required.

We sought to proactively address some stakeholder concerns associated with increasing the number of eCQMs for which reporting will be required by aligning data submission deadlines between the Hospital IQR Program and the Medicare EHR Incentive Program to help reduce some reporting burden on hospitals. We note that deadlines for the Medicaid EHR Incentive Program differ by State, and therefore our proposal to align data submission deadlines for eCQMs applies only to the Hospital IQR Program and the Medicare EHR Incentive Program and not to the Medicaid EHR Incentive Program. For more details on Hospital IQR Program reporting requirements and eCQM submission deadlines, we refer readers to section VIII.A.10.d.(5) of the preamble of this final rule.

We invited public comment on our proposal to require hospitals to report a full year of eCQM data.

Comment: Several commenters supported the proposed requirement that hospitals report a full year of eCQM data.

Response: We thank the commenters for their support.

Comment: Many commenters did not support the proposed requirement that hospitals report a full year of eCQM data because of the burden it would impose on hospitals. One commenter indicated that the increase would be four times greater than previous years and would cause increased difficulties for hospitals transitioning to a new EHR system. Commenters noted that EHR vendors are still struggling to overcome the barriers encountered during the first year of eCQM reporting because the designing, building, reviewing, and testing that takes place between hospitals and vendors is extremely expensive and extensive. A few commenters suggested an incremental approach requiring reporting on only 8 eCQMs for two quarters for the first increase. Several commenters specifically expressed concern that the period of time between when the final rule is published and the beginning of the CY 2017 reporting period is too short to make the appropriate health IT and workflow adjustments to accommodate transmission of a full year of eCQM data.

One commenter noted that requiring hospitals to submit a full year of eCQM data for the CY 2017 reporting period would require hospitals to begin data collection on a full year of data prior to completion of the first deadline to report only one quarter of data which is February 28, 2017.

Another commenter acknowledged that once an eCQM is in place, it can continue to gather data beyond implementation, but expressed concern that the ability of EHR vendors and health care providers to have all 15 eCQMs in place by January 1, 2017 is unreasonable. The commenter suggested that CMS continue the current reporting

period of one of the two final quarters of the reporting year.

Response: We appreciate the commenters' concerns that reporting a full year of eCQM data may impose a greater burden on hospitals than reporting one quarter of eCQM data, but in response to the commenter's concern that the increase would be four times greater than previous years and would cause increased difficulties for hospitals transitioning to a new EHR system, we disagree. We believe that the burden associated with submitting a full year of eCQM data will not be substantially greater than the burden associated with transmission of a single quarter of data. As described in section VII.A.10.d of the preamble of this final rule, the CMS data receiving system requires that each QRDA I file include data for one patient, per quarter, per reporting CCN. Whether hospitals and vendors are transitioning to a new EHR or utilizing an established system, this reinforces the importance of reporting eCQMs from a properly certified and successfully mapped system. Once hospitals establish their protocols to ensure this is maintained, hospitals and vendors should not experience much added burden reporting an additional 3 quarters of data. The CMS data receiving system will re-open late spring 2017 to receive test QRDA I files and production QRDA I files for the CY 2017 reporting period eCQM data submissions. Providing this option allows hospitals and vendors greater flexibility to submit QRDA I files on a quarterly, semi-annual, or annual basis rather than waiting to submit all QRDA I files during the last two months of the submission period.

We encourage all hospitals to submit files early, as well as to use one of the available presubmission testing tools for electronic reporting—such as the CMS Pre-submission Validation Application (PSVA), which can be downloaded from the Secure File Transfer (SFT) section of the QualityNet Secure Portal at: *https://cportal.qualitynet.org/QNet/pgm_select.jsp*. We refer readers to section VIII.A.11.b.(5) of the preamble of this of this final rule for more information about the PSVA.

In response to the commenter's concern that EHR vendors are still struggling to overcome the barriers encountered during the first year of eCQM reporting because the designing, building, reviewing, and testing that takes place between hospitals and vendors is extremely expensive and extensive, we acknowledge the time, effort, and resources that hospitals expend on building these measures. However, we disagree with commenters' suggestion to take an incremental approach requiring reporting on only 8 eCQMs for two quarters for the first increase. Although reporting a full year of eCQM data for the CY 2017 reporting period would require hospitals to begin data collection on a full year of data prior to completion of the first deadline to report only one quarter of data which is February 28, 2017, we believe that hospitals have had adequate time to prepare. We disagree that the period of time between when the final rule is published and the beginning of the CY 2017 reporting period is too short to make the appropriate health IT and workflow adjustments to accommodate transmission of a full year of eCQM data. We believe that the FY 2019 payment determination is the appropriate time to require reporting of a full year of eCQM data because hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and Hospital IQR Program (3 years of voluntary reporting and 3 years of reporting as part of a pilot). In addition, we believe that our finalized policy requiring a lesser number of eCQMs than originally proposed (that is, 8 eCQMs instead of all available eCQMs) provides hospitals with sufficient time to augment their eCQMs and satisfy electronic reporting requirements. We believe this policy will also lessen burden on hospitals.

Comment: Some commenters expressed concern that the increase in the volume of information being reported might increase susceptibility to inaccurate data. A few commenters did not support the proposed requirement that hospitals report a full year of eCQM data because they believed the proposal is premature due to hospitals' inability to ensure that eCQM data is accurate and reliable.

Response: We believe that collecting as much data from hospitals as feasible is an important step toward helping hospitals to report more accurate and reliable data. In section VIII.A.11.b. of the preamble of this final rule, we outline an addition to the Hospital IQR Program validation process to include validation of eCQM data. Analysis of validation results will help us to better understand the difficulties hospitals are experiencing in reporting eCQM data and enable us to provide assistance to help resolve those issues, ultimately resulting in more accurate and reliable data which will improve patient outcomes.

Comment: One commenter suggested that CMS should delay this proposal and focus more on validating eCQM data prior to requiring that hospitals report the data on all eCQMs for a full year in the Hospital IQR Program.

Response: We disagree with the commenter's suggestion that we delay this proposal and focus more on validating eCQM data prior to requiring hospitals report data on all eCQMs for a full year in the Hospital IQR Program because we believe that collecting as much data from hospitals as feasible is an important step toward helping hospitals to report more accurate and reliable data.

Comment: Some commenters expressed concern that this effort will take resources away from true quality improvement efforts.

Response: We disagree and believe that when EHRs are appropriately structured in a way that fits in with the clinical work flow to yield reliable data through eCQMs, eCQMs promote higher quality outcomes and lower costs while ultimately decrease reporting burden on hospitals as compared with chart-abstraction. Moreover, we believe that it is appropriate to require reporting and validation of eCQMs given that measures available now and those being developed for the future are increasingly based on electronic standards (80 FR 49696).

Comment: One commenter questioned whether CMS has considered its ability to receive data submissions for hundreds of thousands of cases from hospitals within a 2 month period (January 1 through the Feb 28).

Response: We are working to ensure that CMS infrastructure is in place to receive the full volume of eCQM data transmissions (for 8 eCQMs) from hospitals by the February 28, 2018 deadline for the CY 2017 reporting period and February 28, 2019 for the CY 2018 reporting period. As stated above, the CMS data receiving system will re-open late spring 2017 to receive test QRDA I files and production QRDA I files for the CY 2017 reporting period eCQM data submissions. Providing this option allows hospitals and vendors greater flexibility to submit QRDA I files on a quarterly, semi-annual, or annual basis rather than waiting to submit all QRDA I files during the last two months of the submission period. As of the publication of this final rule, the CMS data receiving system is open to receive QRDA I test file submissions to allow hospitals and vendors to prepare and test their files for CY 2016 eCQM reporting requirements before the system will be available to receive production files.

Comment: A few commenters noted that upgrading CEHRT to a new edition of certification criteria during the same reporting period (CY 2017) that would

require hospitals report a full year of eCQM data could pose additional implementation difficulties. Other commenters suggested as an alternative to annual reporting of a full year of eCQM data, that CMS require quarterly submission of the eCQM data, with submission being required four and a half months after the end of the reporting quarter to align the e-submission requirements with the Hospital IQR Program chart-abstracted reporting requirements and with other quality reporting programs, such as the SNF Quality Reporting Program and the EHR Incentive Program, to ensure sufficient time for providers to final-bill code all cases for a reporting quarter before being required to generate QRDA files for submission to CMS, and to alleviate pressure on providers, vendors, and the QualityNet team to put together and submit the required information for eCQM data submission. Finally, a few commenters noted that upgrading CEHRT to a new edition of certification criteria during the same reporting period (CY 2017) that would require hospitals report a full year of eCQM data could pose additional implementation difficulties. One commenter expressed the opinion that quarterly reporting would reduce the volume of data that vendors and CMS must process at one time, give providers more frequent benchmarking of their performance on these measures, and make the timing of electronic reporting consistent with reporting of chart-abstracted measures.

Response: We thank commenters for their suggestions. While we acknowledge that upgrading to a new edition of certified EHR during the same reporting period that would require hospitals report a full year of eCQM data could pose additional implementation difficulties, we believe that setting an annual submission deadline at two months following the end of the reporting calendar year provides hospitals more time to make necessary modifications to their health IT systems. This annual submission deadline will allow hospitals the flexibility to submit production files on a quarterly, semi-annual, or annual basis. In addition, we encourage hospitals to test their preparedness to submit eCQM data prior to the submission deadline of the applicable reporting period by using one of the available presubmission testing tools for electronic reporting as discussed in section VIII.A.11.b.(5) of the preamble of this final rule.

Comment: One commenter expressed concern that CMS would increase the amount of data electronically submitted without the benefit of lessons learned from the first year of the electronic submission requirement. The commenter urged CMS not to increase the amount of eCQM data reported for CY 2017 until experience from the 2016 data submission is available to inform proposals.

Response: We acknowledge the commenter's concern that we are increasing the amount of data electronically submitted, by increasing the eCQM reporting requirement from one quarter of data to a full year of data, before data from the first year of required eCQM submission for CY 2016 are available for us to analyze and garner lessons learned, but we disagree that we should delay our proposal to require submission of a full year of data. Hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program (3 years of pilot reporting and 3 years of voluntary reporting). As stated previously, 95 percent of hospitals attest to successful electronic clinical reporting under the Medicare EHR Incentive program. As stated above, we believe that collecting as much data from hospitals as feasible is an important step toward helping hospitals to report more accurate and reliable data.

In section VIII.A.11.b. of the preamble of this final rule, we outline an addition to the Hospital IQR Program validation process to include validation of eCQM data. Analysis of validation results will help us to better understand the difficulties hospitals are experiencing in reporting eCQM data and enable us to provide assistance to help resolve those issues, ultimately resulting in more accurate and reliable data which will improve patient outcomes. Therefore, we believe the CY 2017 reporting period is the appropriate time to move forward with our proposed requirement that hospitals report a full year of eCQM data.

Comment: One commenter expressed concern with the proposals to align the EHR Incentive Programs and the Hospital IQR Program because there are differences in the reporting time periods between the MU measure reporting and the eCQM reporting. The commenter requested that CMS change the eCQM reporting period in FY 2017 to one quarter to align with the MU.

Response: We refer readers to section VIII.E.2.b. of the preamble of this final rule in which reporting time periods for the Medicare and Medicaid EHR Incentive Programs are aligning with the Hospital IQR Program to require that hospitals report a full year of eCQM data by the same submission deadline.

After consideration of the public comments we received, we are finalizing the proposal that for the CY 2017 reporting period/FY 2019 payment determination and subsequent years, hospitals must submit one year's worth (that is, 4 quarters) of eCQM data for each required eCQM by the annual submission deadline as proposed.

c. Clarification Regarding Data Submission for ED–1, ED–2, PC–01, STK–4, VTE–5, and VTE–6

In the FY 2016 IPPS/LTCH PPS final rule, we finalized our policy that hospitals must continue to submit data on ED–1, ED–2, PC–01, STK–4, VTE–5, and VTE–6 via chart abstraction as previously required and that the results will be publicly displayed (80 FR 49695 through 49698). We also finalized a policy that hospitals may choose to submit electronic data on any of these 6 measures in their eCQM form, in addition to the chart-abstraction requirements, in order to meet the eCQM reporting requirement to report 4 self-selected eCQMs out of 28 available eCQMs (80 FR 49695 through 49698).

For the FY 2019 payment determination and subsequent years, as discussed in section VIII.A.3.b.(3)(a)(ii) of the preamble of this final rule, we are finalizing our proposal to remove the electronic version of the STK–4 measure. As discussed in section VIII.A.3.b.(3)(d) of the preamble of this final rule, we are finalizing our proposal to remove the electronic versions of the VTE–5 and VTE–6 measures. Lastly, in section VIII.A.3.b.(2) of the preamble of this final rule, we are finalizing our proposal to remove the chart-abstracted versions of the STK–4 and VTE–5 measures. Because these proposals are being finalized as proposed, the STK–4 and VTE–5 measures are completely removed from the Hospital IQR Program measure set, but the VTE–6 measure continues to be included in its chart-abstracted form. Therefore, for the FY 2019 payment determination and subsequent years, we are clarifying that requirements for the chart-abstracted versions of ED–1, ED–2, PC–01, and VTE–6 remain the same as previously finalized—that hospitals must continue to submit data via chart abstraction (covering each of Q1, Q2, Q3, and Q4) as previously required and that the results will be publicly displayed.

We received the following comments on clarifying the reporting requirements for ED–1, ED–2, PC–01, and VTE–6.

Comment: A few commenters recommended that the Hospital IQR Program continue to require hospitals to submit chart-abstracted data for measures ED–1, ED–2, and PC–01 and

that these measures should be prioritized for eCQM data collection as well to facilitate data validation. The commenters requested that CMS make publicly available the results of analysis comparing chart-abstracted data with eCQM data for measures that are reported in both forms because it would provide valuable information to inform decisions about keeping or retiring measures and it would highlight issues ascribed to differences between chart-abstraction methods and eCQM measure specifications to help vendor and provider communities understand these issues. Lastly, commenters encouraged CMS to require CEHRT to adopt a standardized definition of ''admit decision'' and recommended that CMS consult with existing consensus definitions and experts in the field to help identify potential variance in the chart-abstracted version and the eCQM versions of these measures.

Response: We thank the commenters for their support and suggestions and will take these into consideration in developing future policy. In addition, we direct readers to the Office of the National Coordinator for recommendations on developing or new standards for health IT which should be considered for future adoption.[158]

Comment: Some commenters expressed concern that the submission of eCQM data would not replace chart-abstracted and claims-based measures, which must still be submitted in addition to eCQMs. The commenters suggested that CMS allow hospitals to select the format in which to report, to encourage more hospitals to make eCQMs more accurate. Further, the commenters suggested that if hospitals submit eCQM data for measures ED–1 and ED–2, that they not be required to submit chart-abstracted data for these measures because chart-abstraction is redundant and costly. The commenters requested that CMS consider flexibility in requirements for submission of different measure types because maintaining different reporting mechanisms is a daunting task for hospitals and requires expertise in different areas of health IT, as well as in clinician workflow and medical coding. One commenter specifically requested that chart-abstracted measures be removed when an eCQM is available because reporting on the same measure in two forms duplicates efforts, creates variation in the data, and takes time away from hospitals improving their electronic medical record systems. Another commenter also noted that clinician documentation for the generation of clinical quality measures is no easy feat, and that CMS should be more cognizant of this. The commenter recommended that CMS slow the pace of eCQM reporting and focus on testing and validation of measures instead.

Response: We thank the commenters for their suggestion that we allow hospitals to select the format in which to report on measures specified both as eCQMs and as chart-abstracted measures, however, we believe that in order to collect the highest quality data, at this time, submission of data in both forms for the ED–1, ED–2, PC–01, and VTE–6 measures is necessary. As described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we have received anecdotal comments about performance level differences between chart-abstracted and eCQM data. We do not have sufficient data to be able to confirm or refute the accuracy of those comments (79 FR 50258). In order to substantiate or refute the existence of performance-level differences between eCQM data and chart-abstracted measure data, we believe that we must collect more eCQM data and develop a process for validating the accuracy of that data.

Moreover, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50815 through 50818), we adopted a policy under which we would only publicly report eCQM data in the Hospital IQR Program if we determined that the data are accurate enough to be reported. We believe that our current policy to delay public reporting of eCQM data submitted by hospitals for the CY 2017 reporting period/FY 2019 payment determination in conjunction with the adoption of an eCQM validation process in this final rule is consistent with our stated policy on eCQM public reporting. Until we have determined that eCQM data are accurate enough to be publicly reported, we believe it is important to collect the chart-abstracted data on ED–1, ED–2, PC–01, and VTE–6 to be able to continue publicly reporting, since these measures are not topped out like the previously removed chart-abstracted measures and data on the PC–01 chart-abstracted measure is used in the Hospital VBP Program. We acknowledge that maintaining different reporting mechanisms is costly and may appear redundant to hospitals and that it requires expertise in different areas of health IT, as well as in clinician workflow, and medical coding. Nevertheless, we believe the value of the additional data outweighs the burden of collecting the data in both forms.

We disagree that reporting on the same measure in two forms duplicates efforts, creates variation in the data, and takes time away from hospitals improving their electronic medical record systems. Until eCQM data is validated and ready to be publicly reported, it is important to have sufficient data on the chart-abstracted versions of the measures to continue publicly reporting on them. In addition, because hospitals can choose which four eCQMs they report for CY 2016 and which 8 eCQMs they report for CY 2017 and CY 2018, it may be several more years before we have collected sufficient, reliable data for publicly reporting on these measures using eCQM data alone. We believe that reporting chart-abstracted data will supplement eCQM data on the same measure and that reporting data in both forms will facilitate eCQM validation efforts.

Comment: One commenter supported the retention of VTE–6 in chart-abstracted form because chart abstractors can manually find required data elements in clinical notes and not structured data fields, but the commenter noted that this rationale should be extended to many, if not all, of the chart abstracted measures that are being considered for eCQM reporting. The commenter encouraged CMS to utilize chart-abstraction rather than an eCQM as the preferred method of data collection and reporting for public reporting and pay-for-performance programs because, while labor intensive, chart-abstraction focuses data collection to a select set of professionals who can be trained to provide high quality data for use in public reporting and pay-for-performance programs and free clinical providers and physicians to focus on providing patient-centered care without the distraction of documenting in structured fields to the detail required for the purposes of eCQM reporting.

Response: We appreciate the commenter's recommendation to continue utilizing chart abstraction for quality reporting until EHR systems are more mature, but as we stated in section VII.A.8.a. of the preamble of this final rule, when hospitals work with their vendors to ensure that EHRs are appropriately structured in a way that fits in with the clinical work flow to yield reliable data through eCQMs, we believe that eCQMs promote high quality outcomes and lower costs while ultimately decrease reporting burden on hospitals as compared with chart-abstraction.

In summary, for the FY 2019 payment determination and subsequent years, we

[158] Office of the National Coordinator, Health IT Certification Program *www.healthit.gov.*

clarify that requirements for the chart-abstracted versions of ED–1, ED–2, PC–01, and VTE–6 remain the same as previously finalized—that hospitals must continue to submit data via chart abstraction (covering each of Q1, Q2, Q3, and Q4) as previously required and that the results will be publicly displayed. This is regardless of whether data also are submitted electronically in accordance with the applicable submission requirements.

9. Possible New Quality Measures and Measure Topics for Future Years

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25196 through 25199), we provided information about new quality measures and measure topics under consideration for future inclusion in the Hospital IQR Program. We are considering to propose in future rulemaking: (1) A refined version of the Stroke Scale for the Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure; (2) a new measure, the National Healthcare Safety Network (NHSN) Antimicrobial Use Measure (NQF #2720); and (3) one or more potential measures of behavioral health for the inpatient hospital setting, including measures previously adopted for the IPFQR Program (80 FR 46694), for adoption into the Hospital IQR Program measure set. Also, we are considering public reporting of Hospital IQR Program data stratified by race, ethnicity, sex, and disability on *Hospital Compare.* These topics are further discussed below.

a. Potential Inclusion of the National Institutes of Health (NIH) Stroke Scale for the Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure Beginning as Early as the FY 2022 Payment Determination

(1) Background

Mortality following stroke is an important adverse outcome that can be measured reliably and objectively and is influenced by the quality of care provided to patients during their initial hospitalization; therefore, mortality is an appropriate measure of quality of care following stroke hospitalization.[159] [160] Specifically, post-stroke mortality rates have been shown to be influenced by critical aspects of care such as response to complications, speediness of delivery of care, organization of care, and appropriate imaging.[161] [162] [163] [164] Therefore, we are refining the previously adopted CMS Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following Acute Ischemic Stroke Hospitalization Measure (hereafter referred to as the Stroke 30-day Mortality Rate) (78 FR 50802) by changing the measure's risk adjustment to include stroke severity. We are considering proposing this refinement to the measure in the future.

The previously adopted Stroke 30-day Mortality Rate (78 FR 50802) includes 42 risk variables, but does not include an assessment of stroke severity. For more details on the measure as currently adopted and implemented, we refer readers to its measure methodology report and measure risk-adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Mortality Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

In the future, we are considering proposing a refinement to the Stroke 30-day Mortality Rate for several reasons. First, the refined measure would allow for more rigorous risk adjustment by incorporating the NIH Stroke Scale (discussed in more detail below) as an assessment of stroke severity.[165] Second, the inclusion of the NIH Stroke Scale is aligned with and supportive of clinical guidelines, as use of the NIH Stroke Scale to assess stroke severity upon acute ischemic stroke patient presentation is Class I recommended in the American Heart Association and American Stroke Association (AHA/ASA) guidelines.[166] Third, clinicians and stakeholders, including AHA, ASA, and other professional organizations, highlight the importance of including an assessment of stroke severity in risk-adjustment models of stroke mortality. Therefore, the refined Stroke 30-day Mortality Rate is responsive to comments received from the feedback of measure developers during measure development, the TEP, and the NQF endorsement process (78 FR 50802). Fourth, in addition to a modestly higher c-statistic, which evaluates the measure's ability to discriminate or differentiate between high and low performing hospitals, the refined Stroke 30-day Mortality Rate includes a more parsimonious risk model than the publicly reported stroke mortality measure, with a total of 20 risk adjustment variables including the NIH Stroke Scale, compared to the current use of 42 risk adjustment variables.

Initial stroke severity score, such as the NIH Stroke Scale score, is one of the strongest predictors of mortality in ischemic stroke patients,[167] [168] [169] and is part of the national guidelines on stroke care.[170] The NIH Stroke Scale is a 15-item neurologic examination stroke scale used to provide a quantitative measure of stroke-related neurologic deficit. The NIH Stroke Scale evaluates the effect of acute ischemic stroke on a patient's level of consciousness, language, neglect, visual-field loss, extra-ocular movement, motor strength, ataxia (the loss of full control of bodily movements), dysarthria (difficult or unclear articulation of speech), and sensory loss. The NIH Stroke Scale was designed to be a simple, valid, and reliable tool that can be administered at the bedside consistently by neurologists, physicians, nurses, or therapists. In

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[169] Smith EE, Shobha N, Dai D, et al. Risk score for in-hospital ischemic stroke mortality derived and validated within the Get With the Guidelines—Stroke Program. *Circulation.* Oct 12 2010;122(15):149615041496–1504.

[170] Jauch EC, Saver JL, Adams HP, Jr., et al. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* Mar 2013;44(3):870–947.

October 2016, codes for the NIH Stroke Scale are expected to be added to the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD–10). The currently adopted measure covers 3 years of claims data using administrative claims from July 2011–June 2014. In order to give hospitals time to adjust to reporting the NIH Stroke Scale, we are considering this measure refinement for as early as the July 2017 through June 2020 reporting period (3 years of data), which would correspond to the FY 2022 payment determination in the Hospital IQR Program.

The measure refinement was developed in collaboration with the AHA/ASA. We sought to update the current publicly reported measure to include an assessment of stroke severity at this time, because it has become feasible to do so due to both the increased use of the NIH Stroke Scale related to the AHA/ASA guidelines that recommend administering the NIH Stroke Scale on all stroke patients, as well as due to the upcoming availability to obtain the scores through claims data (incorporation into ICD–10).

The Stroke 30-day Mortality Rate (MUC ID 15–294) with the refined risk adjustment was included on a publicly available document entitled ''List of Measures under Consideration for December 1, 2015'' with identification number MUC ID 15–294, (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*) and has been reviewed by the MAP. The MAP conditionally supported this measure pending NQF review and endorsement and asked that CMS consider a phased approach in regards to implementation to avoid multiple versions of the same measure.[171] The MAP also noted that mortality is not the most meaningful outcome for stroke patients and to consider cognitive or functional outcomes such as impaired capacity.[172] The Stroke 30-day Mortality Rate with the refined risk adjustment was submitted to NQF for endorsement in the neurology project on January 15, 2016.

(2) Overview of Measure Change

The measure cohort for the refined measure would not be substantively different from the currently adopted, publicly reported Stroke 30-day Mortality Rate. In addition, the data sources, three-year reporting period, inclusion and exclusion criteria, as well as the assessment of the outcome of mortality would all align with the currently adopted measure.

(3) Risk Adjustment

The statistical modeling, measure calculation, and risk-adjustment calculation for this refined measure would align with the currently adopted Stroke 30-day Mortality Rate. However, we reselected risk variables, resulting in a final model with 20 risk-adjustment variables including the NIH Stroke Scale as an assessment of stroke severity. For the full measure specifications of the refined measure, we refer readers to the AMI, HF, PN, COPD, and Stroke Mortality Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

In summary, we are considering proposing in the future a refinement of the Stroke 30-day Mortality Rate, which would change the risk adjustment to include an assessment of stroke severity, in the Hospital IQR Program for as early as the July 2017–June 2020 reporting period/FY 2022 payment determination and for subsequent years.

We invited comments on the possibility of a future proposal of refinements to the previously adopted Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure to include the NIH Stroke Scale beginning as early as the FY 2022 payment determination.

Comment: All commenters supported the inclusion of the NIH Stroke Scale score in the Stroke 30-day Mortality Rate measure for future inclusion in the Hospital IQR Program. Commenters noted it is a significant improvement over the current Stroke 30-Day Mortality Rate measure, which uses an administrative claims-based risk adjustment model that does not include stroke severity. Some commenters suggested that the current lack of risk adjustment for stroke severity could cause misclassification of hospital performance, and that the more rigorous risk adjustment facilitated by the NIH Stroke Scale will help ensure that the measure accurately risk adjusts for different hospital populations without unfairly penalizing high-performance providers.

In addition, commenters agreed that the NIH Stroke Scale is well validated (having been vetted by the ASA and the AHA), highly reliable, widely used, and a strong predictor of mortality and short- and long-term functional outcomes. Several commenters supported the proposed timeframe for the implementation of the refined Stroke 30-Day Morality Rate measure, noting that data for the measure would not be required until FY 2020, which allows hospitals sufficient time to adjust to reporting NIH Stroke Scale scores.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS also account for decline or improvement in status that could be related to interventions, by incorporating the NIH Stroke Scale score administered at discharge. Commenters suggested that CMS consider whether the measure will risk adjust for the score taken upon admission, during the first 24 hours of the admission, or upon discharge. A commenter urged CMS to consider standardizing the qualifications of the individual administering the NIH Stroke Scale. In addition, one commenter requested clarification as to how the NIH Stroke Scale score would be reported to CMS.

Response: In regard to the timing of the NIH Stroke Scale score, we note that the intent of the risk adjustment for stroke severity is to account for patients' clinical status at the time they are admitted to the hospital. Therefore, the refined Stroke 30-Day Morality Rate measure would utilize the initial NIH Stroke Scale score, administered upon admission. We refer readers to the current clinical guidelines describing the qualifications and appropriate administration of the NIH Stroke Scale. As noted in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25196), the NIH Stroke Scale is expected to be added to ICD–10 in October 2016, and could therefore be reported via claims submitted to CMS. We will take the additional suggestions into consideration for future policy.

Comment: A few of commenters supported the inclusion of the NIH Stroke Scale for the Stroke 30-day Mortality Rate measure for future inclusion in the Hospital IQR Program, pending NQF endorsement. One commenter added that it would also support using the refined Stroke 30-Day Morality Rate measure once it has been field-tested by hospitals. Commenters noted that mortality is not the only outcome for stroke patients that should be measured and recommended that CMS work with measurement stakeholders and developers to explore more measures that are highly meaningful to patients, such as cognitive or functional outcomes. These commenters acknowledged that the addition of the NIH Stroke Scale scores is a technical improvement, but cautioned CMS in moving forward in

[171] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/*.

[172] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/*.

implementation of this measure until it is clear that the measure provides an unambiguous and unbiased signal of the underlying quality of care provided by the hospital.

Response: We thank commenters for their suggestions and support. The refined Stroke 30-Day Morality Rate measure was submitted to the NQF neurology project on January 15, 2016. We will continue to move forward with the NQF endorsement process for the measure. We will take this feedback regarding the timing of implementation and future stroke outcomes measures into consideration as we conduct implementation planning for the measure. We thank the commenters for their feedback and we will consider it as we develop future policy.

b. Potential Inclusion of National Healthcare Safety Network (NHSN) Antimicrobial Use Measure (NQF #2720)

(1) Background

The emergence of antibiotic drug resistance is a clinical and public health problem that threatens the effective prevention and treatment of bacterial infections. The CDC estimates that each year at least two million people become infected with bacteria that are resistant to antibiotics, and at least 23,000 people die as a direct result of these drug-resistant bacterial infections. In addition, antibiotic resistance contributes an estimated $20 billion in excess direct healthcare costs.[173]

In order to promote the efficiency and coordination of efforts to detect, prevent, and control antibiotic resistance, HHS announced in 2015 the establishment of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council).[174] The Advisory Council makes recommendations to the Secretary regarding policies to support the implementation of the National Strategy for Combating Antibiotic-Resistant Bacteria [175] and the National Action Plan for Combating Antibiotic-Resistant Bacteria.[176] Evidence is accumulating that programs dedicated to optimizing inpatient antibiotic use, known as antimicrobial stewardship programs (ASPs), may slow the emergence of antibiotic resistance and improve appropriateness of antimicrobial use and patient outcomes.[177] [178] [179] Therefore, the CDC and several professional societies have published guidelines and resources to support hospitals in implementing antimicrobial stewardship programs.[180]

In the future, we are considering proposing the NHSN Antimicrobial Use measure to advance national efforts to reduce the emergence of antibiotic resistance by enabling hospitals and CMS to assess national trends of antibiotic use to facilitate improved stewardship by comparing antibiotic use that hospitals report to antibiotic use that is predicted based on nationally aggregated data. The measure was included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2015,'' [181] in compliance with section 1890A(a)(2) of the Act. The measure received conditional support, pending CDC recommendation that the measure is ready for use in public reporting as referenced in the MAP 2016 Final Recommendations.[182] The MAP recognized the high importance of antimicrobial stewardship and conditionally supported the inclusion of this measure in the Hospital IQR Program while acknowledging that additional testing may be necessary to address feasibility issues for public reporting, quality implications of measuring the amount of antibiotics used versus appropriate use of antibiotics, and risk-adjustment. Further, MAP noted these issues should be addressed before the measure is reported on *Hospital Compare*.[183] The measure received endorsement from NQF on December 10, 2015.[184]

(2) Overview of Measure

The NHSN Antimicrobial Use measure assesses antibiotic use in hospitals based on medication administration data that hospitals collect electronically at the point of care. The measure compares antibiotic use that hospitals report, via electronic file submissions to the CDC's NHSN, to antibiotic use that is predicted based on nationally aggregated data. Data on administered antibiotics are required to be extracted from an electronic medication administration record (eMAR) [185] and/or bar coded medication administration (BCMA) system.[186] The antibiotic use data that are in scope for this measure include antibiotic agents administered to adult and pediatric patients in a specified set of ward and intensive care unit (ICU) locations. Locations include adult and pediatric medical, medical/surgical, and surgical wards and adult and pediatric medical, medical/surgical, and surgical ICUs as defined by the NHSN at: *http://www.cdc.gov/nhsn/PDFs/pscManual/15LocationsDescriptions_current.pdf*.

The measure is comprised of a discrete set of risk-adjusted summary ratios, known as Standardized Antimicrobial Administration Ratios (SAARs), which summarize observed-to-predicted antibacterial use for one of sixteen antibiotic agent-patient care location combinations. The specific antibiotic agent-location combinations were selected based on extensive consultation with infectious disease physicians and pharmacists at the forefront of ASPs. The specified categories of antibiotic agents include:

- Broad spectrum agents predominantly used for hospital-onset/multi-drug resistant bacteria;
- Broad spectrum agents predominantly used for community-acquired infection;
- Anti-MRSA agents; and
- Agents predominantly used for surgical site infection prophylaxis.

[173] Centers for Disease Control and Prevention. Antibiotic Resistance Threats in the United States, 2013. Available from: *http://www.cdc.gov/drugresistance/threat-report-2013/*.

[174] Centers for Disease Control and Prevention. Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. Available from: *http://www.hhs.gov/ash/carb/index.html*.

[175] *National Strategy for Combating Antibiotic-Resistant Bacteria, 2014. Available from: https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf*.

[176] *National Action Plan for Combating Antibiotic-Resistant Bacteria, 2015. Available from: https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf*.

[177] Davey P, Brown E, Charani E, Fenelon L, Gould IM, Holmes A, et al. Interventions to improve antibiotic prescribing practices for hospital inpatients. Cochrane Database Syst Rev. 2013;4:CD003543.

[178] Feazel LM, Malhotra A, Perencevich EN, Kaboli P, Diekema DJ, Schweizer ML. Effect of antibiotic stewardship programmes on Clostridium difficile incidence: a systematic review and meta-analysis. J Antimicrob Chemother. 2014;69(7):1748–54. *http://jac.oxfordjournals.org/content/69/7/1748.full.pdf*.

[179] Kaki R, Elligsen M, Walker S, Simor A, Palmay L, Daneman N. Impact of antimicrobial stewardship in critical care: a systematic review. J Antimicrob Chemother. 2011;66(6):1223–30.

[180] Centers for Disease Control and Prevention. Core Elements of Hospital Antibiotic Stewardship Programs. Available from: *http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html*.

[181] 2015 Measures Under Consideration List Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[182] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/*.

[183] Ibid.

[184] *http://www.qualityforum.org/QPS/2720*.

[185] eMAR is defined as technology that automatically documents the administration of medication into CEHRT using electronic tracking sensors (for example, radio frequency identification (RFID)) or electronically readable tagging such as bar coding (77 FR 54034).

[186] Barcode Medication Administration (BCMA) System is defined as a system that allows users to electronically document medications at the bedside or other points-of-care using an electronically readable format. More information. Available at: *http://www.ahrq.gov/downloads/pub/advances/vol3/wideman.pdf*.

The SAARs are designed to serve as high value targets or high-level indicators for hospital ASPs to assess hospital antimicrobial use. A SAAR that is not significantly different from 1.0 indicates ''expected'' antibiotic use. A SAAR that is above 1.0 may indicate excessive antibiotic use or a SAAR that is below 1.0 may indicate antibiotic underuse. We note that the SAARs do not provide a definitive indication of antibiotic appropriateness of use. Outlier SAAR values should prompt hospitals to do further analysis to assess overuse, underuse, or inappropriate use of antibacterial medications. In addition, the SAARs may be used by hospital ASPs to identify opportunities to improve antibiotic use and gauge the impact of stewardship efforts.

(3) Data Sources

The data submission and reporting standard procedures for the NHSN Antimicrobial Use measure have been set forth by the CDC for NHSN participation, in general, and for submission of measure data. We refer readers to the CDC's NHSN Web site (*http://www.cdc.gov/nhsn*) for detailed data submission and reporting procedures. Although the NHSN Antimicrobial Use measure is not specified as an eCQM, manual data entry is not available. Data must be electronically extracted from an eMAR [187] and/or BCMA system.[188] The format for data submission must adhere to the data format prescribed by the CDC HL7 Clinical Data Architecture (CDA) Implementation Guide available at: *http://www.cdc.gov/nhsn/cdaportal/toolkits/guidetocdaversions.html*.

(4) Measure Calculation

Each SAAR is an observed to expected ratio and is calculated by dividing the numerator, or total number of observed antimicrobial days (days of therapy reported by a healthcare facility for a specified category of antimicrobial agents in a specified patient care location or group of locations), by the denominator, or expected (predicted on the basis of nationally aggregated antimicrobial use data for a healthcare facility's use of a specified category of antimicrobial agents in a specified patient care location or group of locations) number of antimicrobial days, for each antibiotic agent category-patient care location combination. The total number of observed antimicrobial days for each patient care location is defined as the aggregated sum of days for which any amount of a specific antibiotic agent within an antibiotic agent category was administered as documented in the eMAR or BCMA system. The predicted number of antimicrobial days for each patient care location is determined by multiplying the observed days present by the corresponding antimicrobial use rate in the standard population obtained from the relevant regression model. Hospital patient care locations other than adult and pediatric medical, medical/surgical, and surgical wards and adult and pediatric medical, medical/surgical, and surgical ICUs are excluded from this measure. For more information regarding the specifications for the Antimicrobial Use measure, we refer readers to the NHSN Antimicrobial Use and Resistance Module (AUR): *http://www.cdc.gov/nhsn/PDFs/pscManual/11pscAURcurrent.pdf*.

We invited public comment on the possibility of future inclusion of the NHSN Antimicrobial Use measure (NQF #2720).

Comment: Many commenters supported the future inclusion of the NHSN Antimicrobial Use measure in the Hospital IQR Program indicating that it is critically important to reduce the amount of unnecessary antibiotic prescriptions, help practitioners and public health officials alike assess antibiotic use in hospitals based on medication administration data that hospitals collect thereby helping to combat a growing clinical and public health concern (antimicrobial resistance), and improve the appropriateness of both antimicrobial use and patient outcomes. In addition, one commenter noted that the measure will enable facilities to monitor antibiotic use and guide stewardship efforts in hospitals but recommended further validation and testing to ensure accurate and meaningful application of the measure prior to its inclusion. The commenter noted that inclusion of the measure would encourage facilities to: (1) Benchmark antibiotic use; (2) assess appropriateness of antibiotic prescribing; and (3) target stewardship interventions and gauge their impact.

Another commenter noted that in order for measures of this kind to become widely used, a broad interoperability standard needs to be adopted across all vendors providing accessibility to the requisite electronic drug administration data. A third commenter added that CMS is the only entity that can address the overuse of antibiotics through its Conditions of Participation and public reporting and payment accountability tools. The commenter encouraged CMS to target this measure for public reporting that is subsequently tied to payment incentive programs. Similarly, another commenter stated that reporting of antibiotic use data to the NHSN Antibiotic Use Reporting (AUR) module is of great importance because doing so would provide vital statistics on which stewardship of use of antibiotics can be assessed, and help facilities evaluate their antimicrobial utilization over time. The commenter noted that there are currently no national data on antibiotic use, and at the broadest level it is difficult to chart national improvement without having systematically collected antibiotic use data from all acute care hospitals in the U.S. Lastly, one commenter urged CMS to recognize that hospital antimicrobial stewardship is only one aspect of the multifaceted and worldwide efforts needed to address the increasing challenge of antimicrobial resistance.

Response: We thank the commenters for supporting the future inclusion of the Antimicrobial Use measure. We will take these comments and suggestions into consideration in developing future policy.

Comment: One commenter supported future inclusion of the NHSN Antimicrobial Use measure in the Hospital IQR Program, but suggested that this measure should be voluntary because required reporting at this time would place an undue burden on hospitals without a fully integrated IT system.

Response: We thank the commenter for supporting the proposed future inclusion of the Antimicrobial Use measure and will consider the commenter's suggestion in developing future policy.

Comment: One commenter did not support future inclusion of the Antimicrobial Use Measure, because better methods are available for prescribing antibiotics than what is described in the measure text, such as adherence to the local facility antibiogram for the type of infection present and technologic identification of gene resistance markers. The commenter also suggested that the measure data that is provided is aged and indicated that the usage of the measure's data for payment purposes is counterproductive to clinical improvement.

[187] eMAR is defined as technology that automatically documents the administration of medication into CEHRT using electronic tracking sensors (for example, radio frequency identification (RFID)) or electronically readable tagging such as bar coding (77 FR 54034).

[188] Barcode Medication Administration (BCMA) System is defined as a system that allows users to electronically document medications at the bedside or other points-of-care using an electronically readable format. More information available at: *http://www.ahrq.gov/downloads/pub/advances/vol3/wideman.pdf*.

Response: We acknowledge the commenter's concern, but note that the NHSN Antimicrobial Use Measure assesses antibiotic use (the amount of antibiotics used) rather than appropriateness of use. The measure result is not a definitive measure of appropriateness and should not be interpreted in isolation to assess prescribing practices. Instead, the Antimicrobial Use measure should prompt hospitals to do further analysis of prescribing practices to assess overuse, underuse, or appropriateness of use. This additional analysis to assess appropriateness of use may include consulting the facility antibiogram, the facility antimicrobial stewardship program, as well as other evidence based treatment guidelines as appropriate.

We disagree with commenter's suggestion that NHSN measure data is ''aged'' and ''counterproductive to clinical improvement.'' The NHSN has various analytic functions that enable hospitals to analyze their own surveillance data at any time. We encourage hospitals to use these functions for continuous quality improvement efforts. Additional information regarding analysis is available on the NHSN Web site at: *http://www.cdc.gov/nhsn/ps-analysis-resources/index.html*.

Comment: One commenter questioned whether the use of ''days of therapy'' (DOT) is an adequate component of measurement, indicating that not all health information systems will be able to extract a clean result for this data point. Instead, the commenter suggested that the ''defined daily dose'' (DDD) be the unit of measurement, as it is more readily available, more easily obtained, and provides useful information.

Response: We appreciate the commenter's observations about summarizing antimicrobial consumption using DDD. A major reason why NHSN opted to use DOT is that DDD is not applicable in children (aged >1 month) due to the large variation in body weight within this population. Further, NHSN's experience with antimicrobial use surveillance—in which over 140 hospitals ranging widely in bed size, information technology resources, and geographic location have successfully submitted antimicrobial use data to NHSN—suggests that DOT data can be consistently collected and reported to NHSN. While investments in a technical solution are necessary to enable data extraction, aggregation, and reporting, the NHSN experience provides clear evidence that information technology vendors and, in some instances, health systems themselves, are capable of developing and deploying those solutions.

Comment: A few commenters expressed concern about the vendor tool currently used to collect data for the measure. Commenters indicated that the tool is inefficient and urged the CDC to correct the problems with the tool prior to program inclusion. One commenter noted that hospitals have difficulty reporting directly to the module which requires a direct HL7 feed, a functionality not offered by many EHR vendors, and because the measure requires additional testing and validation before introduction into public reporting or payment programs.

Response: While the CDC continuously strives to be abreast of issues that arise with vendor tools and to provide feedback as a method of aiding in the maintenance of vendor tools, we will share the commenters' concerns with the CDC. We will also take these comments into consideration in developing future CMS policy.

Comment: One commenter suggested that the NHSN Antimicrobial Use measure assess administration of antibiotics in the ED and those used pre-operatively, noting that if hospitals only gather data from eMAR or barcode-administration, the data on administration of antibiotics will be overlooked, and therefore, the overall measure results will be skewed. The commenter urged that CMS evaluate the administration of antibiotics in the ED and operating room.

Response: We appreciate commenter's suggestion to include the emergency department (ED) and operating room (OR) in the measure and will share it with the CDC. Although the ED and OR are not included in the measure, the NHSN Antibiotic Use and Resistance Module does allow for optional submission of ED and OR data. For more information, we refer readers to: *http://www.cdc.gov/nhsn/acute-care-hospital/aur/*.

Comment: One commenter supported the potential inclusion of the NHSN Antimicrobial Use measure but recommended that the measure be specified as an eCQM rather than a chart-abstracted measure.

Response: We thank the commenter for this support and we will share the recommendation with the CDC.

Comment: A few commenters did not support the inclusion of the NHSN Antimicrobial Use measure. A few commenters believed the measure would place an information handling burden on hospitals, especially smaller hospitals that would likely have to contract with an outside vendor. The commenter encouraged CMS to consider another alternative for reporting progress on antibiotic stewardship. Another commenter stated that the measure is too broad and the measure calculation is unclear.

Response: We acknowledge the commenters' concerns and will consider them should we propose to adopt the measure in future rulemaking. For more information regarding measure calculation, we refer readers to the Antibiotic Use and Resistance Module manual available at: *http://www.cdc.gov/nhsn/pdfs/pscmanual/11pscaurcurrent.pdf*.

Comment: Many commenters supported the concept of antimicrobial stewardship and inclusion of an antimicrobial use measure in the Hospital IQR Program, but did not support inclusion of this NHSN Antimicrobial Use measure for various reasons. Specifically, several commenters objected to the measure because Standardized Antimicrobial Administration Ratios (SAARs) measure the amount of antibiotics used but does not account for the appropriateness of antibiotic use nor does it separate community hospitals from academic hospitals when defining the expected number. Commenters noted that including this measure in the Hospital IQR Program and publicly reporting it on *Hospital Compare* may create incentives for providers to lower the number of antimicrobial days to improve their SAAR irrespective of the appropriateness of antimicrobial use.

Commenters urged CMS to explore the use of a measure that looks at both number of antimicrobial days and the appropriateness of use to promote true antimicrobial stewardship and improved patient outcomes. One commenter suggested that CMS develop process metrics around the appropriate use of diagnostic test(s) that help determine if antibiotic use is appropriate by first identifying the microbe causing the infection prior to prescribing the antibiotic in cases where patient health status allows for the diagnostic first and also the time to effective treatment.

Some commenters also expressed concern that the testing sample used to develop the measure was too small which could lead to unintended consequences of reporting the measure on a nation scale and the use of the measure in public reporting may result in misleading comparisons complexity of the patient population can contribute to differences in antibiotic use rates. These commenters suggested that CMS conduct large-scale pilot studies to further evaluate and validate the metric

prior to including the SAAR as part of the measure set.

For all of these reasons, some commenters expressed concern that these data have a high probability of misinterpretation by the public and may provide inaccurate justification for hospitals to avoid dedicating resources to antimicrobial stewardship programs if their SAARs are already within goal. Other commenters expressed concern about issues related to feasibility of public reporting, risk-adjustment, and providing hospitals sufficient time for technical set-up required with this measure.

Response: We acknowledge commenters' concerns regarding public reporting, risk adjustment, and technical feasibility and will consider the comments them should we propose to adopt the measure in future rulemaking.

Comment: One commenter suggested that CMS explore additional hospital strategies to support efforts to reduce the threat of multidrug resistant organisms in the hospital setting. One noted approach was addressing infection control through the use of technology that relies on antiseptics, such as ionic silver and molecular iodine. Another noted approach was the use of silver antimicrobial dressings, following surgeries conducted on geriatric patients. This tactic can be an important part of protocols to reduce surgical site infections and further combat antibiotic resistance. Lastly, the commenter mentioned that combining antimicrobial agents with anti-biofilm agents would be effectual because the anti-biofilm would disrupt biofilm to expose associated organisms to antibiotics.

Response: We thank the commenter for these suggestions and we will consider them for the future.

Comment: Several commenters expressed the opinion that the NHSN Antimicrobial Use measure is appropriate for use in quality improvement efforts, but not for public reporting at this time. The commenters urged CDC and CMS to work together to refine the measure should it be considered in the future for public reporting.

Response: We thank the commenters for their suggestions and we will continue to work with colleagues at the CDC to improve the measure's feasibility for potential future public reporting.

c. Potential Measures for Behavioral Health in the Hospital IQR Program

Although the IPFQR Program incorporates measures of inpatient psychiatric treatment (80 FR 46694), the Hospital IQR Program does not include any measures directly related to behavioral health. Based on MedPAC analyses, over a third of Medicare inpatient psychiatric admissions are treated ''in acute care hospital beds not within distinct-part psychiatric units.'' [189] Thus, there may be a gap in understanding the quality of care given to inpatient psychiatric patients not paid for under the IPFQR Program.

To address this gap, we invited public comments on potential behavioral health quality measures appropriate to include in the Hospital IQR Program in future years, including the possible use of one or more measures previously adopted in the IPFQR Program (80 FR 46417). The comments we received and our responses are set forth below.

Comment: Several commenters supported the future inclusion of behavioral health quality measures in the Hospital IQR Program. One commenter noted that in small community hospitals, patients with alcohol or drug abuse issues for medical detox, withdrawal, or overdose are not routinely admitted to psychiatry after medical treatment, which is largely problematic. Therefore, including measures of behavioral health in the Hospital IQR Program to address these behavioral issues will help to improve outcomes for this patient population. Another commenter was particularly interested in measures that examine health conditions such as schizophrenia and bipolar disorder and noted that successful implementation of behavioral health measures in the Hospital IQR Program should lead to subsequent inclusion in the Hospital VBP Program. A few commenters specifically requested that tobacco cessation and substance abuse treatment measures be included because of their importance in treating inpatient populations. Another commenter recommended the addition of the ''Substance Use Screening'' measures, ''Tobacco Use'' measures, the ''Screening for Metabolic Disorders'' measure, the ''Hours of Physical Restraint Use'' measure, and the ''Seclusion Use'' measure.

Response: We thank the commenters for this support of behavioral health measures in the Hospital IQR Program to improve patient outcomes. We will consider these recommendations should we propose to adopt behavioral health measures in future rulemaking.

Comment: Some commenters supported the future inclusion of behavioral health quality measures in the Hospital IQR Program, but only if the population for these measures is correctly identified and reliable. These commenters urged CMS to consider measures that better reflect the quality of inpatient psychiatric care than Tobacco and Substance Use, stating that these measures are currently structured so that the inpatient stay can be focused on stabilizing the patient to be transferred to the next appropriate level of care. The commenters urged CMS to recognize the patient's right to refuse treatment so that if a hospital educates and offers treatment to a patient, and the patient refuses treatment for substance abuse, the measure would not capture this as a reflection of poor care, but rather exclude the patient from the measure population.

Commenters encouraged CMS to consider adopting the HBIPS–5 measure (Discharge on multiple anti-psychotic medications with appropriate justification for use), the Transition of Care Measures for all inpatients (not just those with a psychiatric diagnosis), the Screening for Metabolic Disorders with antipsychotic medications measure, and other measures that capture the change in a patient's presenting psychiatric condition between admission and discharge.

Response: We appreciate commenters' recommendations and will consider them in developing future policy.

Comment: One commenter requested specific examples of measures from the IPFQR Program to be able to give feedback. The commenter recognized that there are measures from the IPFQR Program that may be appropriate for the Hospital IQR Program, but indicated that inclusion of these measures would require time to implement workflows. On the other hand, some commenters cautioned CMS about adopting measures from the IPFQR Program. Specifically, some commenters stated that while the hospital-based inpatient psychiatric services (HBIPS) measures are the most appropriate for this population, these measures have been phased-out over time in favor of measures that are less applicable to this specific patient population. Therefore, commenters urged CMS to collaborate with stakeholders to develop new measures of behavioral health.

Response: We thank commenters for sharing their suggestions and concerns. We understand that the addition of any new measures may cause workflow concerns, and we will consider these issues when evaluating any behavioral health measures we propose to adopt in future rulemaking.

[189] Medicare Payment Advisory Commission (U.S.). (2010). MedPAC June 2010 Report to the Congress: Washington, DC: MedPAC, available at: *http://www.medpac.gov/documents/reports/Jun10_Ch06.pdf?sfvrsn=0.*

Comment: One commenter did not support including quality measures of behavioral health in the Hospital IQR Program in the future because introducing these measures within an inpatient medical facility would introduce workflow documentation challenges and likely result in unintended consequences. Further, the commenter suggested that prior to any measure migration there be a review of the appropriate regulations (that is, HIPAA or State-specific guidance) regarding the sharing of sensitive mental health data.

Response: We acknowledge commenter's concerns and recommendations regarding the use of behavioral health measures in the Hospital IQR Program and will consider them should we propose behavioral health measures in future rulemaking.

d. Potential Public Reporting of Quality Measures Data Stratified by Race, Ethnicity, Sex, and Disability and Future Hospital Quality Measures That Incorporate Health Equity

We sought comment on the possibility of including Hospital IQR Program measure data stratified by race, ethnicity, sex, and disability on *Hospital Compare,* if feasible and appropriate (that is, statistically appropriate, etc.) in the future. By stratification, we mean that we would report quality measures for each group of a given category (age, race, sex, and disability status). For example, if we were to report the Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) (NQF #1789) stratified by sex, we would report a hospital's measure result for females and then again separately for males, in addition to reporting a hospital's unstratified rate, as is currently displayed. In addition, we also sought comment on potential hospital quality measures, including composite measures, for inclusion in the Hospital IQR Program measure set and thus, future postings on *Hospital Compare,* that could help consumers and stakeholders not only assess the measurement of the quality of care furnished by hospitals in inpatient settings, but also monitor trends in health equity. Any data pertaining to these areas that are recommended for collection through measure reporting for the Hospital IQR Program and public disclosure on *Hospital Compare,* would be addressed through a separate and future notice-and-comment rulemaking.

We invited public comment on the possibility of future inclusion of stratified quality measures data on *Hospital Compare* and on stratification categories, including any categories not specified in this preamble. We also sought comment on potential future hospital quality measures that incorporate health equity. The comments we received and our responses are set forth below.

Comment: Several commenters supported future reporting of measures in the Hospital IQR Program stratified by race, ethnicity, sex, and disability status if feasible and statistically appropriate. Commenters noted that stratification would contribute to greater transparency for consumers and provide an incentive for hospitals to improve the reporting of these factors. A few commenters recommended that CMS consider stratifying by additional factors including primary language and other social determinants of health because this type of data will enable more accurate evaluation in coverage gaps and disparities, particularly among minority and vulnerable populations, and are essential to improving the impact of adult immunization efforts and expanding coverage. Another commenter encouraged CMS to include age, income, and education level along with any of the above demographic factors it may use in stratification of measure reporting and suggested that CMS consider enabling multiple cross-cutting factors to be applied to any stratification to facilitate stratification by more than one factor at the same time. Another commenter recommended that CMS also consider stratification by age bands.

Several commenters also expressed the opinion that a uniform approach to data collection and stratification is necessary to ensure appropriate comparisons. One commenter suggested that, in order for the stratification information that would be shared to be meaningful, the standards used for the Hospital IQR Program for race, ethnicity, and sex must align with the Medicare and Medicaid EHR Incentive Programs. Further, this commenter stated that a standardized definition of ''disability'' needs to be developed, as currently one does not exist. Another commenter urged CMS to engage in a national dialogue on this important matter and to consider the Health Research and Educational Trust (HRET) Disparities Toolkit as an appropriate place to start discussion regarding a uniform data collection. Another commenter urged CMS to engage in a national dialogue on this important matter as these conversations are also ongoing across the health insurance exchange and MA markets.

Response: We thank the commenters for their support and suggestions. We will consider these recommendations should we propose to adopt stratified measure reporting in future rulemaking.

Comment: Several commenters supported use of performance measure stratification as a tool to identify and reduce health disparities, but urged CMS to continue to explore appropriate risk adjustment of measures, including risk adjustment for SDS factors. Commenters stated that differences in performance measure outcomes due to actual variation in the quality of care provided to subgroups of patients should not be tolerated.

Response: We thank the commenters for their support and recommendations. We will consider these recommendations should we propose to adopt stratified measure reporting in future rulemaking.

Comment: A few commenters did not support future reporting of measures in the Hospital IQR Program stratified by race, ethnicity, sex, or disability status. One commenter raised specific concerns about the method of data collection, indicating that patient demographic information is collected by entry level registration staff who are often not skilled in collecting sensitive information. In addition, the commenter stated that the inclusion of this information would pose additional administrative burden. Another commenter believed that the reasons for variation in performance by patient characteristics may or may not be related to hospital performance, and this type of reporting therefore raises more questions than it answers and could lead to misinterpretation and unintended consequences.

Response: We thank commenters for voicing their concerns and will consider them should we propose to adopt stratified measure reporting in future rulemaking.

Comment: One commenter suggested that CMS and AHRQ continue to conduct research on the impact of socioeconomic determinants upon health care outcomes. The commenter also requested that the results of this research be shared publicly.

Response: As we have previously noted, we have not risk-adjusted measures for SDS factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. However, as stated in section VIII.A.6.a.(1) of the preamble of this final rule, several measures developed by CMS have been brought to NQF since the beginning of the SDS trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not

to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, ASPE is conducting research to examine the impact of SDS on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available. Moreover, we will continue to collaborate with colleagues across HHS to evaluate the impact of SDS factors on healthcare outcomes and to develop an effective and transparent method for communicating results to the public.

Comment: Several commenters warned that it may not be a simple task to stratify measures by race, ethnicity, sex, and disability because specific considerations are required for every measure and each reporting mechanism to implement such a requirement. Specifically, one commenter noted that small denominator sample sizes are inherently problematic, and, if further stratified by factors such as race, age, and gender, will skew the reliability of the measure data. Therefore, the commenter stated that the stratified data should not be used for financial accountability programs. Instead, the commenter recommended that CMS develop educational material that will assist stakeholders in interpreting stratified quality measures. Another commenter supported the concept of CMS gathering data in the ways that can best lead to improved outcomes, but requested at minimum 18 months to implement changes.

Response: We thank commenters for voicing their concerns and will consider them in should we propose to adopt stratified measure reporting in future rulemaking.

Comment: One commenter acknowledged the importance of the policy aim to better understand health disparities and health equity, but recommended delaying the inclusion of stratified measures in the Hospital IQR Program until the collection of race, ethnicity, and disability data have matured. The commenter noted that CMS requires the capture of REAL (race, ethnicity, age, and language) data as part of the Medicare and Medicaid EHR Incentive Programs, but that this activity is relatively new and the quality of the REAL data captured through the EHRs needs to be studied to determine whether it can be used for this purpose. The commenter noted that Hospital Engagement Networks (HENs) are required to work with hospitals to standardize the collection of REAL data. This work, it stated, will continue in the future through the newly created Hospital Improvement Innovation Networks (HIINs), which will be required to identify gaps in the collection of REAL data in their network and to provide interventions and assistance to reduce these gaps leading to improvement of the quality of REAL data in the next few years.

Response: We appreciate the comments regarding ongoing efforts to standardize and improve the collection of race, ethnicity, age, and language data. In addition, we acknowledge commenter's recommendation for delaying stratification and will consider these comments should we propose to adopt stratified measure reporting in future rulemaking.

Comment: One commenter expressed interest in learning the submission requirements for patient characteristics data provided for quality measures. The commenter also noted that the benefit of health equity data would need to be weighed against any new data collection burden.

Response: Submission requirements for patient characteristics vary from measure to measure. If in the future we move forward with a proposal to stratify measure data by race, ethnicity, sex, and disability on *Hospital Compare,* we will balance the benefit health equity data would provide against any new data collection burden associated with measures not currently subject to REAL requirements. We thank the commenters for their feedback and suggestions and we will consider them as we develop future policies.

10. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the description above. In accordance with the statute, the FY 2016 payment determination began the second year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements. For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period of time. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. Hospitals must register and submit quality data through the secure portion of the QualityNet Web site. There are safeguards in place in accordance with the HIPAA Security Rule to protect patient information submitted through this Web site.

b. Procedural Requirements for the FY 2019 Payment Determination and Subsequent Years

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811). In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25199), we did not propose any changes to these procedural requirements.

However, as discussed below in section VIII.A.11. of the preamble of this final rule, we proposed to amend § 412.140(d)(2) in connection with our proposal to modify our validation processes beginning with the FY 2020 payment determination.

c. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25199), we did not propose any changes to the data submission requirements for chart-abstracted measures.

d. Alignment of the Hospital IQR Program With the Medicare and Medicaid EHR Incentive Programs for Eligible Hospitals and CAHs

(1) Background

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49709) for our policies aligning eCQM data reporting and submission periods on a calendar year basis for both the Medicare EHR Incentive Program for eligible hospitals and CAHs and the Hospital IQR Program for the FY 2017 payment determination and subsequent years for the Hospital IQR Program.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25199 through 25201), we proposed the following changes to the Hospital IQR Program to further align eCQM data reporting for the Hospital IQR Program with the Medicare and Medicaid EHR Incentive Programs: (1) Maintaining the eCQM data certification process we previously adopted for the FY 2018 payment determination, including requiring hospitals to report eCQM data using EHR technology certified to either the 2014 or 2015 Edition of the Office of the National Coordinator for Health Information Technology's (ONC's) certification criteria for health information technology and which meets the electronic health record technology (CEHRT) definition for the CY 2017 reporting period/FY 2019 payment determination; and (2) requiring the use of EHR technology certified to the 2015 Edition beginning with the CY 2018 reporting period/FY 2020 payment determination and subsequent years.

In addition, we proposed to require eCQM data submission by the end of 2 months following the close of the reporting period calendar year for the CY 2017 reporting period/FY 2019 payment determination and subsequent years to further align eCQM data reporting for the Hospital IQR Program with the Medicare EHR Incentive Program. These proposals are discussed in more detail below.

(2) Continuation of eCQM Certification Processes for the FY 2019 Payment Determination and Requirements for Subsequent Years

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708), we finalized policies regarding eCQM certification for the FY 2018 payment determination. Specifically, we finalized that: (1) Hospitals can report using EHR technology certified to either the 2014 or 2015 Edition for the CY 2016 reporting period/FY 2018 payment determination since certification to the 2015 Edition is expected to be available in 2016; and (2) hospitals must submit eCQM data via Quality Reporting Document Architecture Category I (QRDA I) file format (80 FR 49706–49708). In addition, hospitals may use third parties to submit QRDA I files on their behalf (80 FR 49706) and can either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I (80 FR 49706).

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25200), we proposed to continue these eCQM certification policies. Specifically, for the CY 2017 reporting period/FY 2019 payment determination (not subsequent years), we proposed to require that hospitals report using EHR technology certified to either the 2014 or 2015 Edition as previously required. We note that we proposed to change these policies, however, for the CY 2018 reporting period/FY 2020 payment determination as discussed in the following section.

In addition, for the CY 2017 reporting period/FY 2019 payment determination and subsequent years, we proposed that hospitals: (1) Must submit eCQM data via QRDA I files as previously required; (2) may continue to use a third party to submit QRDA I files on their behalf; and (3) may continue to either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I. This would align the Hospital IQR Program with the Medicare EHR Incentive Program. We refer readers to section VIII.E.2.c. of the preamble of this final rule for discussion of the certification requirements for the Medicare EHR Incentive Program.

We invited comment on these proposals. In addition, we refer readers to section VIII.A.11.b.(5) of the preamble of this final rule where we encourage hospitals to take advantage of eCQM pre-submission testing tools to help reduce submission errors related to improperly formatted QRDA I files.

Comment: One commenter supported alignment with the Medicare and Medicaid EHR Incentive Programs to use the QRDA I standard, to permit the use of third party entities to submit QRDA I files, and to use CEHRT for capturing and reporting data in QRDA I. The commenter expressed concern that requiring electronic submission of eCQM data using the most recent version of CEHRT might create a disconnect in the timing cycle of the regulatory adoption of standards and the rapid evolution of electronic standards for eCQM reporting. The commenter recommended that CMS and ONC collaborate to establish a regulatory framework that is more responsive to the speed at which standards are developed, maintained, upgraded, and improved. One commenter supported the intent to align the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program reporting requirements to reduce provider burden and minimize confusion about reporting criteria across various quality reporting programs, but expressed concern about the expansion of eCQMs with the current state of EHR technology. One commenter urged CMS, as part of its certification process, to seek stakeholder input and to define standards for EHR organization and structure that allows for documentation to fit into the clinical workflow and interact with providers at the point-of-contact to guide them to provide timely and appropriate care.

Response: We thank the commenter for this support. We appreciate the commenter's concerns about the current timeframe of evolving electronic standards and the timing cycle for the regulatory adoption of standards. We will continue to seek stakeholder input and collaborate with colleagues at ONC to define standards for EHR organization and structure that allows for documentation to fit into the clinical workflow and to ensure that our policies are responsive to evolving electronic standards to the greatest extent feasible.

Comment: One commenter recommended that CMS not require a hospital to combine eCQM data from two CEHRT solutions if a hospital switches vendors during a reporting quarter or year but rather to submit only one QRDA I file from the CEHRT solution on which the hospital was utilizing for a majority of the reporting quarter because QRDA I files do not allow for combining data from multiple sources while ensuring that patient data is not repeated as a result of the combination.

Response: We thank the commenter for this suggestion, but we disagree that QRDA I files do not allow for combining data from multiple sources while ensuring that patient data are not repeated. We expect that QRDA I files submitted for the Hospital IQR Program electronic reporting requirement are one patient per file per quarter and cumulative in nature, thus allow for the combination of data from multiple sources to contain all the episodes of care and the measures associated with the patient file for the same reporting quarter. When QRDA I files are

submitted, the following four key elements are utilized to identify the file:

- CMS Certification Number (CCN);
- CMS Program Name;
- EHR Patient ID; and
- Reporting period specified in the Reporting Parameters Section.

Utilization of the four key elements for file identification, and the requirement to ensure the QRDA I file is cumulative and representative of one quarter of data, greatly reduces the likelihood of receiving repeated patient data. We note, however, that the system will overwrite the original file with the most recent submission if all four key elements are an exact match.

We refer readers to the succession management criteria outlined within the CMS Implementation Guide for Quality Reporting Document Architecture Category I and Category III Eligible Professional Programs and Hospital Quality Reporting (HQR) Version 1.0 for additional details. The document is updated annually and posted on the eCQM Library on the CMS Web site available at: *https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/ecqm_library.html.*

Comment: A few commenters requested clarification on the use of abstraction to extract data from non-certified sources into CEHRT for capture and reporting through QRDA I files. One commenter expressed concern that a hospital might chart-abstract data to complete the data set necessary to report on an eCQM because this duplicative transcription process could lead to errors and conflict with the medical record maintained in the certified EHR. Some commenters expressed the opinion that clinical data used to satisfy eCQM reporting should originate from a credible source, and if not, abstraction of data from a non-certified source would undermine the integrity of the EHR Incentive Program. The commenters recommended that chart-abstraction should never be permitted for eCQMs and that reporting should be based solely on information available in CEHRT through the normal record management process in place at the hospital. One commenter urged CMS to utilize chart abstraction for quality reporting until the EHR transformation is made to allow clinicians to focus on delivering high quality patient focused care without the distraction of eCQM reporting using an EHR structure that has yet to evolve to support true meaningful use.

Response: We appreciate the commenters' concerns about information from non-certified sources into CEHRT for capture and reporting through QRDA I files. Ideally, information available in CEHRT through normal record management process should be in place and used to report on eCQMs. However, many hospitals are still undergoing the time consuming and labor intensive process of data mapping their EHR systems. Data mapping is necessary in order to be able to capture required data elements, such as diagnostic study results/reports or other measure information, in discrete structured data fields to support the eCQMs because they are often found as free text in clinical notes or PDF documents attached to the medical record instead.

In recognition of the reality that hospitals are in a state of transition, it is our intent to allow hospitals some flexibility in reporting methods if necessary during this period of transition. Therefore, at this time, we will continue to permit the use of abstraction to extract data from non-certified sources into CEHRT for capture and reporting through QRDA I files. However, we encourage hospitals to continue making progress to fully achieve electronic data capture and reporting or to work with their vendors to do so. We acknowledge the commenters' concerns that using chart-abstracted data to complete the data set necessary to report on an eCQM could result in a duplicative transcription process that could lead to errors and conflict with the medical record maintained in the CEHRT, but we believe that the potential for error exists any time providers enter information into an EHR. In order to identify mismatches and inaccuracies in data, in this final rule we are finalizing a policy to validate eCQM data beginning with the FY 2020 payment determination. We refer readers to section VIII.A.11.b. of the preamble of this final rule for more details on the validation process for eCQM data.

Comment: One commenter expressed concern with these proposals because a number of hospitals have not successfully submitted QRDA I files and CEHRT is not capable of generating QRDA I files for submission without modifications. The commenter suggested that CMS provide more detailed guidance, education, and support on QRDA I file generation and release lessons learned to improve the process.

Response: We note that our data show that 95 percent of hospitals already attest to successful eCQM reporting under the Medicare EHR Incentive Program and, accordingly, we believe that the majority of hospitals will successfully report eCQMs. We recognize that technical mapping may be potentially burdensome, but we disagree that CEHRT is not capable of generating QRDA I files for submission without modifications. We encourage hospitals to work with their vendors to overcome these issues. We encourage all hospitals to submit files early, as well as to use one of the available presubmission testing tools for electronic reporting—such as the CMS Pre-Submission Validation Application (PSVA), which can be downloaded from the Secure File Transfer (SFT) section of the QualityNet Secure Portal at *https://cportal.qualitynet.org/QNet/pgm_select.jsp.* We refer readers to section VIII.A.11.b.(5) of the preamble of this final rule for more information about the PSVA. In addition, we acknowledge the commenter's suggestion to put additional focus on QRDA I file generation in our education and outreach activities for the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing that hospitals must report using EHR technology certified to either the 2014 or 2015 Edition for the CY 2017 reporting period/FY 2019 payment determination (not subsequent years) as proposed. We also refer readers to section VIII.A.10.d.(5) of the preamble of this final rule, in which we finalize alignment of this policy in the Medicare and Medicaid EHR Incentive Programs. We are also finalizing, for the CY 2017 reporting period/FY 2019 payment determination and subsequent years, that hospitals: (1) Must submit eCQM data via QRDA I files as previously required; (2) may use a third party to submit QRDA I files on their behalf; and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I as proposed.

(3) Required Use of EHR Technology Certified to the 2015 Edition for the FY 2020 Payment Determination and Subsequent Years

As stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705), some commenters requested that hospitals be given the opportunity to use the most recent version of CEHRT (2015 Edition) for the CY 2016 reporting period/FY 2018 payment determination if they are able. We believe this requirement will mitigate the existing vendor issue of system comparability between hospitals and vendors and facilitate consistency regarding the version of CEHRT to which vendors are certified by establishing uniformity in the version of the product used. Therefore, in the FY

2017 IPPS/LTCH PPS proposed rule (81 FR 25200), we proposed to require the use of EHR technology certified to the 2015 Edition beginning with the CY 2018 reporting period for the FY 2020 payment determination and subsequent years. This would align the Hospital IQR Program with the Medicare and Medicaid EHR Incentive Programs. We also refer readers to section VIII.E.2.c. of the preamble of this final rule for discussion of the certification requirements for the Medicare and Medicaid EHR Incentive Programs.

We invited public comment on our proposal to require the use of EHR technology certified to the 2015 Edition for the CY 2018 reporting period/FY 2020 payment determination and subsequent years as stated above.

Comment: Several commenters supported the proposals to align the CEHRT requirements, measure set, and deadlines between the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program because these proposals will decrease the burden on organizations that currently report for both programs.

Response: We thank the commenters for their support.

Comment: One commenter expressed concern that the vendor community will not have adequate time to deliver the updated products to the market place in time for all providers to meet the 2018 reporting, which would require use of version 2015 CEHRT. The commenter explained that the proposed changes in eCQM reporting would necessitate sufficient time for vendors and providers to test and deploy CEHRT. The commenter acknowledged that measures need to evolve, but stated that a balance needs to be reached such that the churn around development and deployment is not endless. For this reason, the commenter urged CMS to make greater strides to enact a ''predictable'' cycle from measure development to provider data submission.

Response: We note that the 2015 Edition certification criteria is available for testing beginning in 2016,[190] but EHR technology certified to the 2015 Edition will not be required until the CY 2018 reporting period. We recognize there is burden associated with development and deployment, but we believe requiring use of the most recent version of CEHRT is important in allowing us to collect relevant electronic data. In addition, we are finalizing a modified version of our proposal to require reporting on only 8 self-selected eCQMs (instead of all eCQMs) to reduce burden, in part so that hospitals and vendors can focus on implementation of the 2015 Edition. We refer readers to section VIII.A.8.a. of the preamble of this final rule for more details on this modification. We believe that these modified requirements provide sufficient time for hospitals to test and deploy CEHRT. While we appreciate the commenter's suggestion that we strive to enact a ''predictable'' cycle from measure development to provider data submission, we must balance the importance of keeping pace with evolving electronic standards and the timing cycle for the regulatory adoption of standards when adopting policies for the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing the required use of EHR technology certified to the 2015 Edition for the CY 2018 reporting period/FY 2020 payment determination and subsequent years as proposed. We also refer readers to section VIII.A.10.d.(5) of the preamble of this final rule, in which we finalize alignment of policies in the Medicare and Medicaid EHR Incentive Programs.

(4) Electronic Submission Deadlines for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) for our previously adopted policies to align eCQM data reporting and submission periods for both the Medicare EHR Incentive Program for eligible hospitals and CAHs and the Hospital IQR Program for the FY 2018 payment determination.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50249 through 50252), we finalized our policy that hospitals may voluntarily report 16 electronic measures by submitting one quarter of eCQM data from CY Q1 (January 1–March 31, 2015), CY Q2 (April 1–June 30, 2015), or CY Q3 (July 1–September 30) by November 30, 2015. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49693 through 49698), for the FY 2018 payment determination, we finalized a policy that hospitals must submit one quarter of data (either Q3 or Q4 of CY 2016) for at least 4 eCQMs by the submission deadline of February 28, 2017.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25200), in order to align the Hospital IQR Program eCQM data submission deadline with that of the Medicare EHR Incentive Program, which requires eCQM data submission by the end of two months following the close of the reporting period calendar year (80 FR 62896 through 62897), we proposed to establish an eCQM submission deadline for the Hospital IQR Program which requires eCQM data submission by the end of two months following the close of the calendar year for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. For example, for the CY 2017 reporting period/FY 2019 payment determination, hospitals would be required to submit eCQM data for the Hospital IQR Program by February 28, 2018, which is the end of 2 months following the close of the calendar year (December 31, 2017). This would align the Hospital IQR Program with the Medicare EHR Incentive Program deadlines. We note that deadlines for the Medicaid (not Medicare) EHR Incentive Program differ by State, and therefore our proposal to align data submission deadlines for eCQMs applies only to the Hospital IQR Program and the Medicare EHR Incentive Program and not to the Medicaid EHR Incentive Program. For more information about the Medicaid EHR Incentive Program for eligible hospitals and CAHs, we refer readers to: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Eligible_Hospital_Information.html.*

We invited public comment on our proposal to align the Hospital IQR Program eCQM submission deadline with that of the Medicare EHR Incentive Program for the CY 2017 reporting period/FY 2019 payment determination and subsequent years as discussed above.

Comment: One commenter expressed support for the policy that the submission period for reporting eCQMs electronically is the two months following the close of the calendar year because this policy allows for continued improvement over the course of the year without the interruption of submission.

Response: We thank the commenter for its support. With regard to the submission period for eCQM reporting, however, we note that we are finalizing our proposal to require eCQM data submission by the end of 2 months following the close of the reporting period calendar year for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. We wish to clarify that the submission period would not be limited to only a two-month submission window from the end of the reporting period to the end of 2 months following the close of the reporting period as commenter suggested (for example, for CY 2017

[190] 2015 Edition CEHRT Information available at: *https://www.healthit.gov/sites/default/files/final2015certedfactsheet.022114.pdf.*

reporting, a submission window of January 1, 2018 through February 28, 2018). We anticipate that following the close of the CMS data receiving system for CY 2016 reporting period eCQM data submissions, we will re-open the system in late spring 2017 to be able to receive both QRDA I test files and QRDA I production files for CY 2017 reporting period eCQM data submissions. This would allow hospitals and vendors greater flexibility to submit QRDA I files earlier as soon as each calendar quarter ends rather than waiting to submit all QRDA I files during the last two months of the submission period.

We encourage all hospitals and vendors to submit QRDA I files early, as well as to use one of the presubmission testing tools for electronic reporting, such as the CMS Pre-Submission Validation Application (PSVA), to allow additional time for testing and to make sure all required data files are successfully submitted by the deadline. The PSVA can be downloaded from the Secure File Transfer (SFT) section of the QualityNet Secure Portal at: *https://cportal.qualitynet.org/QNet/pgm_select.jsp.* We refer readers to section VIII.A.11.b.(5) of the preamble of this of this final rule for more information about the PSVA. We also refer readers to section VIII.E.2.b. of the preamble of this final rule in which the submission deadline for the Medicare EHR Incentive Program is finalized.

Comment: A few commenters supported the effort to align the proposals for both the Hospital IQR Program and the EHR Incentive Programs, but expressed concern about the same challenges in reporting all eCQMs in both the Medicare and Medicaid EHR Incentive Programs and in the Hospital IQR Program. The commenters urged CMS to maintain the current requirements in the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs for CY 2017 to give hospitals time to plan and prepare.

Response: We thank the commenters for their support. We refer readers to section VIII.A.8.a. of the preamble of this final rule for our discussion of the modified required number of eCQMs and our final policy.

Comment: A commenter expressed concern with the proposals to align the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program because there are differences in the available and required number of eCQMs for reporting between IQR and the Medicare and Medicaid EHR Incentive Programs. The commenter requested that CMS require the same number of eCQMs regardless of how the eCQMs are reported.

Response: We are aligning the programs and finalizing the same number of eCQMs that will be required to be reported for the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program (that is, 8 of the available eCQMs in the programs). We refer readers to section VIII.A.8.a. of the preamble of this final rule in which we finalize a modified policy to require 8 eCQMs, and section VIII.E.2. of the preamble of this final rule in which the measure set and the required number of eCQMs to be reported for the Medicare and Medicaid EHR Incentive Programs are finalized. We note that as part of our alignment efforts, a hospital may report the same eCQMs for the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs. With regard to the available set of eCQMs, the Medicare and Medicaid EHR Incentive Programs have one additional eCQM available, ED–3 (Median Time from ED Arrival to ED Departure for Discharged ED Patients), that is applicable only for the outpatient hospital setting (77 FR 54083 through 54087), and would not count towards meeting Hospital IQR Program eCQM reporting requirements.

After consideration of the public comments we received, we are finalizing the alignment of the Hospital IQR Program eCQM submission deadline with that of the Medicare EHR Incentive Program—the end of two months following the close of the calendar year—for the CY 2017 reporting period/FY 2019 payment determination and subsequent years as proposed. We also refer readers to section VIII.E.2.b. of the preamble of this final rule where we discuss submission deadlines in the Medicare EHR Incentive Program.

(5) Summary of Alignment

We are finalizing our proposals to align the Hospital IQR Program with the Medicare and Medicaid EHR Incentive Programs as summarized below:

ALIGNMENT OF HOSPITAL IQR PROGRAM WITH BOTH THE MEDICARE AND MEDICAID EHR INCENTIVE PROGRAMS

- Removal of 13 eCQMs.
- Requirement for submission of 8 self-selected eCQMs out of the available eCQMs for the CY 2017 reporting period/FY 2019 payment determination.*
- Requirement for annual submission of four quarters of eCQM data.
- Required use of EHR technology certified to the 2014 or 2015 Edition of CEHRT for CY 2017 reporting period/FY 2019 payment determination.**

*The Hospital IQR Program is also finalizing the required reporting of 8 eCQMs for the CY 2018 reporting period/FY 2020 payment determination.

**The Hospital IQR Program is also finalizing the required use of EHR technology certified to the 2015 Edition for the CY 2018 reporting period/FY 2020 payment determination. We note that in the proposed rule (81 FR 25200 through 25201), this chart stated ''Proposed use of 2015 CEHRT for CY 2018 reporting period/FY 2020 payment determination'' for the Hospital IQR Program and both the Medicare and Medicaid EHR Incentive Programs. The Medicare and Medicaid EHR Incentive Programs have not finalized this policy for CY 2018 reporting period/FY2020 payment determination. Technical revisions made here for accuracy.

ALIGNMENT OF HOSPITAL IQR PROGRAM WITH ONLY THE MEDICARE EHR INCENTIVE PROGRAM

- Required submission of eCQM data by the end of 2 months following the close of the reporting period calendar year.*

*We note that in the proposed rule (81 FR 25200 through 25201), this chart stated ''proposed submission of eCQM data 2 months following the close of the calendar year'' and did not accurately capture our proposal and final policy that submission would be required *by the end* of 2 months following the close of the reporting period calendar year. Technical revisions made here for accuracy.

e. Sampling and Case Thresholds for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 24588), we revised our sampling and case thresholds policy so that, for the FY 2018 payment determination and subsequent years, hospitals will be required to submit population and sample size data only for those measures that a hospital submits as chart-abstracted measures under the Hospital IQR Program.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25201), we did not propose any changes to our sampling and case thresholds policy; however, we did receive several comments related to this policy.

f. HCAHPS Requirements for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS requirements. We also refer hospitals and HCAHPS survey vendors to the official HCAHPS Web site at *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25201), we did not propose any changes to the HCAHPS requirements.

g. Data Submission Requirements for Structural Measures for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539) for details on the data submission requirements for structural measures. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25201), we did not propose any changes to data submission requirements for structural measures.

h. Data Submission and Reporting Requirements for HAI Measures Reported via NHSN

For details on the data submission and reporting requirements for HAI measures reported via the CDC's NHSN Web site, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25201), we did not propose any changes to data submission and reporting requirements for HAI measures reported via the NHSN.

11. Modifications to the Existing Processes for Validation of Hospital IQR Program Data

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), we finalized the processes and procedures for validation of chart-abstracted measures in the Hospital IQR Program for the FY 2015 payment determination and subsequent years; the FY 2013 IPPS/LTCH PPS final rule also contains a comprehensive summary of all procedures finalized in previous years that are still in effect. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712) for detailed information on the modifications to these processes finalized for the FY 2016, FY 2017, and FY 2018 payment determinations and subsequent years.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25201 through 25204), we proposed to update the validation process in order to incorporate a process for validating eCQM data.

b. Modifications to the Existing Processes for Validation of Hospital IQR Program Data

(1) Background

In the proposed rule, we proposed to update the existing process for validation of Hospital IQR Program data, which has previously included up to 600 hospitals for chart-abstracted validation, to also include eCQM validation of up to 200 hospitals, for a total of up to 800 hospitals for validation for the FY 2020 payment determination and subsequent years. Specifically, 200 hospitals would be randomly selected for eCQM validation but among those hospitals some may be granted Extraordinary Circumstances Exemption (ECEs) or meet other exclusion criteria (discussed in additional detail below) potentially resulting in a number totaling less than 200 hospitals that actually participate in eCQM validation. Furthermore, we proposed that hospitals would be required to submit timely and complete medical record information from the Electronic Health Records (EHRs) for at least 75 percent of sampled records, but would not be scored on the basis of measure accuracy for FY 2020 payment determinations.

As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53555), determining the equivalence of eCQM data and chart-abstracted measures data requires extensive testing given that the data for the Hospital IQR Program support public reporting for both the Hospital IQR and the Hospital VBP Programs; in addition, for the Hospital VBP Program, the data are used to calculate hospitals' performance on a subset of measures which tie payment directly to measure performance. As described in the Hospital IQR Program discussion in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we have received anecdotal comments about performance level differences between chart-abstracted and eCQM data. We stated that we did not have sufficient data to be able to confirm or refute the accuracy of those comments (79 FR 50258). In order to substantiate or refute the existence of performance-level differences between eCQM data and chart-abstracted measure data, we believe that we must collect more eCQM data and develop a process for validating the accuracy of those data.

As a result, we conducted a validation pilot test for eCQMs (discussed below). Our findings from this pilot test have informed what we believe the initial future direction of eCQM validation in the Hospital IQR Program should be. In the proposed rule, we proposed to adopt a validation process for eCQM data submissions beginning in spring of CY 2018, as further explained below.

(2) Validation Pilot Test

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50269 through 50273), we finalized a proposal to conduct a validation pilot test for eCQMs in FY 2015. The results of the pilot test yielded measure record matching rates (that is, the rates of medical record abstracted values as compared to the values reported in the QRDA I file) of

less than 50 percent for all of the measures reported. For all measures, the inconsistencies between abstracted values and values reported in the QRDA I files appear to be mainly due to missing data rather than actual differences in reported versus abstracted values. The highest rate of accuracy was 48 percent on both the STK–04 and VTE–1 eCQMs. In addition, all of the participating hospitals demonstrated significant difficulty in reporting the ED–1 and ED–2 eCQMs due to the ED Admit Date/Time data element, which contributed to the ED measure mismatch rates. Specifically, hospitals systematically reported a later date and time for the decision to admit a patient to the hospital in the QRDA I file than that identified by the Clinical Data Abstraction Center (CDAC) in the review of the medical record.

Follow-up interviews conducted by CDAC revealed that low accuracy rates and reporting difficulties were a result of a lack of targeted outreach and education efforts at the time of the pilot to adequately prepare participating hospitals for the specific reporting mechanisms. In order to improve data accuracy and diminish reporting difficulties, the CMS Education and Outreach contractor (EOC) as well as the Validation Support Contractor (VSC) plan to continue to conduct provider education follow-up and refine the validation process. We will work in conjunction with the EOC and VSC to enlarge the cohort of eligible hospitals that are able to successfully submit QRDA I files, as well as encourage hospitals that were not able to successfully submit QRDA I files to participate in follow-up interviews. These follow-up interviews will inform the eCQM validation process moving forward, and allow us to derive ''best reporting practices'' to consider once we begin scoring the measures. Additional details about the 2015 Validation Pilot are available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1140537256076*.

(3) Validation of eCQMs Beginning Spring CY 2018/FY 2020 Payment Determination

In response to the findings of the pilot test and in light of our proposal to increase the number of eCQMs on which hospitals are required to submit data for the Hospital IQR Program discussed in section VIII.A.8.a. of the preamble of this final rule, we believe that it is increasingly important to validate eCQM data to ensure the accuracy of future information submitted by hospitals and reported to the public. Therefore, we proposed to adopt a validation process for eCQM data submissions beginning in Spring of CY 2018, as further explained below.

(a) Number and Selection of Hospitals

We proposed to validate eCQM data submitted by up to 200 hospitals selected via random sample. Furthermore, we proposed that the following hospitals be excluded from this random sample of 200 hospitals selected for eCQM validation:

- Any hospital selected for chart-abstracted measure validation; and
- Any hospital that has been granted a Hospital IQR Program ''Extraordinary Circumstances Exemption'' for the applicable eCQM reporting period.

We acknowledge that the burden associated with both the chart-abstracted and eCQM validation processes would be significant. We do not intend to impose an undue burden on any hospital by requiring that it be subject to more than one of these processes in a program year. Thus, if a hospital is selected for chart-abstracted targeted or random validation, we proposed that hospital would be excluded from the eCQM validation sample.

In addition, although our targeted criteria permit that a hospital may be selected for chart-abstracted validation even if it has been granted an Extraordinary Circumstances Exemption with respect to one or more chart-abstracted measures for the applicable data collection period (77 FR 53552 through 53553), if a hospital is granted an Extraordinary Circumstances Exemption with respect to eCQM reporting for the applicable eCQM reporting period, we proposed that the hospital would be excluded from the eCQM validation sample due to its inability to supply data for validation. We note that due to these proposed exclusions, the total number of hospitals validated for eCQMs might be less than 200.

Adding the proposed eCQM validation would result in a total of up to 800 hospitals in the validation process, as described in the below tables.

Current Validation Process Number of Hospitals	
Chart-Abstracted Random	400
Chart-Abstracted Targeted	200
Total	600

Proposed Validation Process Number of Hospitals	
Chart-Abstracted Random	400
Chart-Abstracted Targeted	200
eCQM Random	200
Total	800

We believe that as we expand the required reporting of eCQMs in the Hospital IQR Program, we need to validate eCQM data to ensure the accuracy of information submitted by hospitals and reported to the public, as well as for future consideration of eCQMs for potential use in the Hospital VBP Program. In addition, during the first round of eCQM validation, we could better assess strategies to offset the resources required to conduct a scored method of eCQM validation for future rulemaking cycles.

We invited public comment on our proposals for the FY 2020 payment determination and subsequent years to: (1) Validate eCQM data submitted by up to 200 hospitals selected via random sample; and (2) to exclude any hospital selected for chart-abstracted measure validation as well as any hospital that has been granted a Hospital IQR Program ''Extraordinary Circumstances Exemption'' for the applicable eCQM reporting period as discussed above.

Comment: Several commenters supported the proposal to modify the existing validation process for the Hospital IQR Program to include validation of eCQM data for a variety of reasons. One commenter believed validation of eCQM data will promote transparency about the quality of the eCQM data being submitted as well as identify challenges inherent with data validity and eCQM reporting. The commenter recommended that CMS validate the accuracy of the content in the structured fields to see how consistent it is with the rest of the medical record because unless the accuracy of the structured fields is assured, the quality of the data reported by eCQM reporting will continue to be suspect and unfit for use in public reporting or pay-for-performance programs.

Response: We thank the commenters for their support and we will take recommendations related to the validation of the content in the structured files and its impact on medical record accuracy into consideration as we implement the validation of eCQM data. We understand the importance of reliable and valid information and share the commenter's desire to ensure the integrity of the data provided for public

reporting and pay-for-performance programs.

Comment: One commenter expressed concern that insufficient testing could result in unintended consequences to patient safety and health care quality, but expressed concern that the validation pilot may be too narrow for an accurate review. Another commenter noted that data extracted from EHRs differ from the data obtained from chart-abstracted measures and, therefore, currently are not reliable for display in a public reporting program.

Response: We acknowledge the commenter's concern about insufficient testing resulting in unintended consequences. We recognize that we must thoroughly evaluate the electronic data provided to us in order to promote patient safety and health care quality. We appreciate the commenter's concern that the validation pilot may be too narrow for an accurate review and to address this concern we are expanding the validation process for eCQM data to include 200 hospitals initially. After the first year of validation data is evaluated, we will be able to more accurately determine the most appropriate mechanisms for validating the information and consider if we need to expand the number of participating hospitals.

In response to the commenter's point about differing data extraction methods, we recognize that performance-level differences between eCQM data and chart-abstracted measure data may exist, however, we believe that we must collect more eCQM data and develop a process for validating the accuracy of those data. Further, we do not intend to publicly report eCQM data from the CY 2017 reporting period.

Comment: One commenter supported the proposed modifications to the existing validation process to include the validation of eCQM data, but expressed concern that the validation pilot focused only on the apparent lack of outreach and education to explain the mismatch between QRDA I and medical record abstraction to explain low level of accuracy. The commenter noted that other possible explanations for low accuracy include: Process workflows; data definitional issues; non-structured data requiring manual input; and the level of data completeness and reliability captured in CEHRT. The commenter recommended that CMS pursue additional strategies to increase the validity and reliability of the QRDA I reported measures. Also, because of the demonstrably poor concordance between eCQMs and their chart-abstracted counterparts, the commenter recommended that penalties be limited to pay-for-reporting, rather than pay-for-performance, programs until there are significantly better results. A few commenters expressed concern with the proposal to begin validating eCQM data because hospitals and vendors require more education and guidance to accurately report eCQM data. The commenters suggested that CMS improve the resources available to healthcare organizations regarding the implementation of eCQMs beyond validation. Another commenter expressed interest in engaging with CMS to further provide education to ensure that providers and vendors alike are aligned.

Response: We thank the commenter for these observations and we will consider these factors as we implement the validation process for eCQM data. The findings of the validation pilot revealed that hospitals indicated that they encountered difficulties in mapping the information in the EHR systems to the QRDA I specifications due to the use of unstructured data fields and multiple sources of information for various events. As stated in the proposed rule (81 FR 25202), the inconsistencies between abstracted values and values reported in the QRDA I files appear to be mainly due to missing data rather than actual differences in reported versus abstracted values. The highest rate of accuracy was 48 percent on both the STK–04 and VTE–1 eCQMs. In addition, all of the participating hospitals demonstrated significant difficulty in reporting the ED–1 and ED–2 eCQMs due to the ED Admit Date/Time data element, which contributed to the ED measure mismatch rates. Specifically, hospitals systematically reported a later date and time for the decision to admit a patient to the hospital in the QRDA I file than that identified by the Clinical Data Abstraction Center (CDAC) in the review of the medical record. The difficulties in mapping, which were caused by missing information, resulted in failure of the data to be translated to QRDA I. During the pilot, hospitals also indicated that much of the required information is documented in the hospital EHR system through free text notes, dictation, and scanned PDF documents, rather than discrete data fields. For this reason, data elements could not be extracted or mapped to create the data elements in the QRDA I files. In addition, hospitals indicated that clinical workflows and the use of clinical terminology did not align with the eCQM specifications at the time of the pilot, which hindered efficient data mapping by hospitals and their vendors. For more details on the eCQM validation pilot test, titled ''The Hospital IQR eCQM Pilot Summary,'' we refer readers to the pilot test findings available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1140537256076*.

As a result of these findings, we have updated the eCQM specifications to improve implementation and will continue outreach and education efforts, particularly regarding data mapping techniques/requirements to improve submission efforts moving forward. We appreciate the commenter's interest in education and outreach and encourage the commenter to engage with CMS. In addition, we will take the commenters' feedback into consideration as we provide education and outreach to hospitals and vendors about the eCQM validation requirements and we will solicit feedback on additional strategies to increase the validity and reliability of the QRDA I reported measures. We intend to continuously evolve our resources to ensure that healthcare organizations are equipped with the tools and knowledge to not only successfully submit eCQM data for validation, but to ensure that accurate and reliable data are submitted as part of regular eCQM reporting, prior to validation.

We note that accuracy of the data submitted for eCQM validation will have no impact on determination of the hospital's APU for at least the first year of validation in CY 2018; however, hospitals selected for eCQM validation still must submit timely (within 30 days of the records request) and sufficient (at least 75 percent complete) medical records to receive a full APU for the FY 2020 payment determination. We refer readers to section VIII.A.11.b.(3)(e) of the preamble of this final rule where we finalize our eCQM validation scoring policies.

Comment: A few commenters recommended delaying implementation of the proposal to begin validating eCQM data because the current timeline does not allow providers enough time to implement new processes in order to prevent receiving a penalty under the proposed validation policies. One commenter specifically recommended delaying validation by 24 months to allow providers to learn the rules of validation. Another commenter noted that the EHR vendor guidance for mapping data elements is not sufficient for full automation of the data extraction process such that most of the mapping is completed by hospital staff using their own procedures, resulting in a heavy burden for hospitals as well as

high potential for inconsistency in measure reporting output, even among hospitals using the same EHR vendor product. The commenter recommended delaying implementation of the eCQM data validation proposal to allow more time for vendors to develop standardized procedures and hospitals to implement efficient workflows based on these standardized procedures and encouraged CMS to ensure that hospitals are reasonably able to comply with these new requirements. A commenter stated that the experience of participants in the eCQM data validation pilot suggests that more time is needed before data validation can be successfully implemented in the broader Hospital IQR Program.

Response: We thank the commenters for their recommendations, but we disagree with the suggestion to delay implementation of an eCQM validation process. We note that we will not conduct the first validation of eCQM data until spring of 2018 to validate data from the CY 2017 reporting period and that the measures accuracy of data submitted for eCQM validation will have no impact on determination of the hospital's APU for purposes of the Hospital IQR Program for at least the first year this validation process is in effect. We believe this timeline does allow providers enough time to implement new processes and to learn the requirements of validation in order to prevent receiving a penalty under the validation policies.

We acknowledge that the data extraction process has been such that most of the mapping is completed by hospital staff using their own procedures, resulting in a high potential for inconsistency in measure reporting output, even among hospitals using the same EHR vendor product. It is precisely those types of inconsistencies on which we would be able to provide feedback to participating hospitals when sharing their validation results. Precisely because the results of the validation pilot demonstrated that there were significant inaccuracies in reported eCQM data, we believe that validation of eCQM data is critically important in order to guide improvement efforts and to tailor education and outreach to help hospitals improve the quality of the data they submit.

To address the suggestion of the creation of standardized data extraction procedures, we will utilize any input provided from EHR vendors during our education and outreach efforts that might be beneficial in such procedures. We also recognize that hospitals may have their own unique workflows, so input from both hospitals and EHR vendors would be utilized to help establish ''best practices.''

Comment: Some commenters acknowledged the importance of eCQM validation, but expressed concerns about the process, specifically, variable methods of recording data within the EHR at the user level, non-intuitive data collection requirements imposed by the measures and/or product design, the differences between manually-abstracted and electronically-abstracted measures, and the workflow changes required for chart review. One commenter recommended that CMS consider the EHR vendor role in the validation plan, and work with vendors to understand some of these variations, as well as to identify EHR system functional requirements and query vendors as to current product capabilities relative to these requirements.

Response: Our proposed eCQM validation process is intended to help hospitals identify and correct inconsistencies associated with varying methods of recording data within the EHR and different interpretations of data collection requirements at the user level in order to improve the accuracy of data reported. Instituting an eCQM validation process will help us to better understand how to help hospitals resolve these data reporting concerns. We acknowledge that many hospitals will most likely continue to have concerns about the accuracy of their data in the first few years of required eCQM reporting. It is for this reason that we have proposed and are finalizing that the measures accuracy of data submitted for eCQM validation will have no impact on determination of the hospital's APU for at least the first year (that is, the FY 2020 payment determination).

In response to the commenter's recommendation that we consider the EHR vendor role in the validation plan and work with vendors to understand some of these variations, identify EHR system functional requirements, and query vendors as to current product capabilities relative to these requirements, we acknowledge that EHR vendors could provide feedback invaluable to the eCQM validation process. We will make efforts, to the extent feasible, to include vendors in our outreach and education efforts, to provide them an opportunity to share their knowledge related to EHR system functional requirements and product capabilities that can inform the validation process and help to improve it over time.

Comment: One commenter recommended that, rather than focusing on validating eCQM data, CMS only include an eCQM in a quality reporting program if it has been fully tested by CMS to ensure the measure functions as intended, is deemed feasible by an appropriate process that considers the views of multiple applicable stakeholders, is fully field tested, and is endorsed by NQF.

Response: We note that our data show that 95 percent of hospitals already attest to successful eCQM reporting under the Medicare EHR Incentive Program and, accordingly, we believe that the majority of hospitals will successfully report eCQMs. Hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program (3 years of pilot reporting and 3 years of voluntary reporting), which demonstrate that the eCQMs included in the Hospital IQR Program measure set function as intended and are feasible. In addition, as noted in the table in section VIII.A.7.c. of the preamble of this final rule, almost all of the eCQMs available in the Hospital IQR Program measure set for the FY 2019 payment determination are endorsed by the NQF (only the CAC–3 and STK–08 eCQMs are not NQF-endorsed). Whenever feasible, we adopt measures that are NQF-endorsed, but note that, sometimes, there are important areas of clinical concern for which NQF-endorsed measures do not exist. In these instances, we may elect to adopt measures that have not yet been NQF-endorsed.

Comment: A number of commenters recommended that CMS share the findings from the 2015 eCQM Validation Pilot as a method of keeping stakeholders informed about the validation process. The commenters noted that sharing this information will improve eCQM reporting accuracy and also facilitate an educational forum that allows hospitals and stakeholders to understand how to better implement eCQMs. One commenter also stated CMS' transparency with the results will allow hospitals to better understand the results and their general applicability to the greater hospital community.

Response: We agree with commenters and note that a summary of the findings from the eCQM validation pilot test we conducted, titled ''The Hospital IQR eCQM Pilot Summary,'' is available on the QualityNet Web site at: *http://www.QualityNet.org/.* Stakeholders were notified of the availability of this summary of the findings on June 13, 2016 via email. To access the summary, select the ''Data Validation'' link from

the ''Hospitals-Inpatient'' tab. On the Data Validation Overview page, select the ''Resources'' link in the left-side navigation pane. A list of communications regarding the Hospital IQR Program is available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228765304720*.

Comment: One commenter recommended that CMS extend the EHR pilot testing beyond two hospitals and two EHR systems, to gather adequate information to understand how the eCQMs will work. The commenter further recommended that CMS collect a minimum of one year's worth of data from all hospitals and vendors chosen to participate in the EHR pilot testing, and explained that these data should be considered ''test'' data and not released publicly, but instead be released to hospitals for feedback to CMS. One commenter recommended additional testing of the eCQMs to avoid the unnecessary use of resources by facilities and CMS. Another commenter recommended that the implementation of eCQM data validation be delayed and that CMS convene stakeholders to discuss issues arising from the pilot project, clarify operational validation procedures based on that input, and then implement a larger pilot test before proposing and finalizing a validation process.

Response: The CMS eCQM validation pilot included 29 hospitals and 29 EHR systems, which we believe is an adequate sample size for a pilot. We disagree that eCQM validation should be delayed or that we should conduct another pilot because implementation of a validation process is intended to help hospitals identify and correct inconsistencies in eCQM data to improve the accuracy of data reported. Instituting an eCQM validation process will help us to better understand how to help hospitals resolve these data reporting concerns. Additional validation pilots would rely on voluntary participation by hospitals, which will produce a small sample size, as noted above with the 29 participating hospitals in the previous pilot.

We believe that implementing a broader validation process with mandatory participation better serves to achieve our goals of improving the accuracy of data reported and help us to better understand how to help hospitals resolve data reporting concerns because it will include a larger sample size. The objective of eCQM validation is to be responsive to concerns related to the reliability and validity of eCQM data, and ultimately to be able to confirm the accuracy of data sufficient for public reporting. If we continue to conduct pilot studies, we will continue to have inconclusive results based on a small sample size. We note that our data show that 95 percent of hospitals already attest to successful eCQM reporting under the Medicare EHR Incentive Program and, accordingly, we believe that the majority of hospitals will successfully report eCQMs; therefore, we do not believe additional testing is necessary or that implementation of an eCQM data validation process be delayed.

We note that we will not conduct the first validation of eCQM data until spring of 2018 to validate data from the CY 2017 reporting period, that the measures accuracy of data submitted for eCQM validation will have no impact on determination of the hospital's APU for at least the first year (that is, FY 2020 payment determination), and that the results of the validation will not be publicly reported. We believe that sharing eCQM validation results with hospitals will provide invaluable feedback that will enable them to identify issues and correct issues to improve their EHRs as well as the quality of their eCQM data.

Comment: One commenter expressed concern regarding the results of the eCQM validation pilot, which highlighted challenges for implementing eCQMs including the burden associated with mapping necessary data elements from the EHR to the appropriate QRDA format.

Response: We appreciate the commenter's concerns and acknowledge the burden associated with mapping necessary data elements from the EHR to the appropriate QRDA I format. We encourage hospitals to work with their vendors to resolve these issues. Precisely because the results of the validation pilot demonstrated that there were significant inaccuracies in reported eCQM data, we believe that validation of eCQM data is critically important in order to guide improvement efforts and to tailor education and outreach to help hospitals improve the quality of the data they submit.

Comment: One commenter opposed the eCQM validation proposal, stating that the addition of the eCQM validation process puts undue burden on facilities. The commenter noted that because QRDA I files contain information from the electronic medical record, submitting the complete medical record in PDF format will not provide the various codifications contained in the EHR. Further, the commenter added that the data reported will be more accurate and valuable if the rollout includes fewer, well-tested measures.

Response: We believe that appropriately mapped QRDA I files contain information from the EHR, and that submitting the complete medical record in PDF format will provide the various information contained in the EHR. We recognize that technical mapping may be potentially burdensome and we encourage hospitals to work with their vendors to overcome these issues. When hospitals work with their vendors to ensure that EHRs are appropriately structured in a way that fits in with the clinical work flow to yield reliable data through eCQMs, we believe that eCQMs promote higher quality outcomes and lower costs while ultimately decrease reporting burden on hospitals as compared with chart-abstraction of quality measure data.

We disagree that reporting or validation of eCQMs puts undue burden on facilities. We believe that it is appropriate to require reporting and validation of eCQMs given that measures available now and those being developed for the future are increasingly based on electronic standards (80 FR 49696). We also note that progress on the meaningful use of electronic health data is a national priority, as evidenced by the HITECH Act and the EHR Incentive Programs' Meaningful Use requirements. We believe that collection of eCQM data will enable hospitals to efficiently capture and calculate quality data that can be used to address quality at the point of care and track improvements over time. We also believe that the removal of 13 eCQMs, as detailed in section VIII.A.3.b. of the preamble of this final rule for the FY 2019 payment determination and subsequent years, appropriately addresses that implementation of the validation process includes fewer, well-tested measures as suggested by the commenter. We acknowledge that there are initial costs, but believe that long-term benefits associated with electronic data capture outweigh those costs. For these reasons, we believe that it is appropriate to require hospitals to report on an increasing number of eCQMs, as well as to implement a process to validate the data as these go hand-in-hand.

Comment: One commenter expressed concern with the proposal to validate eCQM data because the sample size may not be large enough to ensure selection of 200 hospitals. The commenter suggested that additional hospitals be included in the random sample to provide the ability to substitute hospitals into the sample if they are

needed and to ensure that the match rate is 90 percent.

Response: We acknowledge that among those hospitals selected for eCQM validation, some may be granted Extraordinary Circumstances Exemptions or meet other exclusion criteria (discussed in additional detail below) potentially resulting in a number totaling less than 200 hospitals that actually participate in eCQM validation. We believe that the sample size of 200 hospitals, consistent with the targeted sample size for chart-abstracted validation, will be sufficient even taking into account the possibility that some hospitals selected for validation may not participate in validation if they satisfy any of the exclusion criteria. We may consider increasing the sample size in the future.

Comment: One commenter supported the proposal to modify the existing validation process to include validation of eCQM data, but recommended changes to the proposed validation methodology. Specifically, the commenter recommended that CMS: compare performance rates for all populations within an eCQM to their chart-abstracted counterparts, which would require comparable chart abstracted specifications; convene a multi-stakeholder group to address the detailed methodology of comprehensive data validation prior to submission and conduct an audit post-submission; and establish a National Test Collaborative for fully testing new eCQMs prior to their implementation in CMS programs.

Response: We thank the commenter for its suggestions, and we will take them into consideration as we implement the validation process for eCQM data. In response to the commenter's suggestion that we compare performance rates for all populations within an eCQM to their chart-abstracted counterparts, we do not have data available to conduct such comparisons at this time, but as our eCQM validation process matures, we will take this recommendation into consideration in the future. However, we note that eCQM data and chart-abstracted data are not always one hundred percent comparable due to the use of structured data fields in eCQMs and free text in chart-abstracted measures. In response to the commenter's suggestion that we convene a multi-stakeholder group to address the detailed methodology of comprehensive data validation prior to submission and conduct an audit post-submission, we acknowledge the importance of having multi-stakeholder input to inform pre and post submission validation efforts, and we believe that input from such a group would be meaningful as we continue to evolve our validation policies. Currently, we gather this type of input from Technical Expert Panels (TEPs) that assist in evaluating the information collected during field testing as a part of the eCQM development process. In addition, we gather feedback from stakeholders via public comment during both the alpha and beta testing phases of measure development. As such, we will make every effort to engage stakeholders in a similar manner, through outreach and education about eCQM validation. In response to the commenter's point about establishing a National Test Collaborative, we will take this recommendation into consideration in the future.

Comment: One commenter expressed concern that the validation methodology could negatively impact hospitals because the CMS contractor will look at free text fields, which likely are not reviewed by the CEHRT tool.

Response: We acknowledge the commenter's concerns, but we disagree that the validation methodology could negatively impact hospitals because as we have stated above, accuracy of the data submitted for eCQM validation will have no impact on determination of the hospital's APU for at least the first year and the results of the validation will not be publicly reported. Further, as discussed in section VIII.A.10.d.(5) of the preamble of this final rule, we are finalizing the required use of EHR technology certified to the 2015 Edition beginning with the CY 2018 reporting period, to better ensure that the information provided in the free text fields has been adequately reviewed.

After consideration of the public comments we received, for the FY 2020 payment determination and subsequent years, we are finalizing our proposals to: (1) Validate eCQM data submitted by up to 200 hospitals selected via random sample; and (2) to exclude any hospital selected for chart-abstracted measure validation as well as any hospital that has been granted a Hospital IQR Program ''Extraordinary Circumstances Exemption'' for the applicable eCQM reporting period as proposed.

(b) Number of Cases

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25203), we proposed to randomly select 32 cases (individual patient-level reports) from the QRDA I file submitted per hospital selected for eCQM validation. Each randomly selected case (individual patient-level report) contains eCQM data elements [191] for one patient for one or more eCQMs available in the program's eCQM measure set. The CDAC would then request that each of the selected hospitals submit patient medical record data for each of their 32 randomly selected cases (transmitted by the hospital to the Clinical Data Warehouse) within 30 days of the medical records request date. We refer readers to our discussion in section VIII.A.11.b.(3)(c) of the preamble of this final rule, below, for more information on our submission requirements.

Based on the statistical properties of estimates as discussed below, we believe that a sample size of 32 cases is necessary to assess hospital performance on eCQMs. More specifically, at the individual hospital level, if we assume the average agreement rate between the QRDA I file data and data abstracted from the patient medical record is around 90 percent, and we want the hospital's confidence interval to vary by no more than plus or minus 10 percentage points (80 to 100 percent), then we need to select at least 32 cases per year. Also, 32 cases aligns with the number of cases currently selected for chart-abstracted validation of clinical process of care measures. We currently select eight cases per quarter per hospital, which equates to 32 cases annually (79 FR 50264).

We invited public comment on our proposal to randomly select 32 cases from the QRDA I file submitted per hospital selected for eCQM validation for the FY 2020 payment determination and subsequent years as discussed above.

We did not receive any comments on this proposal, and therefore, we are finalizing our proposal to randomly select 32 cases from the QRDA I file submitted per hospital selected for eCQM validation for the FY 2020 payment determination and subsequent years as proposed.

(c) Submission Requirements

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25203), we proposed to require hospitals selected for eCQM validation to submit timely and complete medical record information to CMS on eCQMs selected for the validation sample. These are defined below.

[191] A data element is a representation of a clinical concept that represents a patient state or attribute. This may be a diagnosis, lab value, sex, etc., which is encoded using standardized terminologies. The e-specifications for an eCQM include the data elements, logic, and definitions for that measure, available from: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Electronic_Reporting_Spec.html.*

Consistent with the Hospital IQR Program chart-abstracted and NHSN validation submission deadline, which is 30 calendar days following the medical records request date listed on the CDAC request form (76 FR 51645), we proposed to require eCQM validation submission by 30 calendar days following the medical records request date listed on the CDAC request form for the FY 2020 payment determination and subsequent years. Also, we proposed to require sufficient patient level information (defined below) necessary to match the requested medical record to the original Hospital IQR Program submitted eCQM measure data record for the FY 2020 payment determination and subsequent years. Sufficient patient level information is defined as the entire medical record that sufficiently documents the eCQM measure data elements, which would include but would not be limited to, patient arrival date and time, inpatient admission date, and discharge date from inpatient episode of care. Lastly, we proposed that, if selected as part of the random sample for eCQM validation, a hospital would be required to submit records in PDF file format through QualityNet using the Secure File Transfer (SFT) for the FY 2020 payment determination and subsequent years. The data submission deadlines and additional details about the eCQM validation procedures would be posted on the QualityNet Web site at: *http://www.QualityNet.org/*.

We invited public comment on our proposals regarding eCQM validation submission requirements for the FY 2020 payment determination and subsequent years as discussed above.

Comment: A few commenters supported the validation of eCQM data, but recommended the timeline for submission be extended from 30 to 60 days to allow hospitals sufficient time to work with their EHR vendor on compiling data and to reduce overall administrative burden.

Response: We thank the commenters for their support and their recommendation to extend the submission timeline to 60 days. However, we have selected the 30 day timeline to be consistent with chart-abstracted and NHSN timelines for validation. We believe that aligning the timelines between chart-abstracted and eCQM validation will minimize confusion and burden on hospitals.

Comment: One commenter expressed concern about the timing of the request for the validation information for eCQMs. Specifically, the commenter took issue with the expansion of work required if a hospital is selected for both chart-abstracted and eCQM validation, since the selection for each process is random. Moreover, the commenter advised that the eCQM data request should not occur at the same time the quarterly request goes out for the chart-abstracted cases.

Response: As stated in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25202), we acknowledge that the burden associated with both the chart-abstracted and eCQM validation processes would be significant. We do not intend to impose an undue burden on any hospital by requiring that it be subject to more than one of these processes in a program year. For this reason, we proposed that if a hospital is selected for chart-abstracted targeted or random validation, that hospital would be excluded from the eCQM validation sample. We refer readers to section VIII.A.11.b.(3)(a) of the preamble of this final rule, above, where we finalize our exclusions.

Comment: A few commenters requested clarification about what constitutes ''sufficient patient level information'' to successfully pass validation, including a list of specific information to provide for each eCQM that can be consistently applied across vendors and providers. Commenters wanted to know which specific patient data would be required for validation purposes and whether the medical record data includes all encounters for a patient or only one encounter for a patient.

Response: As we stated in the proposed rule (81 FR 25203), sufficient patient level information is defined as the entire medical record that sufficiently documents the eCQM measure data elements, which would include but would not be limited to, patient arrival date and time, inpatient admission date, and discharge date from inpatient episode of care. Any patient information captured in the QRDA I file should also be reflected in the PDF submission of the patient's EHR. Medical record data include all encounters for a patient. The data submission deadlines and additional details about the eCQM validation procedures will be posted on the QualityNet Web site at: *http://www.QualityNet.org/*.

Comment: A few commenters supported the proposal to validate eCQM data, but suggested that the data elements for validation be listed by data element per measure. The commenters stated that this approach of providing measure-specific details of the expected data elements needed for the purpose of eCQM validation would make it more apparent to hospitals which data are expected for eCQM validation. The commenters further stated that having this specified list will streamline the process of data submission by easing the burden of making sure the necessary information is supplied.

Response: We thank the commenters for their support and we will consider the suggestion that data elements for validation be listed by data element per measure in the future. At this time, we believe that providing measure-specific details would be premature. As we learn from the first year of validation results, we will refine the process to ensure it most efficiently captures the necessary information while easing burden on hospitals.

After consideration of the public comments we received, we are finalizing, for the FY 2020 payment determination and subsequent years, the requirements to: (1) Require eCQM validation submission by 30 calendar days following the medical records request date listed on the CDAC request form; (2) require sufficient patient level information necessary to match the requested medical record to the original Hospital IQR Program submitted eCQM measure data record; and (3) require hospitals selected as part of the random sample for eCQM validation to submit records in PDF file format through QualityNet using the Secure File Transfer (SFT) as proposed.

(d) Scoring: Summary of Previously Adopted Chart-Abstracted Measure Validation Scoring

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50226 through 50227), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50832 through 50833), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50268 through 50269), for a detailed description of our previously adopted scoring methodology for chart-abstracted measure data.

We note that in the proposed rule (81 FR 25203), we did not propose any changes to our chart-abstracted measures validation. We are providing this information as background for our discussion of eCQM validation scoring. Under the current validation process for the Hospital IQR Program there are 600 hospitals (400 randomly sampled and 200 targeted) selected for validation on a yearly basis. As stated above, those selected for chart-abstracted measure validation would not be eligible for selection to participate in eCQM validation. For chart-abstracted measure validation, the CDAC contractor requests hospitals to submit eight randomly selected medical charts on a quarterly basis from which data were

abstracted and submitted by the hospital to the Clinical Data Warehouse (for a total of 32 charts per year). Under the validation methodology, once the CDAC contractor receives the charts, it re-abstracts the same data submitted by the hospitals and calculates the percentage of matching Hospital IQR Program measure numerators and denominators for each measure within each chart submitted by the hospital. Each selected case has multiple measures included in the validation score. Consistent with previous years, each quarter and clinical topic is treated as a stratum for variance estimation purposes (70 FR 47423).

As in previous years, for the FY 2020 payment determination, the overall validation score from the chart-abstracted measure validation will be used to determine a hospital's overall annual payment update. Specifically, if a hospital fails chart-abstracted validation, it would not receive the full annual payment update. If a hospital passes chart-abstracted validation, and also meets the other Hospital IQR Program requirements, it would be eligible to receive the full annual payment update. Consistent with previous years, a hospital must attain at least a 75 percent validation score (the percentage of matching Hospital IQR Program measure numerators and denominators for each measure within each chart submitted by the hospital) based upon chart-abstracted data validation to pass the validation requirement and to be eligible for a full annual payment update, if all other Hospital IQR Program requirements are met.

(e) Scoring: eCQM Validation Scoring

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25203 through 25204), for the FY 2020 payment determination, for hospitals selected for eCQM validation, we proposed to require submission of at least 75 percent of sampled eCQM measure medical records in a timely and complete manner. However, unlike chart-abstracted validation, which requires a hospital to attain at least a 75 percent validation score, we proposed that the accuracy of eCQM data (the extent to which data abstracted for validation matches the data submitted in the QRDA I file) submitted for validation would not affect a hospital's validation score for the FY 2020 payment determination only. This is further explained below.

Public comments on the FY 2015 IPPS/LTCH PPS final rule suggested further refinements to the process for eCQM validation. Specifically, several commenters urged CMS to implement the recommendations of a March 2014 Government Accountability Office (GAO) report to develop a comprehensive data collection strategy, which includes testing for and mitigation of reliability issues arising from variance in certified EHR systems tested to different CQM specifications (79 FR 50272). Commenters in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49711) expressed concern over the barriers hospitals encounter associated with reporting eCQMs and encouraged CMS to ensure that a diverse group of hospitals and certified EHRs are represented to inform an assessment of the work required to make eCQM validation feasible, reliable, and valid. In response to these concerns, in light of operational capacity limitations, and due to the time necessary to analyze eCQM validation results, we proposed that eCQM data would be validated, but initially (meaning for the FY 2020 payment determination only), the measure accuracy would not affect hospitals' validation scores.

In other words, although hospitals would be required to submit eCQM data in a timely and complete manner, we proposed that hospitals would not be required to attain at least a 75 percent validation score to pass the validation requirement and to be eligible for a full annual payment update. Hospitals that submit at least 75 percent of sampled eCQM measure medical records (even if those records do not produce a validation score of at least 75 percent) in a timely manner (that is, within 30 days of the date listed on the CDAC medical records request) would not be subject to payment reduction. However, hospitals that fail to submit timely and complete information for at least 75 percent of requested records would not meet the eCQM validation requirement and would be subject to payment reduction. For example, if a hospital submits timely and complete information for at least 75 percent of requested records, but comparison of the QRDA I file and the abstracted data results in a validation score of 28 percent, the hospital would still pass validation and be eligible for a full annual payment update.

Hospitals that pass either chart-abstracted or eCQM validation requirements would receive their full annual payment update, assuming all other Hospital IQR Program requirements are met. Hospitals that fail to attain at least a 75 percent validation score for chart-abstracted validation or fail to submit timely and complete data for 75 percent of requested records for eCQM validation, would not receive their full annual payment update.

In addition, we proposed to update our regulations at 42 CFR 412.140(d)(2) to reflect the above proposals and to specify that the 75 percent score would only apply to chart-abstracted validation.

We invited public comment on our eCQM validation scoring proposals for the FY 2020 payment determination as discussed above.

Comment: A few commenters expressed support for the proposal that eCQM data submitted for validation would not affect a hospital's validation score for the FY 2020 payment determination.

Response: We thank the commenters for their support.

Comment: One commenter did not support the policy that hospitals would be penalized for failing to submit 75 percent of the sampled eCQM data because multiple factors beyond a hospital's control, including failure on the part of the EHR vendor, can impact the capture of data. The commenter stated that hospitals should not be penalized if they have made a good faith effort to accurately submit the data.

Response: We disagree with the commenter that hospitals should not be penalized for failing to submit 75 percent of sampled records. If selected for validation, a hospital would be required to submit at least 75 percent of sampled records. The accuracy of that data will have no impact on determination of the hospital's APU for at least the first year. In other words, if the data in those records does not match the data in the QRDA I files submitted, for example, if a data field in a patient's EHR is not correctly mapped to the QRDA I file such that the EHR indicates arrival time in the Emergency Department at 11:00am but the QRDA I file indicates some other time or leaves the value of that data field blank, the hospital would not receive any penalty for the mismatch.

The purpose of these validation efforts is to ensure that the data provided is reliable, feasible and valid. We believe that submission of 75 percent of the requested records is a necessary threshold to ensure that we have an adequate amount of data to assess and validate. Some commenters expressed concern that the initial sample size of 200 hospitals potentially could be too small, but we believe that establishing a submission threshold of 75 percent of the requested records will ensure that we receive an adequate amount of data to provide reliable and valid results for the sample size of 200 hospitals. We encourage hospitals to work with their vendors to ensure that EHRs are appropriately structured in a

way that fits in with the clinical work flow to yield reliable data through eCQMs. We believe that eCQMs promote high quality outcomes and lower costs while ultimately decrease reporting burden on hospitals. If, however, the hospital has experienced an unforeseen circumstance beyond the hospital's control that may meet our criteria for an Extraordinary Circumstances Exemption (ECE), we suggest that the hospital submit an ECE request.

After consideration of the public comments we received, we are finalizing for the FY 2020 payment determination only and as proposed: (1) To require submission of at least 75 percent of sampled eCQM measure medical records in a timely and complete manner; and (2) that the accuracy of eCQM data submitted for validation would not affect a hospital's validation score. We are also finalizing to update our regulations at 42 CFR 412.140(d)(2) to reflect the above proposals and to specify that the 75 percent score required to receive full APU would only apply to chart-abstracted validation as proposed.

(4) Reimbursement for eCQM Validation

To align with the chart-abstracted validation process, which reimburses hospitals at a rate of $3.00 per chart (78 FR 50956) for submitting charts electronically via Secure File Transfer (SFT), we proposed (81 FR 25204) to similarly reimburse hospitals at a rate of $3.00 per chart for submitting charts electronically via Secure File Transfer (SFT) for eCQM validation for the FY 2020 payment determination and subsequent years. We also refer readers to section X.B.6. of the preamble of this final rule for more information regarding the collection of information for eCQM validation.

We invited public comment on our proposal to reimburse hospitals at a rate of $3.00 per chart for eCQM validation for the FY 2020 payment determination and subsequent years as discussed above.

We did not receive any comments on this proposal, and therefore, we are finalizing our policy to reimburse hospitals at a rate of $3.00 per chart for eCQM validation for the FY 2020 payment determination and subsequent years as proposed.

(5) eCQM Pre-Submission Testing

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25204), we encouraged hospitals to test their eCQM submissions prior to annual reporting using an available CMS pre-submission validation tool for electronic reporting—the Pre-Submission Validation Application (PSVA), which can be downloaded from the Secure File Transfer (SFT) section of the QualityNet Secure Portal at: *https://cportal.qualitynet.org/QNet/pgm_select.jsp*. The PSVA is a downloadable tool that operates on a user's system to allow submitters to catch and correct errors prior to data submission to CMS. It provides validation feedback within the submitter's system and allows valid files to be separated and submitted while identifying invalid files for error correction.[192] While the PSVA does not guarantee the accuracy of data in a hospital's QRDA I file, it helps to reduce submission errors related to improperly formatted QRDA I files. Pre-submission testing would assist in proactively identifying inconsistencies in data mapping, a process used in data warehousing by which different data models are linked to each other using a defined set of methods to characterize the data in a specific definition.[193]

12. Data Accuracy and Completeness Acknowledgement (DACA) Requirements for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously-adopted details on DACA requirements. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25204), we did not propose any changes to the DACA requirements.

13. Public Display Requirements for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), and the FY 2016 final rule (80 FR 49712 through 49713) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* Web site at: *http://www.medicare.gov/hospitalcompare*, but on occasion are reported on other CMS Web sites such as *https://data.medicare.gov*. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25204), we did not propose any changes to our public display requirements.

14. Reconsideration and Appeal Procedures for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25204 through 25205), we did not propose any changes to the reconsideration and appeals procedures.

15. Changes to the Hospital IQR Program Extraordinary Circumstances Extensions or Exemptions (ECE) Policy

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 through 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), and 42 CFR 412.140(c)(2) for details on the Hospital IQR Program ECE policy. We also refer readers to the QualityNet Web site at *http://www.QualityNet.org/* for our current requirements for submission of a request for an extension or exemption.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25205), we proposed to update our ECE policy by: (1) Extending the general ECE request deadline for non-eCQM circumstances from 30 to 90 calendar days following an extraordinary circumstance; and (2) establishing a separate submission deadline for ECE requests related to eCQM reporting circumstances to be April 1 following the end of the reporting calendar year. We proposed that these policies would apply beginning in FY 2017 as related to extraordinary circumstance events that occur on or after October 1, 2016.

a. Extension of the General ECE Request Deadline for Non-eCQM Circumstances

In the past, we have allowed hospitals to submit an ECE request form for non-eCQM measures within 30 calendar days following an extraordinary event that prevents them from providing data for non-eCQM measures (76 FR 51652). In certain circumstances, however, it may be difficult for hospitals to timely evaluate the impact of a certain extraordinary event within 30 calendar days. We believe that extending the deadline to 90 calendar days would

[192] PSVA Demonstration and eCQM Question and Answer Session. Available at: *http://www.qualityreportingcenter.com/wp-content/uploads/2016/03/3-10-16-eCQM_PSVA-Demonstration_FINAL508.pdf*.

[193] Data Mapping Definition Available at: *https://www.techopedia.com/definition/6750/data-mapping*.

allow hospitals more time to determine whether it is necessary and appropriate to submit an ECE request and to provide a more comprehensive account of the ''event'' in their ECE request form to CMS. For example, if a hospital has suffered damage due to a hurricane on January 1, it would have until March 31 to submit an ECE form via the QualityNet Secure Portal, mail, email, or secure fax as instructed on the ECE form. This proposed timeframe (90 calendar days) also aligns with the ECE request deadlines for the Hospital VBP Program (78 FR 50706), the HAC Reduction Program (80 FR 49580), and the Hospital Readmissions Reduction Program (80 FR 49542 through 49543), all of which at least partially rely on the same data collection.

We invited public comment on our proposal related to the Hospital IQR Program's ECE policy for non-eCQM circumstances beginning FY 2017 as related to extraordinary circumstance events that occur on or after October 1, 2016 as described above.

Comment: Several commenters supported the proposal to extend the current submission deadline for ECE requests for non-eCQM measures to 90 days because it promotes alignment with existing quality reporting programs.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to extend the general ECE request deadline for non-eCQM circumstances to 90 calendar days following an extraordinary circumstance event beginning FY 2017 as related to extraordinary circumstance events that occur on or after October 1, 2016 as proposed.

b. Establishment of Separate Submission Deadline for ECE Requests Related to eCQMs

In addition, we proposed to establish a separate submission deadline for ECE requests with respect to eCQM reporting, such that hospitals must submit a request by April 1 following the end of the reporting calendar year. We proposed that this deadline for ECE requests with respect to eCQM reporting would first apply with an April 1, 2017 deadline and apply for subsequent eCQM reporting years. For example, for data collected for the CY 2016 reporting period (through December 31, 2016), hospitals would have until April 1, 2017 to submit an ECE request. This timeframe also aligns with the Medicare and Medicaid EHR Incentive Programs' typical annual hardship request deadline (77 FR 54104 through 54109), which we believe would help reduce burden for hospitals.

We invited public comment on our proposal for the Hospital IQR Program's ECE policy related to eCQMs beginning FY 2017 as related to extraordinary circumstance events that occur on or after October 1, 2016 as described above.

Comment: Several commenters supported the proposal to establish a submission deadline for ECE requests for eCQMs because it promotes alignment with the Medicare and Medicaid EHR Incentive Programs. In addition, commenters stated that this alignment would allow facilities to adequately respond to events and assure patient safety prior to submitting the request for an extension or exemption.

Response: We thank the commenters for their support.

Comment: A few commenters asked for clarification on the circumstance for which an ECE request would be granted. Specifically, the commenters asked if a hospital would be granted an exemption if its EMR is under transition due to a change in vendors during the reporting period. In addition, a commenter asked whether, during the transition phase, the hospital would be required to include and report on all the required eCQMs in both the older and newer EHR. Further, some commenters recommended that CMS develop an expansive definition of ''extraordinary circumstances,'' which provides detail on applicable technology difficulties (that is, switching EHR or third-party data eCQM submission vendors during the reporting period).

Response: Our current policy allows hospitals to utilize the existing ECE form to request an exemption from the Hospital IQR Program's eCQM reporting requirement for the applicable program year based on hardships preventing hospitals from electronically reporting. Such hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing certification) (80 FR 49695). With respect to the question of whether a hospital would be required to include and report on all the required eCQMs in both the older and newer EHR during an EHR transition phase, we note that ECE requests are considered on a case by case basis. Our decision whether to grant an ECE will be based on the specific circumstances of the hospital and the evidence submitted to us as part of the ECE request form.

After consideration of the public comments we received, we are finalizing for beginning FY 2017 as related to extraordinary circumstance events that occur on or after October 1, 2016, our proposals to establish: (1) A separate submission deadline for ECE requests with respect to eCQM reporting; and (2) a deadline of April 1 following the end of the reporting calendar year for ECE requests related to eCQM reporting as proposed.

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

Section 3005 of the Affordable Care Act added new sections 1866(a)(1)(W) and (k) to the Act. Section 1866(k) of the Act establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs'') that specifically applies to PCHs that meet the requirements under 42 CFR 412.23(f). Section 1866(k)(1) of the Act states that, for FY 2014 and each subsequent fiscal year, a PCH must submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules: FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50846); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50288); and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723).

2. Criteria for Removal and Retention of PCHQR Program Measures

We have received public comments on past proposed rules asking that we clarify our policy for measure retention and removal. We generally retain measures from the previous year's PCHQR Program measure set for subsequent years' measure sets, except when we specifically propose to remove or replace a measure. With respect to measure removal, we believe it is important to be transparent in identifying criteria that we would use to evaluate a measure for potential removal from the PCHQR Program. We also believe that we should align these criteria between our programs whenever possible.

Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25205

through 25206), we proposed the following measure removal criteria for the PCHQR Program, which are based on criteria established in the Hospital IQR Program (80 FR 49641 through 49642):

- Measure performance among PCHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures);
- A measure does not align with current clinical guidelines or practice;
- The availability of a more broadly applicable measure (across settings or populations) or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Performance or improvement on a measure does not result in better patient outcomes;
- The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and
- It is not feasible to implement the measure specifications.

For the purposes of considering measures for removal from the program, we would consider a measure to be ''topped-out'' if there is statistically indistinguishable performance at the 75th and 90th percentiles and the truncated coefficient of variation is less than or equal to 0.10.

However, we recognize that there are times when measures may meet some of the outlined criteria for removal from the program, but continue to bring value to the program. Therefore, we proposed the following criteria for consideration in determining whether to retain a measure in the PCHQR Program, which also are based on criteria established in the Hospital IQR Program (80 FR 49641 through 49642):

- Measure aligns with other CMS and HHS policy goals;
- Measure aligns with other CMS programs, including other quality reporting programs; and
- Measure supports efforts to move PCHs towards reporting electronic measures.

We welcomed public comments on these proposed measure removal and retention criteria.

Comment: One commenter supported the proposed criteria for the removal and retention of measures, and recommended flexibility in determining whether measures are ''topped out,'' expressing concern that the proposed criteria could lack validity when applied to the small cohort of PCHs.

Response: We thank the commenter for its support. Although there are only 11 PCHs, we believe if they are all achieving performance within the top quartile that it is reasonable to review the measure to determine whether it has been ''topped out.''

Comment: A commenter recommended that, if the measure retention and removal criteria are adopted, CMS remove three existing PCHQR measures as topped out (NQF #0223, Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis to Patients Under the Age of 80 with AJCC III (Lymph Node Positive) Colon Cancer; NQF #0559, Combination Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis for Women Under 70 with AJCC T1cN0M0, or Stage IB–III Hormone Receptor Negative Breast Cancer; and NQF #0220, Adjuvant Hormonal Therapy).

Response: We thank the commenter for the recommendation and will consider this recommendation in the future.

After consideration of the public comments we received, we are finalizing the measure removal and retention policy as proposed.

3. Retention and Update to Previously Finalized Quality Measures for PCHs Beginning With the FY 2019 Program Year

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561), we finalized five quality measures for the FY 2014 program year and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50847), we finalized one new quality measure for the FY 2015 program year and subsequent years and 12 new quality measures for the FY 2016 program year and subsequent years. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278 through 50280), we finalized one new quality measure for the FY 2017 program year and subsequent years. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49719), we finalized three new CDC NHSN measures for the FY 2018 program year and subsequent years, and finalized the removal of six previously finalized measures for fourth quarter (Q4) 2015 discharges and subsequent years. We refer readers to the final rules referenced in section VIII.B.1. of the preamble of this final rule for more information regarding these previously finalized measures.

Comment: One commenter supported the continued inclusion of the Influenza Vaccination Coverage Among Healthcare Personnel (HCP) in the PCHQR Program.

Response: We thank the commenter for its support.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25206), we did not propose for FY 2019 to remove any of the measures previously finalized for the FY 2018 program year from the PCHQR measure set. However, we did propose to update the Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) measure, described below.

b. Update of Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) Measure for FY 2019 Program Year and Subsequent Years

Beginning with the FY 2019 program year, we proposed to update the specifications of the Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) measure. This measure was originally finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50841 through 50842). In November 2014, subsequent to our adoption of the measure in the PCHQR Program, updated specifications were endorsed by the NQF.

The updated measure specifications expand the patient cohort to include patients receiving 3D conformal radiation therapy for breast or rectal cancer in addition to patients receiving 3D conformal radiation therapy for lung or pancreatic cancers (the original cohort).[194] For additional information about the original measure cohort, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50842), in which we introduced the measure to the PCHQR Program. In 2012, breast cancer was the most common cancer among women, and the second most common cause of cancer related deaths for women.[195] For 2016, the National Institutes of Health estimates that there will be approximately 135,000 new cases of colorectal cancer in the United States, with approximately 39,000 of these cases being rectal cancer.[196]

As these cancer types are so prevalent, we believe that the expansion of the measure cohort to include breast and rectal cancer patients is important

[194] Available at: *http://www.qualityforum.org/QPS/0382.*

[195] CDC Breast Cancer Statistics. Available at: *http://www.cdc.gov/cancer/breast/statistics/.*

[196] NIH Colorectal Cancer Incidence and Mortality. Available at: *http://www.cancer.gov/types/colorectal/hp/rectal-treatment-pdq.*

to ensuring the delivery of high quality care in the PCH setting. In compliance with section 1890A(a)(2) of the Act, this measure update was included in a publicly available document, ''List of Measures under Consideration for December 1, 2015.'' [197] The MAP, a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the PCHQR Program, among other Federal programs, and provides input on those measures to the Secretary. The MAP's 2016 recommendations for quality measures under consideration are captured in the following document: ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015–2016'' (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81599*). The MAP expressed conditional support for the update of Oncology: Radiation Dose Limits to Normal Tissues. The MAP's conditional support was solely pending annual NQF review, and was not based on significant concerns. We considered the input and recommendations provided by the MAP, and the importance of aligning with NQF-endorsed specifications of measures whenever possible in proposing this update for the PCHQR Program.

We welcomed public comments on this proposal for the Oncology: Radiation Dose Limits to Normal Tissues measure cohort expansion for the FY 2019 program year and subsequent years.

Comment: Two commenters supported the expansion of the Oncology: Radiation Dose Limits to Normal Tissue (NQF #0382) measure specifications to include breast and rectal cancers. One commenter that supported the expansion urged delay until the expansion received NQF endorsement.

Response: We thank the commenters for their support. We believe it is important to continue to expand the PCHQR measures to provide meaningful information to patients and facilities. The NQF endorsed the measure with the expanded cohort in 2014. We are aligning our measure with the updated NQF-endorsed specifications. Of note, the 2015 MAP's conditional support was based only on NQF's regular, annual update, out of which we expect to arise no significant concerns. NQF review is still underway for the annual updates to this measure; the expanded cohort, however, was endorsed by NQF in 2014. Our proposal would expand the cohort pursuant to NQF's 2014 endorsement of the cohort expansion and is not impacted by the regular annual review process in which NQF engages on all measures. We considered the MAP's recommendations, and the importance of aligning with NQF-endorsed specifications of measures whenever possible, when we proposed this update for the PCHQR Program.

After consideration of the public comments we received, we are finalizing the update to the measure specifications as proposed.

4. New Quality Measure Beginning With the FY 2019 Program Year

a. Considerations in the Selection of Quality Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50838), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278), we indicated that we have taken a number of principles into consideration when developing and selecting measures for the PCHQR Program, and that many of these principles are modeled on those we use for measure development and selection under the Hospital IQR Program. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25206), we did not propose any changes to the principles we consider when developing and selecting measures for the PCHQR Program.

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Section 1866(k)(3)(B) of the Act provides an exception under which, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25206 through 25210), using the principles for measure selection in the PCHQR Program, we proposed one new measure, described below.

b. Adoption of the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure

We proposed to adopt the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure for the FY 2019 program year and subsequent years. Cancer care is a priority area for outcome measurement because cancer is an increasingly prevalent condition associated with considerable morbidity and mortality. In 2015, there were more than 1.6 million new cases of cancer in the United States.[198] Each year, about 22 percent of cancer patients receive chemotherapy,[199] with Medicare payments for cancer treatment totaling $34.4 billion in 2011 or almost 10 percent of Medicare fee-for-service (FFS) spending.[200] With an increasing number of cancer patients receiving chemotherapy in a hospital outpatient department,[201] a growing body of peer-reviewed literature identifies unmet needs in the care provided to these patients. This gap in care may be due to reasons including: (1) Delayed onset of side effects that patients must manage at home; (2) patients assuming that little can be done and not seeking assistance; and (3) limited access to and communication with providers who can tailor care to the individual.[202] As a result, cancer patients that receive chemotherapy in a hospital outpatient department require more frequent acute care in the hospital setting and experience more adverse events than cancer patients that are not receiving chemotherapy.[203] [204] [205]

[197] CMS List of Measures under Consideration. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81172*.

[198] American Cancer Society. ''Cancer Facts & Figures 2015.'' Available at: *http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pdf*.

[199] Klodziej, M., J.R. Hoverman, J.S. Garey, J. Espirito, S. Sheth, A. Ginsburg, M.A. Neubauer, D. Patt, B. Brooks, C. White, M. Sitarik, R. Anderson, and R. Beveridgel. ''Benchmarks for Value in Cancer Care: An Analysis of a Large Commercial Population.'' *Journal of Oncology Practice,* Vol. 7, 2011, pp. 301–306.

[200] Sockdale, H., K. Guillory. ''Lifeline: Why Cancer Patients Depend on Medicare for Critical Coverage.'' Available at: *http://www.acscan.org/content/wp-content/uploads/2013/06/2013-Medicare-Chartbook-Online-Version.pdf*.

[201] Vandervelde, Aaron, Henry Miller, and JoAnna Younts. ''Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration.'' Washington, DC: Berkeley Research Group, June 2014. Available at: *http://www.communityoncology.org/UserFiles/BRG_340B_SiteofCare_ReportF_6-9-14.pdf*.

[202] McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. ''Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study.'' *Supportive Care in Cancer,* Vol. 19, No. 7, 2011, pp. 963–969.

[203] Sadik, M., K. Ozlem, M. Huseyin, B. AliAyberk, S. Ahmet, and O. Ozgur. ''Attributes of

Unmet patient needs resulting in admissions and ED visits related to chemotherapy treatment pose a heavy financial burden and affect patients' quality of life. Based on available commercial claims data, in 2010 the national average cost of a chemotherapy-related admission was $22,000, and the average cost of a chemotherapy-related ED visit was $800.[206] Furthermore, admissions and ED visits can reduce patients' quality of life by affecting their physical and emotional well-being, disrupting their schedules, decreasing their desire to engage in work and social activities, and increasing the burden on their family.[207] [208]

Hospital admissions and ED visits among cancer patients are often caused by manageable side effects. Chemotherapy treatment can have severe, predictable side effects. Recent studies of cancer outpatients show the most commonly cited symptoms and reasons for unplanned hospital visits following chemotherapy treatment are pain, anemia, fatigue, nausea and/or vomiting, fever and/or febrile neutropenia, shortness of breath, dehydration, diarrhea, and anxiety/depression.[209] These hospital visits may be due to conditions related to the cancer itself or to side effects of chemotherapy. However, treatment plans and guidelines exist to support the management of these conditions. PCHs that provide outpatient chemotherapy should implement appropriate care to minimize the need for acute hospital care for these adverse events. Guidelines from the American Society of Clinical Oncology, National Comprehensive Cancer Network, Oncology Nursing Society, Infectious Diseases Society of America, and other professional societies recommend evidence-based interventions to prevent and treat common side effects and complications of chemotherapy. Appropriate outpatient care should reduce potentially avoidable hospital admissions and ED visits for these issues and improve cancer patients' quality of life.

This measure aims to assess the care provided to cancer patients and encourage quality improvement efforts to reduce the number of unplanned inpatient admissions and ED visits among cancer patients receiving chemotherapy in a PCH outpatient setting. Improved PCH management of these potentially preventable symptoms—including anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—could reduce unplanned admissions and ED visits for these conditions. Measuring unplanned admissions and ED visits for cancer patients receiving outpatient chemotherapy would provide PCHs with an incentive to improve the quality of care for these patients by taking steps to prevent and better manage side effects and complications from treatment. In addition, this measure meets two National Quality Strategy priorities: (1) Promoting effective communication and coordination of care; and (2) promoting the most effective prevention and treatment practices for the leading causes of mortality.

We proposed to adopt this measure under the exception authority in section 1866(k)(3)(B) of the Act under which, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

This proposed measure aligns with the two process measures we adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50842 through 50843) for FY 2016 and subsequent years: (1) Clinical Process/Oncology Care—Plan of Care for Pain (NQF #0383); and (2) Clinical Process/Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384). These NQF-endorsed measures focus on processes of care related to cancer care. Process measures NQF #0383 and NQF #0384, which are not risk-adjusted, support the purpose of the proposed measure by reinforcing that providers of outpatient care should screen for and manage symptoms such as pain. The proposed measure improves upon these two measures in two key ways: (1) It does not target a specific symptom, but rather assesses the overall management of 10 important symptoms that studies have identified as frequent reasons for ED visits and inpatient admissions in this population; and (2) it assesses the care outcomes that matter to patients, rather than measuring processes to detect and treat these conditions. Furthermore, we are not aware of any other measures a consensus organization has endorsed or adopted that assess the quality of outpatient cancer care by measuring unplanned inpatient admissions and ED visits.

The 2015 MAP supported this measure on the condition that it is reviewed and endorsed by NQF. We refer readers to the Spreadsheet of MAP 2016 Final Recommendations available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*. In particular, MAP members recommended considering the measure for sociodemographic status (SDS) adjustment in the ongoing NQF trial period and reviewing it to ensure that the detailed specifications meet the purpose of the measure and align with current cancer care practice.

We understand the important role that SDS plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors.

Cancer Patients Admitted to the Emergency Department in One Year.'' *World Journal of Emergency Medicine,* Vol. 5, No. 2, 2014, pp. 85–90. Available at: *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4129880/#ref4.*

[204] Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. ''Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer.'' *Journal of the National Cancer Institute,* Vol. 98, No. 16, 2006, pp. 1108–1117.

[205] Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. ''Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study.'' *Supportive Care in Cancer,* Vol. 22, No. 9, 2014, pp. 2527–2533.

[206] Fitch, K., and B. Pyenson. ''Cancer Patients Receiving Chemotherapy: Opportunities for Better Management.'' Available at: *http://us.milliman.com/uploadedFiles/insight/research/health-rr/cancer-patients-receiving-chemotherapy.pdf.*

[207] McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. ''Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study.'' *Supportive Care in Cancer,* Vol. 19, No. 7, 2011, pp. 963–969.

[208] Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. ''Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer.'' *Journal of the National Cancer Institute,* Vol. 98, No. 16, 2006, pp. 1108–1117.

[209] Ibid.

During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures. We submitted this measure to NQF with appropriate consideration for SDS for endorsement proceedings as part of the NQF Cancer Consensus Development Project in March 2016 and it is currently undergoing review. However, the measure we are adopting for the PCHQR Program does not include this adjustment.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

In addition, several MAP members noted the alignment of this measure concept with other national priorities, such as improving patient experience, and other national initiatives to improve cancer care, as well as the importance of this measure to raise awareness and create a feedback loop with providers.

This Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure is a risk-standardized outcome measure for patients age 18 years or older who are receiving PCH-based outpatient chemotherapy treatment for all cancer types except leukemia; it measures inpatient admissions or ED visits within 30 days of each outpatient chemotherapy encounter for any of the following qualifying diagnoses: Anemia, dehydration; diarrhea; emesis; fever; nausea; neutropenia; pain; pneumonia; or sepsis, as these are associated with commonly cited reasons for hospital visits among cancer patients receiving chemotherapy.[210]

The proposed measure uses 1 year of Medicare FFS Part A and Part B administrative claims data with respect to beneficiaries receiving chemotherapy treatment in a PCH outpatient setting. The qualifying diagnosis on the admission or ED visit claim must be: (1) The primary diagnosis; or, (2) a secondary diagnosis accompanied by a primary diagnosis of cancer.

We limited the window for identifying the outcomes of admissions and ED visits to 30 days after PCH outpatient chemotherapy treatment encounters, as existing literature suggests the vast majority of adverse events occur within that time frame [211] [212] [213] and we also observed this during testing. In addition, the technical expert panel (TEP) supported this time window because: (1) It helps link patients' experiences to the facilities that provided their recent treatment while accounting for variations in time between outpatient treatment encounters; (2) it supports the idea that the admission is related to the management of side effects of treatment and ongoing care, as opposed to progression of the disease or other unrelated events; and (3) clinically, 30 days after each outpatient chemotherapy treatment is a reasonable timeframe to observe related side effects.

The measure identifies outcomes separately for the inpatient admissions and ED visits. A patient can qualify only once for one of the two outcomes in each measurement period. If patients experience both an inpatient admission and an ED visit after outpatient chemotherapy during the measurement period, the measure counts them toward the inpatient admission outcome because this outcome represents a more significant deterioration in patient quality of life, and is more costly. Among those with no qualifying inpatient admissions, the measure counts qualifying standalone ED visits. As a result, the rates provide a comprehensive performance estimate of quality of care. We calculate the rates separately because the severity and cost of an inpatient admission differ from those of an ED visit, but both adverse events are significant quality indicators and represent outcomes of care that are important to patients.

The measure attributes the outcome to the PCH where the patient received chemotherapy treatment during the 30 days before the outcome. If a patient received outpatient chemotherapy treatment from more than one PCH in the 30 days before the outcome, the measure would attribute the outcome to all the PCHs that provided treatment. For example, if a patient received an outpatient chemotherapy treatment at PCH A on January 1, a second treatment at PCH B on January 10, and then experienced a qualifying inpatient admission on January 15, the measure would count this outcome for both PCH A and PCH B because both PCHs provided outpatient chemotherapy treatment to the patient within the 30-day window. However, if a patient received an outpatient chemotherapy treatment from PCH A on January 1, and a second treatment from PCH B on March 1, and then experienced a qualifying inpatient admission on March 3, the measure would attribute this outcome only to PCH B. In measure testing, using Medicare FFS claims data from July 1, 2012, to June 30, 2013, only 5 percent of patients in the cohort received outpatient chemotherapy treatment from more than one facility during that year.

For additional methodology details, including the code sets used to identify the qualifying outcomes, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Chemotherapy.''

This measure includes all adult Medicare FFS patients because this would enable us to more broadly assess the quality of care provided by the PCH.

This measure focuses on treatments in the PCH outpatient setting because of the increase in hospital-based chemotherapy, which presents an opportunity to coordinate care. From 2008 to 2012, the proportion of Medicare patients receiving hospital-based outpatient chemotherapy increased from 18 to 29 percent, and this trend is likely to continue. As currently specified, the measure identifies chemotherapy treatment using ICD–9–CM procedure and encounter

[210] Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. ''Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer.'' *Journal of the National Cancer Institute,* Vol. 98, No. 16, 2006, pp. 1108–1117.

[211] Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. ''Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study.'' *Supportive Care in Cancer,* Vol. 21, No. 2, 2013, pp. 397–404.

[212] Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. ''Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study.'' *Supportive Care in Cancer,* Vol. 22, No. 9, 2014, pp. 2527–2533.

[213] McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. ''Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study.'' *Supportive Care in Cancer,* Vol. 19, No. 7, 2011, pp. 963–969.

codes and Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) procedure and medication procedure codes. It excludes procedure codes for oral chemotherapy because it is challenging to identify oral chemotherapy without using pharmacy claims data and, according to our TEP, most oral chemotherapies have fewer adverse reactions that result in admissions. We have developed a ''coding crosswalk'' between the ICD–9–CM codes and the ICD–10 codes that became effective beginning on October 1, 2015, and we will test this crosswalk prior to implementation. For detailed information on the cohort definition, including the ICD–9–CM, ICD–10, CPT, and HCPCS codes that identify chemotherapy treatment, we refer readers to the Data Dictionary appendix to the measure Technical Report at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Chemotherapy.''

The measure excludes three groups of patients: (1) Patients with a diagnosis of leukemia at any time during the measurement period because of the high toxicity of treatment and recurrence of disease, and because inpatient admissions and ED visits may reflect a relapse, rather than poorly managed outpatient care; (2) patients who were not enrolled in Medicare FFS Parts A and B in the year before the first outpatient chemotherapy treatment encounter during the measurement period (because the risk-adjustment model uses claims data for the year before the first chemotherapy treatment encounter during the period to identify comorbidities); and (3) patients who do not have at least one outpatient chemotherapy treatment encounter followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the encounter (because the measure cannot assess the 30-day outcome in this group since it uses claims data to determine whether a patient had an ED visit or a hospital inpatient admission).

Risk adjustment takes into account important demographic and clinically-relevant patient characteristics that have strong relationships with the outcome. It seeks to adjust for differences in patient demographics, clinical comorbidities, and treatment exposure, which vary across patient populations and influence the outcome but do not relate to quality. Specifically, the measure adjusts for: (1) The patient's age at the start of the measurement period; (2) sex; (3) comorbidities that convey information about the patient in the 12 months before his or her first outpatient chemotherapy treatment encounter during the measurement period; (4) cancer type; and (5) the number of outpatient chemotherapy treatments the patient received at the reporting PCH during the measurement period.

We developed two risk-adjustment models, one for each dependent variable described above—qualifying inpatient admissions and qualifying ED visits. The separate models are necessary to enable the use of the most parsimonious model with variables tailored to those that are most predictive for each of the measure's two mutually exclusive outcomes. The measure algorithm first searches for a qualifying inpatient admission, and for those patients that do not have a qualifying inpatient admission, searches for a qualifying ED visit. Therefore, the patient-mix and predictive risk factors for each outcome is slightly different. The statistical risk-adjustment model for inpatient admissions includes 20 clinically relevant risk-adjustment variables that are strongly associated with the risk of one or more hospital admissions within 30 days following an outpatient chemotherapy treatment encounter in a hospital outpatient setting; the statistical risk-adjustment model for ED visits includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of one or more ED visits within 30 days following an outpatient chemotherapy treatment encounter in a hospital outpatient setting (3 comorbidities and 2 cancer types significant for inpatient admissions are not significant for ED visits).

The measure uses hierarchical logistic modeling, similar to the approach used in the CMS inpatient hospital 30-day risk-standardized mortality and readmission outcome measures, such as the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.[214] This approach appropriately accounts for both differences in patient-mix and the clustering of observations within PCHs. The measure calculates the PCH-specific risk-adjusted rate as the ratio of the PCH's ''predicted'' number of outcomes to ''expected'' number of outcomes multiplied by the national observed outcome rate. It estimates the expected number of outcomes for each PCH using the PCH's patient-mix and the average PCH-specific intercept (that is, the average intercept among all PCHs in the sample). The measure estimates the predicted number of outcomes for each PCH using the same patient-mix, but an estimated PCH-specific intercept.

The measure calculates two rates, one for each mutually exclusive outcome (qualifying inpatient admissions and qualifying ED visits). It derives the two rates (also referred to as the PCH-level risk-standardized admission rate (RSAR) and risk-standardized ED visit rate (RSEDR)), from the ratio of the numerator to the denominator multiplied by the national observed rate. The numerator is the number of predicted (meaning adjusted actual) patients with the measured adverse outcome. The denominator is the number of patients with the measured adverse outcome the PCH is expected to have based on the national performance with the PCH's case mix. The national observed rate is the national unadjusted number of patients who have an adverse outcome among all the qualifying patients who had at least one chemotherapy treatment encounter in a PCH. If the ''predicted'' number of outcomes is higher (or lower) than the ''expected'' number of outcomes for a given hospital, the risk-standardized rate will be higher (or lower) than the national observed rate.

For more detailed information on the calculation methodology, we refer readers to the methodology report at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Chemotherapy.''

We would publicly report the RSAR and RSEDR for all participating PCHs with 25 or more eligible patients per measurement period to maintain a reliability of at least 0.4 (as measured by the interclass correlation coefficient, ICC). If a PCH does not meet the 25 eligible patient threshold, we would include a footnote on the *Hospital Compare* Web site indicating that the number of cases is too small to reliably measure that PCH's rate. These patients and PCHs would still be included when calculating the national rates for both the RSAR and RSEDR.

To prepare PCHs for public reporting, we would conduct a confidential national reporting (dry run) of measure results prior to public reporting. The objectives of the dry run are to: (1) Educate PCHs and other stakeholders about the measure; (2) allow PCHs to review their measure results and data prior to public reporting; (3) answer questions from PCHs and other stakeholders; (4) test the production and

[214] Methodology reports for these measures are available at the following link: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

reporting process; and (5) identify potential technical changes to the measure specifications that might be needed. We have not yet determined the measurement period to use for the dry run calculations, but acknowledge the importance of including some data based on ICD–10 codes to evaluate the success of the ''coding crosswalk.''

We invited public comment on our proposal to adopt the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure for the FY 2019 program year and subsequent years.

Comment: A few commenters supported the inclusion of the Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy measure into the PCHQR program.

Response: We thank the commenters for their support.

Comment: Several commenters generally opposed the adoption of the proposed new measure because the MAP conditionally supported it pending NQF endorsement, and the NQF has not formally announced its decision. Other commenters opposed the adoption of the measure because of general concerns with its validity and reliability, providing examples of ICD–10 codes not related to chemotherapy or inpatient admissions in which a patient received treatment for pain and nausea but in which the pain and nausea was not related to chemotherapy treatment. One commenter supported the measure provided it has been tested for validity and reliability.

Response: We thank the commenters for their views regarding the MAP review and NQF endorsement. In evaluating and selecting the measure for inclusion in the PCHQR Program, we considered whether there were other available measures that have been endorsed or adopted by the NQF, and were unable to identify any other NQF-endorsed measures that assess admissions and ED visits following outpatient chemotherapy. We developed the measure using the same rigorous process that we have used to develop other publicly reported outcomes measures. As part of that process, we sought and received extensive input on the measure from stakeholders and clinical experts.

We disagree with commenters regarding the proposed measure's reliability and believe that this measure is sufficiently reliable to be included in the PCHQR Program. Measure reliability was calculated using a split sample of one year of data. We randomly split the patient cohort at each hospital into two equal halves, calculated the measure using each half, and then calculated the agreement between these two (the ''test'' and the ''retest''). Following this test-retest methodology, we calculated the Pearson correlation between the performance rate estimates in each half-year sample to assess reliability. We found the RSAR to have a reliability of 0.41 (95 percent confidence interval (CI): 0.37–0.45) and the RSEDR to have a reliability of 0.27 (95 percent CI: 0.22–0.33) which, according to Cohen's classification, represent moderate and borderline weak-to-moderate reliability, respectively.[215] The 95 percent CI gives us a reasonable estimate of the true reliability range.

Our reliability estimate was arguably limited by our use of a half year of split data. We expected our reliability to be higher if we increased the amount of data we used. Therefore, after submitting the measure to NQF for endorsement review, we conducted additional calculations of the reliability testing score, this time using the Intraclass Correlation Coefficient (ICC) and the Spearman-Brown prophecy formula. The Spearman-Brown prophecy formula is an accepted statistical method that estimates the ICC based on what would be expected if the sample size was increased. It therefore provides us with an estimate of what the reliability score would be if CMS were to use a full year of data for public reporting rather than the six months of data that we used. Using the Spearman-Brown prophecy formula, we estimated that our measure will have an ICC of 0.63 (95 percent CI: 0.58–0.68) for RSAR and 0.47 percent (95 percent CI: 0.40–0.53) for RSEDR using a full year of data.

The NQF considers ICC values ranging from 0.41 to 0.60 as ''moderate'' reliability, and 0.61 to 0.80 as ''strong'' reliability. Our calculated ICC values of 0.63 for RSAR and 0.47 for RSEDR are interpreted as ''strong'' and ''moderate'' reliability, respectively.

We also disagree with the concerns regarding the validity of the measure. This measure is an important signal of high quality care and is specified in a way to appropriately differentiate between cancer hospitals providing high and low quality care for these patients. This measure assesses an aspect of care with documented unmet patient needs resulting in reduction of patient's quality of life and increase in healthcare utilization and costs. Several studies[216] [217] [218] illustrate a gap in care for outpatients as they are ''invisible'' from the system when they return home following treatment.

There are currently no outcome measures in the PCHQR Program, and there remains a gap in care that leads to acute, potentially preventable hospitalizations. We note that, on average, cancer patients receiving chemotherapy have one hospital admission and two ED visits per year, and therefore we believe it would be a disservice to patients to delay inclusion of the current outcome measure in quality reporting and quality improvement initiatives. This is why we proposed to adopt this outcome measure for the PCHQR Program under the Secretary's authority set forth at section 1866(k)(3)(B) of the Act.

Comment: Several commenters opposed the adoption of the proposed new measure as currently specified because of concerns that the diagnoses and symptoms that are the subject of the measure, such as pneumonia, could be due to causes other than chemotherapy side effects and are not appropriate to combine. One commenter also stated that the list of ICD–10 codes contained in the measure submission documents includes codes for diagnoses that are unrelated to chemotherapy, and further suggested that the measure does not differentiate between chemotherapy-related and unrelated admissions and emergency department visits.

Response: Given the increase in outpatient hospital-based chemotherapy, understanding and minimizing related unplanned admissions and ED visits is a high priority. The 10 conditions that the measure captures are commonly cited reasons for hospital visits among patients receiving chemotherapy in the hospital outpatient setting, and are potentially preventable through appropriately managed outpatient care and increased communication with the

[215] Jacob Cohen (1988). Statistical Power Analysis for the Behavioral Sciences (2nd Edition). Lawrence Eribaum Associates.

[216] Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. ''Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study.'' Supportive Care in Cancer, vol. 21, no. 2, 2013, pp. 397–404.

[217] Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, S.E. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. ''Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study.'' Supportive Care in Cancer, vol. 22, no. 9, 2014, pp. 2527–2533.

[218] McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. ''Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study.'' Supportive Care in Cancer, vol. 19, no. 7, 2011, pp. 963–969.

patient. This measure will help identify unplanned admissions and ED visits in patients receiving outpatient chemotherapy by reviewing claims in which these 10 conditions, considered potentially preventable through appropriately-managed outpatient care, are listed as a primary diagnosis or a secondary diagnosis accompanied by a primary diagnosis of cancer. Admissions and emergency department visits for these conditions is a potential signal of poor quality care and poor care coordination. While the goal is not to reach zero admissions and ED visits, the premise is that reporting this information will promote an improvement in patient care over time for two reasons. First, transparency in publicly reporting this measure will raise hospital and patient awareness of unplanned hospital visits following chemotherapy. Second, this reporting will incentivize hospital outpatient departments to incorporate quality improvement activities into their chemotherapy care planning in order to improve care coordination and reduce the number of these visits. We also believe that making PCHs aware of their performance, as well as the performance that might be expected given the PCH's case mix is helpful in supporting efforts to improve outcomes. The measure is intended to improve symptom management and care coordination for cancer patients who are undergoing chemotherapy.

We thank the commenter for its suggestion regarding the list of ICD–10 codes. We identified the codes representing the 10 outcome conditions with input from cancer care experts following an inclusive and patient-centric approach to developing the code sets. Cancer and chemotherapy treatment can impact the entire body and it can be challenging to differentiate whether the condition is related to the treatment, cancer, or another disease. We will consider this feedback during ongoing measure evaluation.

Comment: A number of commenters recommended that there be additional or broader denominator exclusions from the measure. Specifically, commenters urged that patients with hematologic malignancies beyond leukemia, such as lymphoma and multiple myeloma, be excluded from the measure as patients with leukemia are currently excluded. Commenters also recommended exclusions for a wide variety of other factors including, but not limited to, patients enrolled in clinical trials and patients receiving palliative care.

Response: We thank the commenters for their suggestions on additional denominator exclusions. We specified the measure to be as inclusive as possible; we excluded, based on clinical rationales, only those patient groups for which hospital visits were not typically a quality signal or for which risk adjustment would not be adequate. Based on feedback from earlier public comments suggesting that exclusion of all patients with a hematologic malignancy would be too broad, and our analyses showing that patients with lymphoma and multiple myeloma have similar rates of admission and ED visits when compared with patients with other cancer types, we decided during development to limit the exclusion criteria to only those patients with leukemia. As part of continued evaluation, we will consider reviewing rates stratified by cancer type to track the impact and inform future measure revisions.

We do not exclude patients enrolled in clinical trials because there are many challenges associated with systematically identifying these patients and collecting information on applicable clinical trials. We cannot identify these patients using claims data and many cancer patients participate in clinical trials.

We do not exclude patients receiving palliative care because published literature shows that all patients receiving outpatient chemotherapy, regardless of the reason for chemotherapy (palliative or curative) may experience a gap in care that leads to acute, potentially preventable hospitalizations. Improving patients' quality of life by keeping patients out of the hospital is a main goal of cancer care, especially at the end of life.

Comment: A few commenters recommended that there be additional numerator exclusions from the measure. Specifically, commenters recommended that we exclude planned admissions and admissions/ED visits without a POA flag. Some commenters also recommended numerator exclusions for a wide variety of other factors including, but not limited to, surgeries within 30 days of admission, patients coded with non-adherence to medication, patients with pain due to disease, and admissions with an ''elective'' admission type.

Response: We thank the commenters for their suggested numerator exclusions. This measure focuses on infusion-based chemotherapy administered in a hospital outpatient department based on filed claims. Therefore, if a patient does not show up for an appointment the encounter is not included in our calculation, thereby controlling for medication adherence. In addition, the outcomes assessed may be due to conditions related to the cancer itself or to side effects of chemotherapy. Pain is an important and common symptom of cancer and requires close outpatient management. We use a specific set of codes to identify admissions and ED visits for 10 potentially preventable symptoms—including anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—none of which are ''elective'' admissions. We will take other suggestions, such as the use of POA flags, under advisement in future evaluation work.

Comment: Commenters identified concerns regarding the risk-adjustment methodology, including the measure's use of administrative data not capturing certain information for risk adjustment or stratification, such as cancer staging, chemotherapy toxicity levels, or patient genetic information.

Response: We cannot identify cancer staging, chemotherapy toxicity levels, or patient genetic information using claims data. However, we believe that the risk-adjustment methodology as specified is valid. The measure is risk adjusted to help account for the variation in patient mix and aggressiveness of treatment, adjusting for demographic factors such as age and sex, comorbidities, cancer type, and the number of treatments during the measurement period. For example, aggressiveness can range by cancer type and age, which are accounted for in our model. Also, we adjust for the number of treatments which may also be an indicator of treatment aggressiveness.

Comment: Several commenters identified other general concerns with the measure specifications, including concerns with appropriately capturing neutropenic fever and the associated 30-day window; the reliance on a pneumonia diagnosis as a proxy for neutropenic fever and its categorization as a preventable complication within 30 days of outpatient chemotherapy; and the exclusion of patients taking oral chemotherapy from the denominator.

Response: We thank the commenters for their consideration and feedback. During measure development, the technical expert panel recommended expanding the diagnoses and symptoms that are the subject of the measure to include both neutropenia and fever to avoid missing any diagnoses of neutropenic fever since a single ICD–9 code for neutropenic fever does not exist. Because the diagnosis of neutropenia requires lab results and is often not coded on a claim, we were further advised to expand the measure to include pneumonia and sepsis as the

most common sequelae of neutropenic fever. We limited the window for identifying the outcomes of admissions and ED visits to 30 days after hospital outpatient chemotherapy treatment because existing literature suggests the vast majority of adverse events occur within that time frame, as was observed during testing.

The decision to not include patients receiving only oral chemotherapy was made during development for several reasons, including attribution and timing. Attributing a prescription to a hospital-based outpatient setting is challenging; patients are likely to receive care from multiple physicians, in multiple settings, and not all physicians are employed by the hospital. Therefore, not all claims for that provider are attributable to the hospital. In addition, the measure algorithm uses the chemotherapy encounter date at the index for the 30-day window to follow patients to ascertain whether they experience an admission or ED visit. Identifying a specific index date on which oral chemotherapy was started is not feasible, since claims data only includes information on the date the prescription was filled, without information on what day the patient started taking the medication. We note, however, that patients receiving oral chemotherapy in combination with infusion-based chemotherapy are included in the cohort. We will take into consideration the inclusion of patients only receiving oral chemotherapy in future evaluation work.

Comment: One commenter recommended that if we adopt the measure for the PCHQR, we retire two currently active measures: NQF #0383, Plan of Care for Pain, and NQF #0384, Pain Intensity Quantified.

Response: We thank the commenter for the recommendation and will consider it in the future. The process measures, which are not risk-adjusted, support the purpose of the proposed measure by reinforcing that those providing outpatient care should screen for and manage symptoms such as pain and anemia/fatigue. We believe that having these process measures, which are directly within the control of the PCH, complements the newly adopted outcome measure. However, we recognize that having all three measures in the program may place undue burden on facilities. We will continue to assess the appropriateness of including all three measures after we have more data on the correlation between PCH performance on each of the three measures.

After consideration of the public comments we received, we are finalizing the adoption of the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure as proposed.

In summary, the previously finalized and newly finalized measures for the PCHQR Program for the FY 2019 program year and subsequent years are listed in the table below.

PREVIOUSLY FINALIZED AND NEWLY FINALIZED PCHQR MEASURES FOR THE FY 2019 PROGRAM YEAR AND SUBSEQUENT YEARS

Short name	NQF No.	Measure name
		Safety and Healthcare-Associated Infection (HAI)
CLABSI	0139	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection Outcome Measure.
CAUTI	0138	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infections Outcome Measure.
SSI	0753	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery].
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure.
HCP	0431	Influenza Vaccination Coverage Among Healthcare Personnel.
		Clinical Process/Cancer Specific Treatment
N/A	0223	Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer.
N/A	0559	Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1cN0M0, or Stage IB—III Hormone Receptor Negative Breast Cancer.***
N/A	0220	Adjuvant Hormonal Therapy.
		Clinical Process/Oncology Care Measures
N/A	0382	Oncology: Radiation Dose Limits to Normal Tissues.*
N/A	0383	Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology.
N/A	0384	Oncology: Medical and Radiation—Pain Intensity Quantified.
N/A	0390	Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients.
N/A	0389	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients.
		Patient Engagement/Experience of Care
HCAHPS	0166	HCAHPS.
		Clinical Effectiveness Measure
EBRT	1822	External Beam Radiotherapy for Bone Metastases.

PREVIOUSLY FINALIZED AND NEWLY FINALIZED PCHQR MEASURES FOR THE FY 2019 PROGRAM YEAR AND SUBSEQUENT YEARS—Continued

Short name	NQF No.	Measure name
Claims Based Outcome Measure		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.**

* Finalized update in FY 2019 program year.
** Newly finalized for FY 2019 program year.
*** In previous final rules, this measure was titled ''Combination Chemotherapy is Considered or Administered Within 4 months (120 days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer. This name change is consistent with NQF updates to the measure name and reflects an update in the AJCC staging, does not reflect a change in the measure inclusion criteria, and is not considered substantive.

5. Possible New Quality Measure Topics for Future Years

We discussed future quality measure topics and quality measure domain areas in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50280), and in the FY 2016 IPPS/LTCH PPS final rule (80 FR4979), we discussed public comment and specific suggestions for measure topics addressing the following CMS Quality Strategy domains: Making care affordable; communication and coordination; and working with communities to promote best practices of healthy living. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25211), we welcomed public comment and specific suggestions for measure topics that we should consider for future rulemaking.

Comment: One commenter thanked CMS for its thoughtful approach to measure development. The commenter urged CMS to incorporate additional outcomes measures into the PCHQR Program, such as patient-reported outcomes measures, condition-specific outcome sets, and an unplanned readmissions measure.

Response: We thank the commenter for its support as we continuously work to develop and implement meaningful quality measures.

Comment: One commenter urged CMS to include stakeholders throughout the measure development process.

Response: We look forward to continuing collaboration efforts with stakeholders through the various mechanisms currently in place, such as the Technical Expert Panels and notice and comment periods during rulemaking.

6. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for the PCHQR Program measures, and we periodically update those specifications. The specifications may be found on the QualityNet Web site at: *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774479863*.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), we adopted a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25211), we did not propose any changes to this policy.

7. Public Display Requirements

a. Background

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures must ensure that a PCH has the opportunity to review the data that are to be made public with respect to the PCH prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS Web site. The measures that we have finalized for public display are shown in the table below.

PREVIOUSLY FINALIZED MEASURES FOR PUBLIC DISPLAY

Measure name	First year of public display
• Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer (NQF #0223).	2014.
• Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (NQF #0559).	
• Adjuvant Hormonal Therapy (NQF #0220)	2015.
• Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382)	2016.
• Oncology: Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383).	
• Oncology: Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384).	
• Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients (NQF #0390).	
• Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (NQF #0389).	
• HCAHPS (NQF #0166).	
• CLABSI (NQF #0139)	No Later Than 2017.
• CAUTI (NQF #0138).	

b. Additional Public Display Requirements

As we strive to publicly display data as soon as possible on a CMS Web site, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25211 through 25212), we proposed the following update to our public display polices. We believe it is best to not specify in rulemaking the exact timeframe during the year for publication as doing so may prevent earlier publication. In the FY 2017 IPPS/LTCH PPS proposed rule, we proposed, then, to make these data

available as soon as it is feasible during the year, starting with the first year for which we are publishing data for each measure. We will continue to propose in rulemaking the first year for which we intend to publish data for each measure. We intend to make the data available on at least a yearly basis.

As stated above, we are required to give PCHs an opportunity to review their data before the data are made public. Because we proposed to make the data for this program available as soon as possible, and the timeframe for this publication may change year-to-year, we did not propose to specify in rulemaking the exact dates for review. However, we proposed that the time period for review would be approximately 30 days in length. We proposed to announce the exact timeframes on a CMS Web site and/or on our applicable listservs.

We welcomed public comments on these updates to our public display and preview policies.

We did not receive any public comments. Therefore, for the reasons discussed above, we are finalizing these proposals.

c. Public Display of Additional PCHQR Measure

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25212), we proposed to publicly display one additional PCHQR measure beginning with FY 2017 program year data (which is data collected during CY 2015). This proposal would mean that we would display the measure data during CY 2017, and that we would use a CMS Web site and/or our applicable listservs to announce the exact timeframe. This measure is External Beam Radiotherapy for Bone Metastases (NQF #1822), which we adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278 through 50280). We believe that it is important to share data collected under the PCHQR Program with healthcare consumers through publication on public Web sites to help inform healthcare choices. We intend to make this data publicly available at the first opportunity.

We welcomed public comment on our proposal to display this measure beginning with the FY 2017 program year data and for subsequent years.

Comment: One commenter supported the proposed public display of data related to the External Beam Radiotherapy for Bone Metastases measure beginning in 2017. The commenter indicated it would welcome the opportunity to collaborate with CMS on best ways to display the data.

Response: We thank the commenter for the support.

After consideration of the public comment we received, we are finalizing the public display of data related to the External Beam Radiotherapy for Bone Metastases measure beginning in 2017 as proposed.

d. Public Display of Updated Measure

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49720 through 49722), we finalized public display of the Oncology: Radiation Dose Limits to Normal Tissues measure in 2016 and subsequent years. In the proposed rule (81 FR 25212) we stated that we proposed that if our proposal to update this measure (described in section VIII.B.3.b. of the preamble of the proposed rule) was finalized, we proposed to begin displaying on *Hospital Compare* data using the updated measure cohort as soon as feasible after the updated data is collected in CY 2017. We intend to denote the cohort expansion on *Hospital Compare* to ensure that consumers are informed about the expansion.

We welcomed public comment on our proposals regarding public display of this updated measure.

Comment: One commenter asked that CMS clarify the data collection dates for the proposed cohort expansion.

Response: PCHs would submit data for the expanded cohort during CY 2017, this data will be submitted according to the data submission schedule that was finalized in the 2015 IPPS/LTCH PPS final rule (79 FR 50283).

After consideration of the public comment we received, we are finalizing this policy as proposed.

e. Postponement of Public Display of Two Measures

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281 through 50282), we finalized public display of the CLABSI and CAUTI measures beginning no later than 2017 and subsequent years. However, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25212) we proposed to defer the public reporting of these two measures' data. At present, all PCHs are reporting CLABSI and CAUTI data to the NHSN under the PCHQR Program; however, due to the low volume of data produced and reported by this small number of facilities, we need additional time to work with CDC to identify an appropriate timeframe for public reporting and collaborate on the analytic methods that will be used to summarize the CLABSI and CAUTI data for public reporting purposes.

We invited public comment on our proposal to defer the public reporting of the CLABSI and the CAUTI measures.

Comment: Two commenters supported CMS's decision to defer the public display of CLABSI and CAUTI data pending collaboration with the CDC.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to continue to defer public reporting of the CLABSI and CAUTI measures pending further collaboration with the CDC.

Our previously finalized and newly finalized public display requirements are summarized in the table below.

PREVIOUSLY FINALIZED AND NEWLY FINALIZED PUBLIC DISPLAY REQUIREMENTS

Measures	Public reporting
Summary of Finalized and Newly Finalized Public Display Requirements	
• Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer (NQF #0223).	2014 and subsequent years.
• Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1cN0M0, or Stage IB—III Hormone Receptor Negative Breast Cancer (NQF #0559).	
• Adjuvant Hormonal Therapy (NQF #0220)	2015 and subsequent years.
• Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382)*	2016 and subsequent years.
• Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383).	
• Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384)	
• Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients (NQF #0390)	

PREVIOUSLY FINALIZED AND NEWLY FINALIZED PUBLIC DISPLAY REQUIREMENTS—Continued

Measures	Public reporting
• Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (NQF #0389) • HCAHPS (NQF #0166) • CLABSI (NQF #0139)**	Deferred.
• CAUTI (NQF #0138)**. • External Beam Radiotherapy for Bone Metastases (NQF #1822)***	Beginning at the first opportunity in 2017 and for subsequent years.

* Update newly finalized for display for the FY 2019 program year and subsequent years in this finalized rule—expanded cohort will be displayed as soon as feasible.
** Deferral newly finalized in this final rule.
*** Measure newly finalized for public display in this final rule.

8. Form, Manner, and Timing of Data Submission

Section 1866(k)(2) of the Act requires that, beginning with the FY 2014 PCHQR program year, each PCH must submit to the Secretary data on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time, as specified by the Secretary.

Data submission requirements and deadlines for the PCHQR Program are generally posted on the QualityNet Web site at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772864228*.

The newly finalized measure for FY 2019 (Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy) is a claims-based measure; therefore, there are no additional data submission requirements for this measure. As this measure uses 1 year of Medicare administrative claims data, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25212 through 25213), we proposed to calculate this measure on a yearly basis, beginning with data from July 1, 2016 through June 30, 2017, and then to calculate the measure for subsequent years using data from July 1 through June 30.

We did not receive any comments on this proposal. Therefore, for the reasons discussed above, we are finalizing the reporting schedules as proposed.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25213), we did not propose any changes to previously finalized data submission requirements.

9. Exceptions From PCHQR Program Requirements

In our experience with other quality reporting and performance programs, we have noted occasions when providers have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). We do not wish to increase their burden unduly during these times. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848), we finalized our policy that, for the FY 2014 program year and subsequent years, PCHs may request and we may grant exceptions (formerly referred to as waivers) with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the PCH warrant. When exceptions are granted, we will notify the respective PCH.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25213), we did not propose any changes to this PCHQR exception process.

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

We seek to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by quality reporting programs coupled with public reporting of that information.

Section 3004(a) of the Affordable Care Act amended section 1886(m)(5) of the Act, requiring the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The LTCH QRP applies to all hospitals certified by Medicare as LTCHs. Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the LTCH PPS standard Federal rate for discharges occurring during such fiscal year by 2 percentage points for any LTCH that does not comply with the requirements established by the Secretary.

Section 1886(m)(5) of the Act requires that for the FY 2014 payment determination and subsequent years, each LTCH submit data on quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. For more information on the statutory history of the LTCH QRP, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286).

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) imposed new data reporting requirements for certain post-acute care (PAC) providers, including LTCHs. For information on the statutory background of the IMPACT Act, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49724).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49728), we reviewed and finalized the activities and the timeline and sequencing of such activities that would occur under the LTCH QRP. In addition, we established our approach for identifying cross-cutting measures and process for the adoption of measures, including the application and purpose of the Measure Application Partnership (MAP) and the notice-and-comment rulemaking process. For information on these topics, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723).

2. General Considerations Used for Selection of Quality, Resource Use, and Other Measures for the LTCH QRP

For a detailed discussion of the considerations we use for the selection of LTCH QRP quality measures, such as alignment with the CMS Quality Strategy,[219] which incorporates the three broad aims of the National Quality Strategy,[220] we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286 through 50287) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728). Overall, we strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest

[219] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[220] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. Quality reporting programs, coupled with public reporting of quality information, are critical to the advancement of health care quality improvement efforts. Valid, reliable, relevant quality measures are fundamental to the effectiveness of our quality reporting programs. Therefore, selection of quality measures is a priority for us in all of our quality reporting programs.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25215), we proposed to adopt for the LTCH QRP one measure that we are specifying under section 1899B(c)(1) of the Act to meet the Medication Reconciliation domain, that is, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP. Further, we proposed for the LTCH QRP to adopt three measures to meet the resource use and other measure domains identified in section 1899B(d)(1) of the Act. These measures include: (1) Total Estimated Medicare Spending Per Beneficiary (MSBP): MSPB–PAC LTCH QRP; (2) Discharge to Community: Discharge to Community-PAC LTCH QRP; and (3) Measures to reflect all-condition risk-adjusted potentially preventable hospital readmission rates: Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP.

In our development and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. To meet this requirement, we provided the following opportunities for stakeholder input: Our measure development contractor convened technical expert panels (TEPs) that included stakeholder experts and patient representatives on July 29, 2015, for the Drug Regimen Review Conducted with Follow-Up for Identified Issues measures; on August 25, 2015, September 25, 2015, and October 5, 2015, for the Discharge to Community measures; on August 12 and 13, 2015, and October 14, 2015 for the Potentially Preventable 30-Day Post-Discharge Readmission Measures; and on October 29 and 30, 2015, for the Medicare Spending Per Beneficiary measures. In addition, we released draft quality measure specifications for public comment for the Drug Regimen Review Conducted with Follow-Up for Identified Issues measures from September 18, 2015, to October 6, 2015; for the Discharge to Community measures from November 9, 2015, to December 8, 2015; for the Potentially Preventable 30-Day Post-Discharge Readmission Measures from November 2, 2015 to December 1, 2015; and for the Medicare Spending Per Beneficiary measures from January 13, 2016 to February 5, 2016. We implemented a public mailbox, *PACQualityInitiative@cms.hhs.gov*, for the submission of public comments. This PAC mailbox is accessible on our PAC quality initiatives Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-MeasuresMeasures.html.*

In addition, we sought public input from the NQF-convened MAP Post-Acute Care, Long-Term Care (PAC/LTC) Workgroup during the annual in-person meeting held December 14 and 15, 2015. The MAP, composed of multi-stakeholder groups, is tasked to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act.

The MAP reviewed each IMPACT Act-related measure proposed for use in the LTCH QRP in the FY 2017 IPPS/LTCH PPS proposed rule. For more information on the MAP's recommendations, we refer readers to the MAP 2016 Final Recommendations to HHS and CMS public report at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for use in the LTCH QRP, we proposed for the LTCH QRP for the purposes of satisfying the measure domains required under the IMPACT Act measures that closely align with the national priorities identified in the National Quality Strategy (*http://www.ahrq.gov/workingforquality/*) and for which the MAP supports the measure concept. Further discussion as to the importance and high-priority status of these proposed measures in the LTCH setting is included under each quality measure section in the preamble of this final rule.

Although we did not solicit feedback on General Considerations Used for Selection of Quality, Resource Use, and Other Measures for the LTCH QRP, we received one comment, which is summarized and discussed below.

Comment: One commenter stated that CMS should recognize burden of data collection and focus on measures that are the most clinically relevant and actionable to the facility and patients. In addition, the commenter recommended that CMS use minimum standards in the development of new measures so that they are as clear and consistent across facilities as possible.

Response: We note that we strive to strike a balance between minimizing burden and addressing gaps in quality of care as we continue to expand the LTCH QRP. We interpret the commenter's suggestion that CMS apply minimum standards in its measure development to suggest that we simplify our approach to quality measure development itself. We will take recommendations into consideration in future measure development.

We also received several comments related to the proposed measures, the IMPACT Act, NQF endorsement, the NQF MAP review process, and the use of TEPs, which are summarized and discussed below.

Comment: Several commenters expressed appreciation for CMS' efforts to implement the requirements of the IMPACT Act and standardize quality measures across PAC settings as required by the IMPACT Act. One commenter noted the importance of functional measures and value of assessing patients' functional status consistently, and is pleased that the IMPACT Act is moving in that direction. Also, one commenter indicated achieving standardized and interoperable patient assessment data will allow for better cross-setting comparisons of quality and will support the development of better quality measures with uniform risk standardization.

Response: We believe that standardizing patient assessment data will allow for the exchange of data among PAC providers in order to facilitate care coordination and improve patient outcomes. We appreciate the importance of functional status measures and will consider inclusion of additional measures.

Comment: Several commenters urged CMS to delay implementation of proposed measures until NQF has completed its review and had endorsed measures that are appropriate for the specific characteristics of the LTCH patient population. One commenter requested that CMS provide a timeline for submission of the proposed measures to NQF. In addition, commenters recommended NQF endorsement prior to public reporting. One commenter suggested that CMS seek NQF's formal consensus development process instead of a time-

limited endorsement, as it was perceived the time-limited endorsement was not sufficient.

Response: We received several comments regarding the NQF endorsement status for the proposed measures, and acknowledge the commenters' recommendation to submit the measures to the NQF prior to implementation. We wish to clarify that the proposed measures are not currently under review for endorsement due to the rigorous timelines associated with the measure development process and meeting the statutory deadlines. However, we intend to seek NQF endorsement in the near future. While we appreciate the importance of consensus endorsement and intend to seek such endorsement, we must balance the need to address gaps in quality and adhere to statutorily required timelines as in the case of the quality and resource use measures as proposed to address the IMPACT Act. We further note that we consider and propose appropriate measures that have been endorsed by the NQF whenever possible. However, when this is not feasible because there is no NQF-endorsed measure, we utilize our statutory authority that allows the Secretary to specify a measure for the LTCH QRP that is not NQF-endorsed where, as in the case for the proposed measures, we have not been able to identify other measures that are endorsed or adopted by a consensus organization. While we appreciate the importance of consensus endorsement and intend to seek such endorsement, we must balance the need to address gaps in quality and adhere to statutorily required timelines as in the case of the quality and resource use measures that we proposed to address the IMPACT Act.

In regard to the comments regarding time-limited endorsement, NQF uses time-limited endorsement for measures that meet all of NQF's endorsement criteria with the exception of field testing and that are critical to advancing quality improvement. When measures are granted this 2-year endorsement rather than the traditional 3-year period, measure developers must test the measure and return results to NQF within the 2-year window. We again note that we have not yet sought endorsement of the proposed measures, time-limited or otherwise.

Comment: Several commenters noted the NQF-convened MAP PAC/LTC Workgroup did not support the proposed measures; instead, it recommended that CMS delay measure implementation until the measures were fully developed and tested and brought back to the NQF for further consideration. One commenter further stated that TEP members and other stakeholders who provided feedback in the measure development process did not support measures moving forward without further testing.

Response: We interpret this comment to address the activities of the MAP, a multi-stakeholder partnership convened by NQF that provides input to the U.S. Department of Health and Human Services (HHS) on its selection of measures for certain Medicare programs. We would like to clarify that the MAP ''encouraged continued development'' for the proposed measure. According to the MAP, the term ''encourage continued development'' is applied when a measure addresses a critical program objective or promotes alignment and the measure is in an earlier stage of development. In contrast, the MAP uses the phrase ''do not support'' when it does not support the measures at all.

Since the MAP provided a recommendation of ''encourage continued development'' for the proposed measures during the December 2015 NQF-convened MAP PAC/LTC Workgroup meeting, further refinement of measure specifications and testing of measure validity and reliability have been performed. These efforts have included: A pilot test in 12 PAC settings, including LTCHs, to determine the feasibility of assessment items for use in calculation of the measure Drug Regimen Review Conducted with Follow-Up for Identified Issues; and further development of risk-adjusted models for the measures, Discharge to Community, Medicare Spending per Beneficiary, and Potentially Preventable 30-Day Post-Discharge Readmission Measure. Additional information regarding testing is further described in the specific measure sections in the preamble of this final rule.

For these reasons, we believe that the measures have been fully and robustly developed, and believe they are appropriate for implementation and should not be delayed.

Comment: Several commenters, including MedPAC, expressed concern regarding the standardization and interoperability of the proposed measures as they perceived the measures to have different inclusion/exclusion criteria, episode constructions and risk factors, and, therefore, do not meet the mandate of the IMPACT Act. Commenters expressed further concern about future implications of such variations and recommend delaying implementation until measures are standardized and interoperable across PAC settings. One commenter further indicated that the measure titles were different for each setting, pointing out the words ''LTCH QRP'' or ''Long-Term Care Hospital'' to designate a difference in the measure. One commenter stated implementing the quality measures in an unstandardized fashion would result in additional costs in the future for aligning measures between PAC providers.

MedPAC suggested that the measures use uniform definitions, specifications, and risk-adjustment methods, conveying that findings from their work on a unified PAC payment system suggest there is overlap or similar care provided for Medicare beneficiaries with similar needs across PAC settings. As a result of this work, MedPAC urged that the IMPACT Act measures be standardized to facilitate quality comparison across PAC settings to inform a Medicare beneficiary's choice of where to seek care and provide an opportunity for CMS to evaluate the value of PAC services, noting that differences in rates should reflect differences in quality of care rather than differences in the way rates are constructed.

Response: We wish to clarify that the IMPACT Act requires that the patient assessment instruments be modified to enable the submission of standardized data, for purposes such as interoperability. However, measures themselves are not ''interoperable.''

CMS, in collaboration with our measure contractors, developed the proposed measures with the intent to standardize the measure methodology so that we are able to detect variation among PAC providers in order to be able to assess differences in quality of care. For example, the patient assessment-based quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, was developed across PAC settings with uniform definitions and specifications. This measure is not risk adjusted. The standardized development of this assessment-based measure follows the mandate of the IMPACT Act to develop standardized patient assessment-based measures for the four PAC settings (section 1899B(c)(1) of the Act). The resource use and other measures, Discharge to the Community-PAC LTCH QRP and Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, were developed to be uniform across the PAC settings in terms of their definitions, measure calculations, and risk-adjustment approach where applicable.

There is variation in each measure primarily due to the data sources for

each PAC setting. The risk-adjustment approach for the resource use and other IMPACT Act measures is aligned, but is tailored to each measure based on measure testing results. Adjusting for relevant case-mix characteristics in each setting improves the validity and explanatory power of risk adjustment models, and helps ensure that any differences in measure performance reflect differences in the care provided rather than differences in patient case-mix. We employ this approach to measure development to enable appropriate cross-setting comparisons in PAC settings and to maximize measure reliability and validity. It should be noted that sections 1899B(c)(3)(B) and 1899B(d)(3)(B) of the Act require that quality measures and resource use and other measures be risk adjusted, as determined appropriate by the Secretary.

Comment: Several commenters expressed concerns regarding the validity and reliability of IMPACT Act measures and encouraged CMS to conduct further analysis of data to ensure comparability across PAC settings, prior to implementation and public reporting of data.

Response: We have tested for validity and reliability all of the IMPACT Act measures, and the results of that testing is available in the document, Measure Specifications for Measures Adopted in the FY 2017 LTCH QRP Final Rule, posted on the CMS LTCH QRP Web page at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html.*

Comment: A few commenters requested that CMS proceed cautiously to ensure new measures are associated with minimal administrative and data collection burden, but also expressed appreciation of CMS efforts to implement the IMPACT Act.

Response: We appreciate the importance of avoiding undue burden on providers and will continue to evaluate and consider any unnecessary burden associated with implementation of the LTCH QRP. We wish to note that the three resource measures are claims-based, and will require no additional data collection by providers and thus result in minimal increases in burden. The measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC LTCH QRP, is calculated using assessment data and requires the addition of three items to the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set, also requiring minimal additional burden. We address the issue of burden further under section I.M. of Appendix A of this final rule.

Comment: One commenter expressed concern regarding CMS' approach to implementing the requirements of the IMPACT Act and requested CMS consider greater flexibility with regard to regulatory requirements.

Response: We appreciate the comment regarding the requirements associated with the proposed quality measures for the IMPACT Act. We note that any flexibility we may have with regard to regulatory requirements is constrained by the statutory requirements of the IMPACT Act. However, we do, and will continue to, monitor the effects of policy changes affecting PAC facilities to ensure appropriate patient access and care and will consider greater flexibility as feasible and appropriate.

Comment: Several commenters urged CMS to engage in several activities which would afford greater transparency with stakeholders regarding measure development. These commenters also requested that measures undergo field testing with providers prior to implementation. Commenters also requested that more detailed measure specifications be posted in order to enable providers to evaluate measure design decisions. Commenters requested that LTCH providers be provided with confidential preview reports as a part of a ''dry run'' process as this would enable providers to review data and provide CMS with feedback on potential technical issues with proposed measure. Finally, the commenters requested that measure data be provided to LTCHs on a patient level on a quarterly basis, similar to other quality reporting programs, in order to make effective use of the data and improve performance.

Response: With regard to the testing and analytic results provided for these measures, since the December 2015 MAP meeting, further refinement of measure specifications and testing of measure validity and reliability have been performed.

We refer readers to the Measure Specifications for Measures Adopted in the FY 2017 LTCH QRP Final Rule, posted on the CMS LTCH QRP Web page at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html,* which includes detailed information regarding measure specifications, including results of the final risk adjustment models for the resource use measures. For resource use measures, our testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), previously adopted into the LTCH QRP.

We appreciate the comment requesting that we provide performance data on LTCH QRP measures on a more frequent, such as quarterly, basis in order to promote quality improvement. We wish to note that the proposed claims-based measures are based on 2 consecutive years of data in order to ensure a sufficient sample size to reliably assess LTCHs' performance. However, we will investigate the feasibility and usability of providing LTCHs with information more frequently, such as unadjusted counts of potentially preventable readmissions (PPRs) and discharge data. We also appreciate the commenters' suggestions related to the implementation of dry run activities, such as confidential reports, for the purposes of identifying any technical issues prior to public reporting, as was successfully provided in the fall of 2015 for the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512).

We intend to provide confidential feedback reports beginning in October 2017, as described in section VIII.C.15. of the preamble of this final rule, and we believe that the reports could serve as an opportunity for LTCHs to provide to us any technical issues they may discover. However, we note that, as described in section VIII.C.14. of the preamble of the proposed rule, we are unable at this time to provide patient level information for the claims-based measure, for example, the readmission measures, because such data comes from a separate entity. Finally, we wish to note that we intend to continue refining specifications and we will consider pilot testing in addition to the performance testing that we currently conduct.

3. Policy for Retention of LTCH QRP Measures Adopted for Previous Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615), for the purpose of streamlining the rulemaking process, we adopted a policy that, when we initially adopt a measure for the LTCH QRP for a payment determination and all subsequent years, it would remain in effect until the measure was actively removed, suspended, or replaced. For further information on how measures are considered for removal, suspension, or replacement, we refer readers to the

FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615).

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25214), we did not propose any changes to the policy for retaining LTCH QRP measures adopted for previous payment determinations.

4. Policy for Adopting Changes to LTCH QRP Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616), we adopted a subregulatory process to incorporate NQF updates to LTCH quality measure specifications that do not substantively change the nature of the measure. Substantive changes will be proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a nonsubstantive change and the subregulatory process for nonsubstantive changes, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616). In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25214), we did not propose any changes to the policy for adopting changes to LTCH QRP measures.

5. Quality Measures Previously Finalized for and Currently Used in the LTCH QRP

A history of the LTCH QRP quality measures adopted for the FY 2014 payment determinations and subsequent years is presented in the table below. The year in which each quality measure was first adopted and implemented, and then subsequently readopted or revised, if applicable, is displayed. The initial and subsequent annual payment determination years are also shown in this table. For more information on a particular measure, we refer readers to the IPPS/LTCH PPS final rule and associated page numbers referenced in this table.

QUALITY MEASURES PREVIOUSLY FINALIZED FOR AND CURRENTLY USED IN THE LTCH QRP

Measure title	IPPS/LTCH PPS Final rule	Data collection start date	Annual payment determination: Initial and subsequent APU years
National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51745 through 51747).	October 1, 2012	FY 2014 and subsequent years.
	Adopted the NQF endorsed version and expanded measure (with standardized infection ratio [SIR]) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53619).	January 1, 2013	FY 2015 and subsequent years.
National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51747 through 51748).	October 1, 2012	FY 2014 and subsequent years.
	Adopted the NQF endorsed and expanded measure (with SIR) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53619).	January 1, 2013	FY 2015 and subsequent years.
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750).	October 1, 2012	FY 2014 and subsequent years.
	Adopted the NQF endorsed version in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863).	January 1, 2013	FY 2015 and subsequent years.
	Adopted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49731 through 49736) to fulfill IMPACT Act requirements.	January 1, 2016	FY 2018 and subsequent years.
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).	Adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627).	January 1, 2014	FY 2016 and subsequent years.
	Revised data collection timeframe in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50858 through 50861).	October 1, 2014	FY 2016 and subsequent years.
	Revised data collection timeframe in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50289 through 50290).	October 1, 2014	FY 2016 and subsequent years.
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).	Adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631).	October 1, 2014	FY 2016 and subsequent years.
	Revised data collection timeframe in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50857 through 50858).	October 1, 2014	FY 2016 and subsequent years.
All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from Long-Term Care Hospitals (NQF #2512).	Adopted in FY 2014 IPPS/LTCH PPS final rule (78 FR 50868 through 50874).	N/A	FY 2017 and subsequent years.
	Adopted the NQF endorsed version in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49730 through 49731).	N/A	FY 2018 and subsequent years.
National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50863 through 50865).	January 1, 2015	FY 2017 and subsequent years.

QUALITY MEASURES PREVIOUSLY FINALIZED FOR AND CURRENTLY USED IN THE LTCH QRP—Continued

Measure title	IPPS/LTCH PPS Final rule	Data collection start date	Annual payment determination: Initial and subsequent APU years
National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50865 through 50868).	January 1, 2015	FY 2017 and subsequent years.
National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure (NQF #N/A).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50301 through 50305).	January 1, 2016	FY 2018 and subsequent years.
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877).	January 1, 2016	FY 2018 and subsequent years.
	Revised data collection timeframe in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290 through 50291).	April 1, 2016	FY 2018 and subsequent years.
	Adopted an application of the measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49736 through 49739) to fulfill IMPACT Act requirements.	April 1, 2016	FY 2018 and subsequent years.
Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50291 through 50298).	April 1, 2016	FY 2018 and subsequent years.
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted an application of the measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747) to fulfill IMPACT Act requirements.	April 1, 2016	FY 2018 and subsequent years.
Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50298 through 50301).	April 1, 2016	FY 2018 and subsequent years.

Although we did not solicit feedback, we received a comment about Quality Measures Previously Finalized for and Currently Used in the LTCH QRP. The comment is summarized and discussed below.

Comment: One commenter supported the continued inclusion of the previously adopted measure, Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) in the LTCH QRP for the FY 2018 payment determination and subsequent years.

Response: We thank the commenter for their support of this measure and its continued inclusion in the LTCH QRP.

6. LTCH QRP Quality, Resource Use and Other Measures Finalized for the FY 2018 Payment Determination and Subsequent Years

For the FY 2018 payment determinations and subsequent years, in addition to the quality measures we are retaining under our policy described in section VIII.C.3. of the preamble of this final rule, we proposed three new measures. These measures were developed to meet the requirements of the IMPACT Act. They are:

- MSPB–PAC LTCH QRP;
- Discharge to Community-PAC LTCH QRP; and
- Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP.

The measures are described in more detail below.

For the risk-adjustment of the resource use and other measures, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

We received several comments on the impact of sociodemographic status (SDS) on quality measures, resource use, and other measures, which are summarized and discussed below.

Comment: Several commenters indicated their support for the inclusion of SDS adjustment in quality measures, resource use, and other measures. Commenters suggested that failure to account for these patient characteristics could penalize LTCHs for providing care to a more medically-complex and socioeconomically disadvantaged patient population and affect provider performance. Some commenters expressed concerns about standardization and interoperability of the measures as it pertains to risk adjusting, particularly for SDS characteristics. Many commenters recommended incorporating socioeconomic status (SES) factors as risk-adjusters for the measures, and several commenters suggested conducting additional testing and/or NQF endorsement prior to implementation of these measures.

Several commenters, including MedPAC, did not support risk adjustment of measures by SES or SDS status. One commenter did not support such risk adjustment because it can hide disparities and create different standards of care for LTCHs based on the demographics in the facility. MedPAC reiterated that risk adjustment can hide disparities in care and suggests risk adjustment reduces pressure on providers to improve quality of care for low-income Medicare beneficiaries. Instead, MedPAC supported peer provider group comparisons with providers of similar low-income beneficiary populations. Another commenter stated that SDS factors should not be included in measures that examine the patient during an LTCH stay, but should only be considered for measures evaluating care after the LTCH discharge.

Response: We appreciate the considerations and suggestions conveyed regarding the measures and the importance in balancing appropriate risk adjustment along with ensuring access to high quality care. We note that in the measures that are risk-adjusted, we do take into account characteristics associated with medical complexity, as well as factors such as age where appropriate to do so. For those cross-setting PAC measures, such as those intended to satisfy the IMPACT Act domains that use the patient assessment-based data elements for risk adjustment, we have either made such items standardized, or intend to do so as feasible. With regard to the incorporation of additional factors, we have and will continue to take such factors into account, which would include further testing as part of our ongoing measure development monitoring activities. As discussed previously, we intend to seek NQF endorsement for our measures.

With regard to the suggestions pertaining to the incorporation of socioeconomic factors as risk-adjusters for the measures, including in those measures that pertain to after the patient was discharged from the LTCH, additional testing and/or NQF endorsement prior to implementation of these measures, comments that pertain to potential consequences associated with such risk adjusters and alternative approaches to grouping comparative data, we wish to reiterate that as previously discussed, NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

a. Measure To Address the IMPACT Act Domain of Resource Use and Other Measures: Total Estimated MSPB–PAC LTCH QRP

We proposed an MSPB–PAC LTCH QRP measure for inclusion in the LTCH QRP for the FY 2018 payment determination and subsequent years. Section 1899B(d)(1)(A) of the Act requires the Secretary to specify resource use measures, including total estimated Medicare spending per beneficiary, on which PAC providers, consisting of LTCHs, Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), and Home Health Agencies (HHAs), are required to submit necessary data specified by the Secretary.

Rising Medicare expenditures for PAC as well as wide variation in spending for these services underlines the importance of measuring resource use for providers rendering these services. Between 2001 and 2013, Medicare PAC spending grew at an annual rate of 6.1 percent and doubled to $59.4 billion, while payments to inpatient hospitals grew at an annual rate of 1.7 percent over this same period.[221] A study commissioned by the Institute of Medicine found that variation in PAC spending explains 73 percent of variation in total Medicare spending across the United States.[222]

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use measures for PAC settings. Therefore, we proposed this MSPB–PAC LTCH QRP measure under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act. Given the current lack of resource use measures for PAC settings, our MSPB–PAC LTCH QRP measure will provide valuable information to LTCHs on their relative Medicare spending in delivering services to approximately 122,000 Medicare beneficiaries.[223]

The MSPB–PAC LTCH QRP episode-based measure will provide actionable and transparent information to support LTCHs' efforts to promote care coordination and deliver high quality care at a lower cost to Medicare. The MSPB–PAC LTCH QRP measure holds LTCHs accountable for the Medicare payments within an ''episode of care'' (episode), which includes the period during which a patient is directly under the LTCH's care, as well as a defined period after the end of the LTCH treatment, which may be reflective of and influenced by the services furnished by the LTCH. MSPB–PAC

[221] MedPAC, ''A Data Book: Health Care Spending and the Medicare Program,'' (2015). 114.

[222] Institute of Medicine, ''Variation in Health Care Spending: Target Decision Making, Not Geography,'' (Washington, DC: National Academies 2013). 2.

[223] Figures for 2013. MedPAC, ''Medicare Payment Policy,'' Report to the Congress (2015). xvii–xviii.

LTCH QRP episodes, constructed according to the methodology described below, have high levels of Medicare spending with substantial variation. In FY 2013 and FY 2014, Medicare FFS beneficiaries experienced 178,538 MSPB–PAC LTCH QRP episodes triggered by admission to an LTCH. The mean payment-standardized, risk-adjusted episode spending for these episodes is $67,181. There is substantial variation in the Medicare payments for these MSPB–PAC LTCH QRP episodes—ranging from approximately $27,502 at the 5th percentile to approximately $115,291 at the 95th percentile. This variation is partially driven by variation in payments occurring after LTCH treatment.

Evaluating Medicare payments during an episode creates a continuum of accountability between providers that should improve post-treatment care planning and coordination. While some stakeholders throughout the measure development process supported the MSPB–PAC measures and believed that measuring Medicare spending was critical for improving efficiency, others believed that resource use measures did not reflect quality of care in that they do not take into account patient outcomes or experience beyond those observable in claims data. However, LTCHs involved in the provision of high quality PAC care as well as appropriate discharge planning and post-discharge care coordination would be expected to perform well on this measure since beneficiaries would likely experience fewer costly adverse events (for example, avoidable hospitalizations, infections, and emergency room usage). Further, it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can publicly report which LTCHs are involved in the provision of high quality care at lower cost.

We developed MSPB–PAC measures for each of the four PAC settings. We proposed an LTCH-specific MSPB–PAC measure in the FY 2017 IPPS/LTCH proposed rule (81 FR 25216 through 25220), an IRF-specific MSBP–PAC measure in the FY 2017 IRF proposed rule (81 FR 24197 through 24201), a SNF-specific MSPB–PAC measure in the FY 2017 SNF PPS proposed rule (81 FR 24258 through 24262), and an HHA-specific MSBP–PAC measure in the CY 2017 HH PPS proposed rule (81 FR 43760 through 43764). The four setting-specific MSPB–PAC measures are closely aligned in terms of episode construction and measure calculation. Each MSPB–PAC measure assesses Medicare Part A and Part B spending during an episode, and the numerator and denominator are defined similarly. However, setting-specific measures allow us to account for differences between settings in payment policy, the types of data available, and the underlying health characteristics of beneficiaries. For example, the MSPB–PAC LTCH QRP measure reflects the dual payment rate of the LTCH PPS by comparing episodes triggered by each payment rate case only with episodes of the same type, as detailed below.

The MSPB–PAC measures mirror the general construction of the IPPS hospital MSPB measure, which was adopted for Hospital IQR Program beginning with the FY 2014 program, and was implemented in the Hospital VBP Program beginning with the FY 2015 program. The measure was endorsed by the NQF on December 6, 2013 (NQF #2158).[224] The hospital MSPB measure evaluates hospitals' Medicare spending relative to the Medicare spending for the national median hospital during a hospital MSPB episode. It assesses Medicare Part A and Part B payments for services performed by hospitals and other healthcare providers during a hospital MSPB episode, which is comprised of the periods immediately prior to, during, and following a patient's hospital stay.[225] [226] Similarly, the MSPB–PAC measures assess all Medicare Part A and Part B payments for fee-for-service (FFS) claims with a start date during the episode window (which, as discussed in this section, is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC LTCH QRP episode). There are differences between the MSPB–PAC measures and the hospital MSPB measure to reflect differences in payment policies and the nature of care provided in each PAC setting. For example, the MSPB–PAC measures exclude a limited set of services (for example, for clinically unrelated services) provided to a beneficiary during the episode window while the hospital MSPB measure does not exclude any services.[227]

MSPB–PAC episodes may begin within 30 days of discharge from an inpatient hospital as part of a patient's trajectory from an acute to a PAC setting. An LTCH stay beginning within 30 days of discharge from an inpatient hospital would therefore be included once in the hospital's MSPB measure, and once in the LTCH's MSPB–PAC measure. Aligning the hospital MSPB and MSPB–PAC measures in this way creates continuous accountability and aligns incentives to improve care planning and coordination across inpatient and PAC settings.

We sought and considered the input of stakeholders throughout the measure development process for the MSPB–PAC measures. We convened a TEP consisting of 12 panelists with combined expertise in all of the PAC settings on October 29 and 30, 2015, in Baltimore, Maryland. A follow-up email survey was sent to TEP members on November 18, 2015, to which 7 responses were received by December 8, 2015. The MSPB–PAC TEP Summary Report is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Technical-Expert-Panel-on-Medicare-Spending-Per-Beneficiary.pdf*. The measures were also presented to the MAP PAC/LTC Workgroup on December 15, 2015. As the MSPB–PAC measures were under development, there were three voting options for members: encourage continued development; do not encourage further consideration; and insufficient information.[228] The MAP PAC/LTC Workgroup voted to ''encourage continued development'' for each of the MSPB–PAC measures.[229] The MAP PAC/LTC Workgroup's vote of ''encourage continued development'' was affirmed by the MAP Coordinating Committee on January 26, 2016.[230] The MAP's concerns about the MSPB–PAC measures, as outlined in their final report, ''MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care,'' and Spreadsheet of Final Recommendations were taken into consideration during the measure development process and are discussed

[224] QualityNet, ''Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure,'' (2015). Available at: *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*.

[225] Ibid.

[226] FY 2012 IPPS/LTCH PPS final rule (76 FR 51619).

[227] FY 2012 IPPS/LTCH PPS final rule (76 FR 51620).

[228] National Quality Forum, Measure Applications Partnership, ''Process and Approach for MAP Pre-Rulemaking Deliberations, 2015–2016'' (February 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81693*.

[229] National Quality Forum, Measure Applications Partnership Post-Acute Care/Long-Term Care Workgroup, ''Meeting Transcript—Day 2 of 2'' (December 15, 2015) 104–106 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81470*.

[230] National Quality Forum, Measure Applications Partnership, ''Meeting Transcript—Day 1 of 2'' (January 26, 2016) 231–232 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81637*.

as part of our responses to public comments, described below.[231] [232]

Since the MAP's review and recommendation of continued development, CMS continued to refine risk adjustment models and conduct measure testing for the IMPACT Act measures in compliance with the MAP's recommendations. The IMPACT Act measures are both consistent with the information submitted to the MAP and support the scientific acceptability of these measures for use in quality reporting programs.

In addition, a public comment period, accompanied by draft measures specifications, was originally open from January 13 to 27, 2016 and extended to February 5, 2016. A total of 45 comments on the MSPB–PAC measures were received during this 3.5 week period. The comments received also covered each of the MAP's concerns as outlined in their Final Recommendations.[233] The MSPB–PAC Public Comment Summary Report is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report.pdf* and the MSPB–PAC Public Comment Supplementary Materials are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report_supplementary_materials.pdf*. These documents contain the public comments (summarized and verbatim), along with our responses including statistical analyses. The MSPB–PAC LTCH QRP measure, along with the other MSPB–PAC measures, as applicable, will be submitted for NQF endorsement when feasible.

To calculate the MSPB–PAC LTCH QRP measure for each LTCH, we first define the construction of the MSPB–PAC LTCH QRP episode, including the length of the episode window as well as the services included in the episode. Next, we apply the methodology for the measure calculation. The specifications are discussed further in this section. More detailed specifications for the MSPB–PAC measures, including the MSPB–PAC LTCH QRP measure, are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

(1) Episode Construction

An MSPB–PAC LTCH QRP episode begins at the episode trigger, which is defined as the patient's admission to an LTCH. The admitting facility is the attributed provider, for whom the MSPB–PAC LTCH QRP measure is calculated. The episode window is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC LTCH QRP episode. Because Medicare FFS claims are already reported to the Medicare program for payment purposes, LTCHs will not be required to report any additional data to CMS for calculation of this measure. Thus, there will be no additional data collection burden from the implementation of this measure.

Our MSPB–PAC LTCH QRP episode construction methodology differentiates between episodes triggered by standard payment rate cases and site neutral payment rate cases, reflecting the LTCH dual-payment policy detailed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623). Standard and site neutral episodes would be compared only with standard and site neutral episodes respectively. Differences in episode construction between standard and site neutral episodes are noted in this section; they otherwise share the same definition.

The episode window is comprised of a treatment period and an associated services period. The treatment period begins at the trigger (that is, on the day of admission to the LTCH) and ends on the day of discharge from that LTCH. Readmissions to the same facility occurring within 7 or fewer days do not trigger a new episode, and instead are included in the treatment period of the original episode. When two sequential stays at the same LTCH occur within 7 or fewer days of one another, the treatment period ends on the day of discharge for the latest LTCH stay. The treatment period includes those services that are provided directly or reasonably managed by the LTCH that are directly related to the beneficiary's care plan. The associated services period is the time during which Medicare Part A and Part B services (with certain exclusions) are counted towards the episode. The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period. The distinction between the treatment period and the associated services period is important because clinical exclusions of services may differ for each period. Certain services are excluded from the MSPB–PAC LTCH QRP episodes because they are clinically unrelated to LTCH care, and/or because LTCHs may have limited influence over certain Medicare services delivered by other providers during the episode window. These limited service-level exclusions are not counted towards a given LTCH's Medicare spending to ensure that beneficiaries with certain conditions and complex care needs receive the necessary care. Certain services that are determined to be outside of the control of an LTCH include planned hospital admissions, management of certain preexisting chronic conditions (for example, dialysis for end-stage renal disease (ESRD), and enzyme treatments for genetic conditions), treatment for preexisting cancers, organ transplants, and preventive screenings (for example, colonoscopy and mammograms). Exclusion of such services from the MSPB–PAC LTCH QRP episode ensures that facilities do not have disincentives to treat patients with certain conditions or complex care needs.

An MSPB–PAC episode may begin during the associated services period of an MSPB–PAC LTCH QRP episode in the 30 days post-treatment. One possible scenario occurs where an LTCH discharges a beneficiary who is then admitted to an IRF within 30 days. The IRF claim would be included once as an associated service for the attributed provider of the first MSPB–PAC LTCH QRP episode and once as a treatment service for the attributed provider of the second MSPB–PAC IRF QRP episode. As in the case of overlap between hospital and PAC episodes discussed earlier, this overlap is necessary to ensure continuous accountability between providers throughout a beneficiary's trajectory of care, as both providers share incentives to deliver high quality care at a lower cost to Medicare. Even within the LTCH setting, one MSPB–PAC LTCH QRP episode may begin in the associated services period of another MSPB–PAC LTCH QRP episode in the 30 days post-treatment. The second LTCH claim would be included once as an associated service for the attributed LTCH of the first MSPB–PAC LTCH QRP episode and once as a treatment

[231] National Quality Forum, Measure Applications Partnership, ''MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care'' Final Report, (February 2016) *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

[232] National Quality Forum, Measure Applications Partnership, ''Spreadsheet of MAP 2016 Final Recommendations'' (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

[233] National Quality Forum, Measure Applications Partnership, ''Spreadsheet of MAP 2016 Final Recommendations'' (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

service for the attributed LTCH of the second MSPB–PAC LTCH QRP episode. Again, this ensures that LTCHs have the same incentives throughout both MSPB–PAC LTCH QRP episodes to deliver quality care and engage in patient-focused care planning and coordination. If the second MSPB–PAC LTCH QRP episode were excluded from the second LTCH's MSPB–PAC LTCH QRP measure, that LTCH would not share the same incentives as the first LTCH of the first MSPB–PAC LTCH QRP episode. The MSPB–PAC LTCH QRP measure was designed to benchmark the resource use of each attributed provider against what their spending is expected to be as predicted through risk adjustment. As discussed further in this section, the measure takes the ratio of observed spending to expected spending for each episode and then takes the average of those ratios across all of the attributed provider's episodes. The measure is not a simple sum of all costs across a provider's episodes, thus mitigating concerns about double counting.

(2) Measure Calculation

Medicare payments for Part A and Part B claims for services included in MSPB–PAC LTCH QRP episodes, defined according to the methodology above, are used to calculate the MSPB–PAC LTCH QRP measure. Measure calculation involves determination of the episode exclusions, the approach for standardizing payments for geographic payment differences, the methodology for risk adjustment of episode spending to account for differences in patient case mix, and the specifications for the measure numerator and denominator. The measure calculation is performed separately for MSPB–PAC LTCH QRP standard and site neutral episodes to ensure that they are compared only to other standard and site neutral episodes, respectively. The final MSPB–PAC LTCH QRP measure combines the two ratios to construct one LTCH score as described in this section.

(a) Exclusion Criteria

In addition to service-level exclusions that remove some payments from individual episodes, we exclude certain episodes in their entirety from the MSPB–PAC LTCH QRP measure to ensure that the MSPB–PAC LTCH QRP measure accurately reflects resource use and facilitates fair and meaningful comparisons between LTCHs. The episode-level exclusions are as follows:

- Any episode that is triggered by an LTCH claim outside the 50 states, District of Columbia, Puerto Rico, and U.S. Territories.
- Any episode where the claim(s) constituting the attributed LTCH's treatment have a standard allowed amount of zero or where the standard allowed amount cannot be calculated.
- Any episode in which a beneficiary is not enrolled in Medicare FFS for the entirety of a 90-day lookback period (that is, a 90-day period prior to the episode trigger) plus episode window (including where a beneficiary dies), or is enrolled in Part C for any part of the lookback period plus episode window.
- Any episode in which a beneficiary has a primary payer other than Medicare for any part of the 90-day lookback period plus episode window.
- Any episode where the claim(s) constituting the attributed LTCH's treatment include at least one related condition code indicating that it is not a prospective payment system bill.

(b) Standardization and Risk Adjustment

Section 1899B(d)(2)(C) of the Act requires that the MSPB–PAC measures are adjusted for the factors described under section 1886(o)(2)(B)(ii) of the Act, which include adjustment for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate. Medicare payments included in the MSPB–PAC LTCH QRP measure are payment-standardized and risk-adjusted. Payment standardization removes sources of payment variation not directly related to clinical decisions and facilitates comparisons of resource use across geographic areas. We proposed to use the same payment standardization methodology as that used in the NQF-endorsed hospital MSPB measure. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH).[234]

Risk adjustment uses patient claims history to account for case-mix variation and other factors that affect resource use but are beyond the influence of the attributed LTCH. To assist with risk adjustment, we create mutually exclusive and exhaustive clinical case-mix categories using the most recent institutional claim in the 60 days prior to the start of the MSPB–PAC LTCH QRP episode. The beneficiaries in these clinical case mix categories have a greater degree of clinical similarity than the overall LTCH patient population, and allow us to more accurately estimate Medicare spending. Our MSPB–PAC LTCH QRP measure, adapted for the LTCH setting from the NQF-endorsed hospital MSPB measure, uses a regression framework with a 90-day hierarchical condition category (HCC) lookback period and covariates including the clinical case mix categories, MS–LTC–DRGs, HCC indicators, age brackets, indicators for originally disabled, ESRD enrollment, and long-term care status, and selected interactions of these covariates where sample size and predictive ability make them appropriate. We sought and considered public comment regarding the treatment of hospice services occurring within the MSPB–PAC LTCH QRP episode window. Given the comments received, we proposed to include the Medicare spending for hospice services but risk adjust for them, such that MSPB–PAC LTCH QRP episodes with hospice are compared to a benchmark reflecting other MSPB–PAC LTCH QRP episodes with hospice services. We believe that this strikes a balance between the measure's intent of evaluating Medicare spending and ensuring that providers do not have incentives against the appropriate use of hospice services in a patient-centered continuum of care.

We understand the important role that sociodemographic status, beyond age, plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We will monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well

[234] QualityNet, ''CMS Price (Payment) Standardization—Detailed Methods'' (Revised May 2015) *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.*

as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

While we conducted analyses on the impact of age by sex on the performance of the MSPB–PAC LTCH QRP risk-adjustment model, we did not propose to adjust the MSPB–PAC LTCH QRP measure for socioeconomic factors at this time. As this MSPB–PAC LTCH QRP measure will be submitted for NQF endorsement, we prefer to await the results of this trial and study before deciding whether to risk adjust for socioeconomic factors. We will monitor the results of the trial, studies, and recommendations. We invited public comment on how socioeconomic and demographic factors should be used in risk adjustment for the MSPB–PAC LTCH QRP measure.

Comment: Several commenters recommended that the MSPB–PAC LTCH QRP risk adjustment model include variables for SES/SDS factors. A commenter recommended that a ''fairer'' approach than using SES/SDS factors as risk adjustment variables would be to compare resource use levels that have not been adjusted for SES/SDS factors across peer providers (that is, providers with similar shares of beneficiaries with similar SES characteristics).

Response: With regard to the suggestions that the model include sociodemographic factors and the suggestion pertaining to an approach with which to convey data comparisons we refer readers to section VIII.C.6. of the preamble of this final rule, where we also discuss these topics.

Comment: Some commenters recommended that additional variables be included in risk adjustment to better capture clinical complexity. A few commenters suggested the inclusion of functional and cognitive status and other patient assessment data. A few commenters suggested patients who transfer from one short stay hospital to another in the pre-admission period may indicate clinical complexity and should be excluded from the measure. One commenter recommended that caregiver support be included in the risk adjustment model.

Response: We thank the commenters for their suggestions. The MSPB–PAC LTCH QRP measure is claims-based and does not incorporate other sources of data which might indicate the availability of family or caregiver support. As noted in the MSPB–PAC Public Comment Summary Report, a link for which has been provided above, even where data on caregiver support is available, there may be inherent subjectivity in determining the availability of such support. We believe that the other risk adjustment variables already included in the risk adjustment model adequately adjust for patients who transfer from one short stay hospital to another prior to admission to the LTCH by accounting for HCCs, clinical case mix categories, and prior inpatient and ICU length of stay. More details of the MSPB–PAC LTCH QRP risk adjustment model are in the MSPB–PAC Measure Specifications, a link for which has been provided above.

We recognize the importance of accounting for beneficiaries' functional and cognitive status in the calculation of predicted episode spending. We considered the potential use of functional status information in the risk adjustment models for the MSPB–PAC measures. However, we decided not to include this information derived from the current setting-specific assessment instruments given the move towards standardized data as mandated by the IMPACT Act. We will revisit the inclusion of functional status in these measures' risk adjustment models in the future when the standardized functional status data mandated by the IMPACT Act become available. Once they are available, we will take a gradual and systematic approach in evaluating how they might be incorporated. We intend to implement any changes if appropriate based on testing.

(c) Measure Numerator and Denominator

The MPSB–PAC LTCH QRP measure is a payment-standardized, risk-adjusted ratio that compares a given LTCH's Medicare spending against the Medicare spending of other LTCHs within a performance period. Similar to the hospital MSPB measure, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation or policy changes.

The MSPB–PAC LTCH QRP measure is calculated as the ratio of the MSPB–PAC Amount for each LTCH divided by the episode-weighted median MSPB–PAC Amount across all LTCHs. To calculate the MSPB–PAC Amount for each LTCH, one calculates the average of the ratio of the standardized spending for LTCH standard episodes over the expected spending (as predicted in risk adjustment) for LTCH standard episodes, and the average of the ratio of the standardized spending for LTCH site neutral episodes over the expected spending (as predicted in risk adjustment) for LTCH site neutral episodes. This quantity is then multiplied by the average episode spending level across all LTCHs nationally for standard and site neutral episodes. The denominator for an LTCH's MSPB–PAC LTCH QRP measure is the episode-weighted national median of the MSPB–PAC Amounts across all LTCHs. An MSPB–PAC LTCH QRP measure of less than 1 indicates that a given LTCH's Medicare spending is less than that of the national median LTCH during a performance period. Mathematically, this is represented in equation (A) below:

$$(A)\ MSPB\text{-}PAC\ LTCH\ Measure_j = \frac{MSPB\text{-}PAC\ Amount_j}{National\ Median\ MSPB\text{-}PAC\ Amount}$$

$$= \frac{\left(\frac{1}{n_j}\sum_{i\in\{I_j\}}\frac{Y_{ij}}{\widehat{Y_{ij}}}\right)\left(\frac{1}{n}\sum_j\sum_{i\in\{I_j\}}Y_{ij}\right)}{Episode-Weighted\ Median\ of\ LTCH\ Providers'MSPB\text{-}PAC\ Amount}$$

Where

- Y_{ij} = attributed standarized spending for episode *i* and provider *j,*
- Y_{ij} = expected standarized spending for episode *i* and provider *j,* as predicted from risk adjustment
- n_j = number of episodes for provider *j*
- n = total number of episodes nationally
- $i\in [I_j]$ = all episodes *i* in the set of episodes attributed to provider *j.*

(3) Data Sources

The MSPB–PAC LTCH QRP resource use measure is an administrative claims-based measure. It uses Medicare Part A and Part B claims from FFS beneficiaries and Medicare eligibility files.

(4) Cohort

The measure cohort includes Medicare FFS beneficiaries with an LTCH treatment period ending during the data collection period.

(5) Reporting

We intend to provide initial confidential feedback to providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and CY 2016. We intend to publicly report this measure using claims data from discharges in CY 2016 and CY 2017.

We proposed to use a minimum of 20 episodes for reporting and inclusion in the LTCH QRP. For the reliability calculation, as described in the measure specifications identified and for which a link has been provided above, we used two years of data (FY 2013 and FY 2014) to increase the statistical reliability of this measure. The reliability results support the 20 episode case minimum, and 98.83 percent of LTCHs had moderate or high reliability (above 0.4).

We invited public comment on our proposal to adopt the MSPB–PAC LTCH QRP measure for the LTCH QRP.

Comment: Several commenters expressed concern about the lack of NQF endorsement for the MSPB–PAC LTCH QRP measure; some believed that the measure should not be finalized until NQF endorsement is obtained.

Response: We thank the commenters for their concern regarding the lack of NQF endorsement and refer readers to section VIII.C.2. of the preamble of this final rule, where we also discuss this topic.

Comment: Several commenters noted the MAP did not endorse the proposed measure, believing that the measure should not be finalized until the support of the MAP is obtained.

Response: We appreciate the comments about the NQF MAP committee and refer readers to section VIII.C.2. of the preamble of this final rule, where we also discuss this topic.

Comment: Several commenters supported a period during which providers would be able to preview and correct measure and quality data.

Response: We appreciate the comments, and refer readers to section VIII.C.14. of the preamble of this final rule, where we discuss this topic in detail.

Comment: Some commenters recommended an initial confidential data preview period for providers, prior to public reporting.

Response: Providers will receive a confidential preview report with 30 days for review in advance of their data and information being publically displayed.

Comment: Some commenters supported an LTCH-specific MSPB–PAC measure, citing important differences (for example, patient characteristics and nature of care provided) between LTCH and other PAC settings.

Response: We thank the commenters for their support.

Comment: Some commenters recommended that the measure be tested for reliability and validity prior to finalization.

Response: As noted in the proposed rule (81 FR 25220), the MSPB–PAC LTCH QRP measure has been tested for reliability using two years of data (FY 2013 and FY 2014). The reliability results support the 20 episode case minimum, and 98.83 percent of LTCHs had moderate or high reliability (above 0.4). Further details on the reliability calculation are provided in the MSPB–PAC Measure Specifications document, a link for which has been provided above.

Comment: A few commenters noted that the MSPB–PAC measures are resource use measures that are not a standalone indicator of quality.

Response: We appreciate the comment regarding the MSPB–PAC measures as resource use measures. The MSPB–PAC LTCH QRP measure is one of four QRP measures that were proposed in the FY 2017 IPPS/LTCH proposed rule for inclusion in the LTCH QRP: In addition to the MSPB–PAC LTCH QRP measure, these proposed measures were the Discharge to Community-PAC LTCH QRP (81 FR 25220 through 25223), the Potentially Preventable 30-day Post-Discharge Readmission Measure for LTCH QRP (81 FR 25223 through 25225), and the Drug Regimen Review Conducted With Follow-Up for Identified Issues—PAC LTCH QRP (81 FR 25225 through 25228). As part of the LTCH QRP, the MSPB–PAC LTCH QRP measure will be paired with quality measures; we refer readers to section VIII.C.5. of the preamble of this final rule for a discussion of quality measures previously finalized for use in the LTCH QRP. We believe it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can publicly report which LTCHs are involved in the provision of high-quality care at lower cost.

Comment: One commenter expressed general support for the MSPB–PAC LTCH QRP measure, provided it has been tested for reliability and validity.

Response: We thank the commenter for their support. We appreciate the thoughtful feedback and engagement with the development and finalization of the MSPB–PAC LTCH QRP measure.

Comment: One commenter believed that the measure is a burden for providers.

Response: We thank the commenter for their concern. The MSPB–PAC LTCH QRP measure relies on Medicare FFS claims, which are reported to the Medicare program for payment purposes. PAC providers will not be required to report additional data to CMS for calculation of this measure.

Comment: One commenter recommended the use of uniform single MSPB–PAC measure that could be used to compare providers across settings, but recognized that CMS does not have

a uniform PPS for all the PAC settings currently. In the absence of a single PAC PPS, the commenter recommended a single MSPB–PAC measure for each setting that could be used to compare providers within a setting. Under a single measure, the episode definitions, service inclusions/exclusions, and risk adjustment methods would be the same across all PAC settings.

Response: We thank the commenter. The four separate MSPB–PAC measures reflect the unique characteristics of each PAC setting and the population it serves. The four setting-specific MSPB–PAC measures are defined as consistently as possible across settings given the differences in the payment systems for each setting, and types of patients served in each setting. We have taken into consideration these differences and aligned the specifications, such as episode definitions, service inclusions/exclusions and risk adjustment methods for each setting, to the extent possible while ensuring the accuracy of the measures in each PAC setting.

Each of the measures assess Medicare Part A and Part B spending during the episode window which begins upon admission to the provider's care and ends 30 days after the end of the treatment period. The service-level exclusions are harmonized across settings. The definition of the numerator and denominator is the same across settings. However, specifications differ between settings when necessary to ensure that the measures accurately reflect patient care and align with each setting's payment system. For example, LTCHs and IRFs are paid a stay-level payment based on the assigned MS–LTC–DRG and Case-Mix Group (CMG), respectively, while SNFs are paid a daily rate based on the Resource Utilization Group (RUG) level, and HHAs are paid a rate based on a 60-day period as determined by the Home Health Resource Group (HHRG) for standard home health claims. While the definition of the episode window is consistent across settings and is based on the period of time that a beneficiary is under a given provider's care, the duration of the treatment period varies to reflect how providers are reimbursed under the PPS that applies to each setting. The length of the post-treatment period is consistent between settings. There are also differences in the services covered under the PPS that applies to each setting: For example, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) claims are covered LTCH, IRF, and SNF services but are not covered HHA services. This affects the way certain first-day service exclusions are defined for each measure.

We recognize that beneficiaries may receive similar services as part of their overall treatment plan in different PAC settings, but believe that there are some important differences in beneficiaries' care profiles that are difficult to capture in a single measure that compares resource use across settings.

Also, the risk adjustment models for the MSPB–PAC measures share the same covariates to the greatest extent possible to account for patient case mix. However, the measures also incorporate additional setting-specific information where available to increase the predictive power of the risk adjustment models. For example, the MSPB–PAC LTCH QRP risk adjustment model uses MS–LTC–DRGs and Major Diagnostic Categories (MDCs), and the MSPB–PAC IRF QRP model includes Rehabilitation Impairment Categories (RICs). The HH and SNF settings do not have analogous variables that directly reflect a patient's clinical profile.

We will continue to work towards a more uniform measure across settings as we gain experience with these measures, and we plan to conduct further research and analysis about comparability of resource use measures across settings for clinically similar patients, different treatment periods and windows, risk adjustment, service exclusions and other factors.

Comment: One commenter recommended that proposed quality measures obtain the support of a TEP including LTCH representatives to ensure the applicability of the measures to the LTCH setting.

Response: We thank the commenter for their recommendation. As discussed in the proposed rule (81 FR 25217), we note that we convened a TEP consisting of 12 panelists with combined expertise in all of the PAC settings, including LTCHs, on October 29 and 30, 2015, in Baltimore, Maryland. While TEPs do not formally support or endorse measures, their feedback on risk adjustment, episode windows, exclusions, and other key elements of measure construction were incorporated into measure development. The MSPB–PAC TEP Summary Report is available, a link for which has been provided above.

Comment: One commenter recommended that LTCH site neutral and standard payment rate episodes be reported separately, rather than being aggregated into one MSPB–PAC LTCH QRP measure. Commenters believed that this would more accurately reflect resource use and be more helpful for providers.

Response: We thank the commenter for their concerns. While LTCH site neutral and LTCH standard patients are paid based on different rates, high quality and efficient treatment of any LTCH patient requires similar processes of care as well as strong care coordination and care transition planning. We believe therefore that performance scores on this measure will offer LTCHs information that will enable them to make meaningful improvements to their care. We will, however, take this comment into consideration as we continue to refine the measure.

Comment: One commenter recommended that adjacent LTCH stays be collapsed based on a 9-day gap, rather than the 7-day gap as proposed. A 9-day gap length would align with the LTCH interrupted stays policy rather than the proposed 7-day gap.

Response: We thank the commenter for their recommendation. As discussed in the MSPB–PAC Public Comment Summary Report, a link for which has been provided above, and to clarify the commenter's concern, a 9-day gap length would not align with the interrupted stays policy as an LTCH interrupted stay is reimbursed by Medicare as one claim under the LTCH PPS. Therefore, the treatment period begins at the episode trigger (that is, admission to the LTCH) and ends at the beneficiary's final discharge from the LTCH. The treatment period does not end when the patient leaves the LTCH for an acute care hospital, IRF, or SNF, nor does the patient's return to the same LTCH from those settings within the allowed number of days under the interrupted stays policy, trigger a new episode. The period during which the beneficiary is away from the LTCH and covered by the interrupted stays policy is included in the treatment period as it is treated as a single, albeit interrupted, LTCH stay under the LTCH PPS.

Comment: One commenter suggested that a 180-day associated services period would better reflect the post-discharge pathways for LTCH patients.

Response: We thank the commenter for their feedback and engagement with the MSPB–PAC LTCH QRP measure. As discussed in the MSPB–PAC Public Comment Summary Report, a link for which has been provided above, the 30-day post-treatment period was favored by the TEP panelists as an appropriate length of time during which a PAC provider can be held accountable for Medicare Part A and Part B spending, subject to certain clinically unrelated service exclusions. While a longer period such as 180 days may reflect care trajectory for an LTCH beneficiary, it

would also capture services that may be less influenced by the attributed PAC provider. Also, the 30-day post-treatment period is consistent with the NQF-endorsed hospital MSPB measure and aligns with widely adopted quality measures for readmissions and mortality.

Comment: One commenter recommended that a geographic-specific (for example, State or regional) median should be used instead of the national median, citing differences in cost, patient population, and regulation.

Response: We appreciate the commenter's input. We clarify that, as noted in the proposed rule (81 FR 25219), we proposed to use the same payment standardization methodology as that used in the NQF-endorsed hospital MSPB measure to account for variation in Medicare spending. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals, including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH). We believe that this approach accounts for the differences that the commenter raises while also maintaining consistency with the NQF-endorsed hospital MSPB measure's methodology for addressing regional variation through payment standardization.

Comment: One commenter suggested that descriptive statistics on the measure scores by provider-level characteristics (for example, rural/urban status and bed size) would be useful to evaluate measure design decisions.

Response: We thank the commenter for their input. The following table shows the MSPB–PAC LTCH provider scores by provider characteristics, calculated using FY 2013 and FY 2014 data.

MSPB–PAC LTCH Provider Scores by Provider Characteristics

Provider characteristic	Number of providers	Mean score	Score percentile						
			1st	10th	25th	50th	75th	90th	99th
All Providers	438	1.00	0.85	0.93	0.96	0.99	1.03	1.07	1.23
Urban/Rural:									
Urban	411	1.00	0.85	0.93	0.96	0.99	1.03	1.07	1.19
Rural	27	1.00	0.92	0.93	0.96	1.00	1.04	1.07	1.24
Ownership Type:									
For profit	284	1.00	0.88	0.94	0.97	1.00	1.03	1.06	1.15
Non-profit	113	1.00	0.86	0.92	0.95	0.99	1.04	1.08	1.27
Government	24	0.91	0.29	0.62	0.88	0.94	1.01	1.06	1.36
Unknown	17	0.99	0.89	0.93	0.94	1.00	1.03	1.07	1.12
Census Division:									
New England	17	0.91	0.53	0.82	0.88	0.94	0.97	0.98	1.01
Middle Atlantic	32	1.02	0.86	0.98	0.99	1.01	1.05	1.08	1.11
East North Central	70	1.00	0.89	0.93	0.97	1.01	1.03	1.07	1.12
West North Central	27	1.00	0.92	0.93	0.96	0.99	1.03	1.07	1.12
South Atlantic	63	0.99	0.88	0.92	0.94	0.98	1.01	1.05	1.36
East South Central	34	0.98	0.90	0.92	0.93	0.98	1.01	1.06	1.24
West South Central	137	1.00	0.88	0.94	0.96	0.99	1.04	1.09	1.23
Mountain	33	1.01	0.90	0.95	0.97	1.00	1.03	1.06	1.27
Pacific	25	1.00	0.29	0.97	1.00	1.02	1.04	1.08	1.18
Bed Count:									
0–49	238	0.99	0.88	0.93	0.95	0.98	1.02	1.06	1.23
50–99	140	1.01	0.88	0.94	0.97	1.00	1.04	1.08	1.18
100–199	40	1.02	0.86	0.93	0.98	1.02	1.05	1.09	1.36
200–299	14	0.95	0.53	0.82	0.92	0.97	1.03	1.09	1.10
300 +	6	0.93	0.85	0.85	0.86	0.92	1.00	1.01	1.01
No. of Episodes:									
0–99	25	0.99	0.29	0.62	0.93	1.01	1.09	1.27	1.47
100–249	105	0.99	0.89	0.92	0.95	0.98	1.03	1.07	1.15
250–499	206	0.99	0.88	0.93	0.96	0.99	1.03	1.06	1.12
500–1000	84	1.00	0.86	0.94	0.97	1.00	1.04	1.06	1.24
1000 +	18	1.01	0.94	0.97	0.99	1.00	1.03	1.08	1.08

Comment: One commenter expressed concern that the public may interpret the MSPB–PAC measures to be applicable across PAC settings.

Response: We appreciate the commenter's concern. While the MSPB–PAC measures are defined as consistently as possible between settings, they compare only providers within each setting. We believe that this distinction is clear as each MSPB–PAC measure will be part of their respective setting's QRP, including the MSPB–PAC LTCH QRP measure which is being finalized as part of the LTCH QRP.

In summary, after consideration of the public comments we received, we are finalizing the specifications of the MSPB–PAC LTCH QRP resource use measure, as proposed. A link for the MSPB–PAC Measure Specifications has been provided above.

We are finalizing the definition of an MSPB–PAC LTCH QRP episode, beginning from episode trigger. An episode window comprises a treatment period beginning at the trigger and ended upon discharge, and associated services period beginning at the trigger and ending 30 days after the end of the treatment period. Readmissions to the same LTCH within 7 or fewer days do not trigger a new episode and are instead included in the treatment period of the first episode.

We exclude certain services that are clinically unrelated to LTCH care and/or because LTCHs may have limited influence over certain Medicare services delivered by other providers during the episode window. We also exclude certain episodes in their entirety from the MSPB–PAC LTCH QRP measure, such as where a beneficiary is not enrolled in Medicare FFS for the

entirety of the lookback period plus episode window.

We are finalizing the inclusion of Medicare payments for Part A and Part B claims for services included in the MSPB–PAC LTCH QRP episodes to calculate the MSPB–PAC LTCH QRP measure.

We are finalizing our proposal to risk adjust using covariates including age brackets, HCC indicators, prior inpatient stay length, ICU stay length, clinical case mix categories, indicators for originally disabled, ESRD enrollment, and long-term care status, hospice claim in episode window, and MS–LTC–DRGs. The measure also adjusts for geographic payment differences such as wage index and GPCI, and adjust for Medicare payment differences resulting from IME and DSH.

We calculate the individual providers' MSPB–PAC Amount which is inclusive of MSPB–PAC LTCH QRP observed episode spending over the expected episode spending as predicted through risk adjustment. Standard and site neutral episode spending is compared only with standard and site neutral episode spending, respectively. Individual LTCHs' scores are calculated as their individual MSPB–PAC Amount divided by the median MSPB–PAC amount across all LTCHs.

b. Measure To Address the IMPACT Act Domain of Resource Use and Other Measures: Discharge to Community-Post Acute Care (PAC) Long-Term Care Hospital Quality Reporting Program

Sections 1899B(d)(1)(B) and 1899B(a)(2)(E)(ii) of the Act require the Secretary to specify a measure to address the domain of discharge to community by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25220 through 25223), we proposed to adopt the measure, Discharge to Community-PAC LTCH QRP, for the LTCH QRP for the FY 2018 payment determination and subsequent years as a Medicare FFS claims-based measure to meet this requirement.

This measure assesses successful discharge to the community from an LTCH setting, with successful discharge to the community including no unplanned rehospitalizations and no death in the 31 days following discharge from the LTCH. Specifically, this measure reports an LTCH's risk-standardized rate of Medicare FFS patients who are discharged to the community following an LTCH stay, and do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. The term ''community,'' for this measure, is defined as home or self care, with or without home health services, based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS claim.[235] [236] This measure is conceptualized uniformly across the PAC settings, in terms of the definition of the discharge to community outcome, the approach to risk adjustment, and the measure calculation.

Discharge to a community setting is an important health care outcome for many patients for whom the overall goals of PAC include optimizing functional improvement, returning to a previous level of independence, and avoiding institutionalization. Returning to the community is also an important outcome for many patients who are not expected to make functional improvement during their LTCH stay, and for patients who may be expected to decline functionally due to their medical condition. The discharge to community outcome offers a multi-dimensional view of preparation for community life, including the cognitive, physical, and psychosocial elements involved in a discharge to the community.[237] [238]

In addition to being an important outcome from a patient and family perspective, patients discharged to community settings, on average, incur lower costs over the recovery episode, compared with those discharged to institutional settings.[239] [240] Given the high costs of care in institutional settings, encouraging LTCHs to prepare patients for discharge to community, when clinically appropriate, may have cost-saving implications for the Medicare program.[241] Also, providers have discovered that successful discharge to community was a major driver of their ability to achieve savings, where capitated payments for PAC were in place.[242] For patients who require long-term care due to persistent disability, discharge to community could result in lower long-term care costs for Medicaid and for patients' out-of-pocket expenditures.[243]

Analyses conducted for ASPE on PAC episodes, using a 5 percent sample of 2006 Medicare claims, revealed that relatively high average, unadjusted Medicare payments are associated with discharge to institutional settings from IRFs, SNFs, LTCHs or HHAs, as compared with payments associated with discharge to community settings.[244] Average, unadjusted Medicare payments associated with discharge to community settings ranged from $0 to $4,017 for IRF discharges, $0 to $3,544 for SNF discharges, $0 to $4,706 for LTCH discharges, and $0 to $992 for HHA discharges. In contrast, payments associated with discharge to non-community settings were considerably higher, ranging from $11,847 to $25,364 for IRF discharges, $9,305 to $29,118 for SNF discharges, $12,465 to $18,205 for LTCH discharges, and $7,981 to $35,192 for HHA discharges.[245]

Measuring and comparing facility-level discharge to community rates is expected to help differentiate among facilities with varying performance in this important domain, and to help avoid disparities in care across patient groups. Variation in discharge to community rates has been reported within and across post-acute settings; across a variety of facility-level characteristics, such as geographic location (for example, regional location, urban or rural location), ownership (for

[235] National Uniform Billing Committee Official UB–04 Data Specifications Manual 2017, Version 11, July 2016, Copyright 2016, American Hospital Association.

[236] This definition is not intended to suggest that board and care homes, assisted living facilities, or other settings included in the definition of ''community'' for the purpose of this measure are the most integrated setting for any particular individual or group of individuals under the Americans with Disabilities Act (ADA) and Section 504.

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[241] *Ibid.*

[242] Doran JP, Zabinski SJ. Bundled payment initiatives for Medicare and non-Medicare total joint arthroplasty patients at a community hospital: bundles in the real world. *The journal of arthroplasty.* 2015;30(3):353–355.

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[245] *Ibid.*

example, for-profit or nonprofit), and freestanding or hospital-based units; and across patient-level characteristics, such as race and gender.[246] [247] [248] [249] [250] [251] Discharge to community rates in the IRF setting have been reported to range from about 60 to 80 percent.[252] [253] [254] [255] [256] [257] Longer-term studies show that rates of discharge to community from IRFs have decreased over time as IRF length of stay has decreased.[258] [259] Greater variation in discharge to community rates is seen in the SNF setting, with rates ranging from 31 to 65 percent.[260] [261] [262] [263] A multi-center study of 23 LTCHs demonstrated that 28.8 percent of 1,061 patients who were ventilator-dependent on admission were discharged to home.[264] A single-center study revealed that 31 percent of LTCH hemodialysis patients were discharged to home.[265] In the LTCH Medicare FFS population, using CY 2012–2013 national data, we found that approximately 25 percent of patients were discharged to the community. One study noted that 64 percent of beneficiaries who were discharged from the home health episode did not use any other acute or post-acute services paid by Medicare in the 30 days after discharge.[266] However, significant numbers of patients were admitted to hospitals (29 percent) and lesser numbers to SNFs (7.6 percent), IRFs (1.5 percent), home health (7.2 percent) or hospice (3.3 percent).[267]

Discharge to community is an actionable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings.[268] [269] [270] [271] Many of these interventions involve discharge planning or specific rehabilitation strategies, such as addressing discharge barriers and improving medical and functional status.[272] [273] [274] [275] The effectiveness of these interventions suggests that improvement in discharge to community rates among PAC patients is possible through modifying provider-led processes and interventions.

A TEP convened by our measure development contractor was strongly supportive of the importance of measuring discharge to community outcomes, and implementing the measure, Discharge to Community-PAC LTCH QRP in the LTCH QRP. The panel provided input on the technical specifications of this measure, including the feasibility of implementing the measure, as well as the overall measure reliability and validity. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also solicited stakeholder feedback on the development of this

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measure through a public comment period held from November 9, 2015, through December 8, 2015. Several stakeholders and organizations, including the MedPAC, among others, supported this measure for implementation. The public comment summary report for this measure is available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this Discharge to Community-PAC LTCH QRP measure in the LTCH QRP. The MAP encouraged continued development of the measure to meet the mandate of the IMPACT Act. The MAP supported the alignment of this measure across PAC settings, using standardized claims data. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

Since the MAP's review and recommendation of continued development, we have continued to refine risk-adjustment models and conduct measure testing for this measure, as recommended by the MAP. This measure is consistent with the information submitted to the MAP, and the original MAP submission and our continued refinements support its scientific acceptability for use in quality reporting programs. As discussed with the MAP, we fully anticipate that additional analyses will continue as we submit this measure to the ongoing measure maintenance process.

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use or other measures for PAC focused on discharge to community. In addition, we are unaware of any other PAC measures for discharge to community that have been endorsed or adopted by other consensus organizations. Therefore, we proposed the measure, Discharge to Community-PAC LTCH QRP, under the Secretary's authority to specify non—NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

We proposed to use data from the Medicare FFS claims and Medicare eligibility files to calculate this measure. We proposed to use data from the ''Patient Discharge Status Code'' on Medicare FFS claims to determine whether a patient was discharged to a community setting for calculation of this measure. In all PAC settings, we tested the accuracy of determining discharge to a community setting using the ''Patient Discharge Status Code'' on the PAC claim by examining whether discharge to community coding based on PAC claim data agreed with discharge to community coding based on PAC assessment data. We found excellent agreement between the two data sources in all PAC settings, ranging from 94.6 percent to 98.8 percent. Specifically, in the LTCH setting, using 2013 data, we found 95.6 percent agreement in coding of community and non-community discharges when comparing discharge status codes on claims and the Discharge Location (item A2100) codes on the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set Version 1.01. We further examined the accuracy of the ''Patient Discharge Status Code'' on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by follow-up acute care claims. We discovered that 88 percent to 91 percent of IRF, LTCH, and SNF claims with acute care discharge status codes were followed by an acute care claim on the day of, or day after, PAC discharge. We believed these data support the use of the claims ''Patient Discharge Status Code'' for determining discharge to a community setting for this measure. In addition, this measure can feasibly be implemented in the LTCH QRP because all data used for measure calculation are derived from Medicare FFS claims and eligibility files, which are already available to CMS.

Based on the evidence discussed above, we proposed to adopt the measure, Discharge to Community-PAC LTCH QRP, for the LTCH QRP for FY 2018 payment determination and subsequent years. This measure is calculated using 2 years of data. We proposed a minimum of 25 eligible stays in a given LTCH for public reporting of the measure for that LTCH. Because Medicare FFS claims data are already reported to the Medicare program for payment purposes, and Medicare eligibility files are also available, LTCHs will not be required to report any additional data to us for calculation of this measure. The measure denominator is the risk-adjusted expected number of discharges to community. The measure numerator is the risk-adjusted estimate of the number of patients who are discharged to the community, do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window. The measure is risk-adjusted for variables such as age and sex, principal diagnosis, comorbidities, ventilator status, ESRD status, and dialysis, among other variables. For technical information about the proposed measure, including information about the measure calculation, risk adjustment, and denominator exclusions, we referred readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We stated in the proposed rule that we intend to provide initial confidential feedback to LTCHs, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and 2016. We intend to publicly report this measure using claims data from discharges in CY 2016 and 2017. We plan to submit this measure to the NQF for consideration for endorsement.

As noted above, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616), we adopted a subregulatory process to incorporate updates to LTCH quality measure specifications that do not substantively change the nature of the measure. In that rule, we noted that we expect to make this determination on a measure-by-measure basis and that examples of non-substantive changes to measures might include exclusions for a measure. For the proposed Discharge to Community-PAC LTCH QRP measure, we have added an exclusion of patients/residents with a hospice benefit in the postdischarge observation window, in response to comments received during measure development and our ongoing analysis and testing. The rationale for the exclusion of patients/residents with a hospice benefit in the post-discharge observation window aligns with the rationale for exclusion of discharges to hospice. Based on testing, we found that patients/residents with a postdischarge hospice benefit have a much higher death rate in the postdischarge observation window compared with patients/residents without a hospice benefit. We determined that the addition of this hospice exclusion enhances the measure by excluding patients/residents with a high likelihood of postdischarge death and improves the national observed discharge to community rate for LTCHs by approximately 0.7 percent. With the

addition of this hospice exclusion, we do not believe burden is added, nor that the addition of this exclusion is a substantive change to the overall measure. Failure to include this hospice exclusion could lead to unintended consequences and access issues for terminally-ill patients/residents in our PAC populations.

We invited public comment on our proposal to adopt the measure, Discharge to Community-PAC LTCH QRP, for the LTCH QRP. The comments we received on this topic, with their responses, appear below.

Comment: Several commenters, including MedPAC, expressed support for the Discharge to Community-PAC LTCH QRP measure. Commenters stated that the discharge to community measure is very aligned with principles of patient-centered care as patients show a preference for care outside of institutional settings, and that successful transitions to the community are expected to decrease potentially preventable readmissions. One commenter noted that measuring the rate that the various PAC settings discharge patients to the community, without an admission (or readmission) to an acute care hospital within 30 days, is one of the most relevant patient-centered measures that exists in the PAC area. Another commenter stated that LTCHs should be encouraged to discharge patients to community-based care settings (home or self care, with or without home health services) where literature shows that average spending per beneficiary is less than in institutional based care settings. One commenter supported the proposed measure, provided it had been tested for validity and reliability. One commenter noted that achieving a standardized and interoperable patient assessment data set and stable quality measures as quickly as possible will allow for better cross-setting comparisons and the evolution of better quality measures with uniform risk standardization.

Response: We thank the commenters for their support of the Discharge to Community-PAC LTCH QRP measure, and appreciate their recognition of the patient-centeredness of this measure, its potential to decrease post-discharge readmissions, and its potential to reduce spending. In our measure development process, we conduct reliability and validity testing for all measures. We will continue to conduct this testing with all future measure development and/or modification. We also thank commenters for their support of standardized and interoperable patient assessment data and quality measures. As mandated by the IMPACT Act, we are moving toward the goal of standardized patient assessment data and quality measures across PAC settings.

Comment: Several commenters stated that the Discharge to Community-PAC LTCH QRP measure is not an appropriate measure of quality for the LTCH setting, stating that the primary function of LTCHs is to provide critical, acute, or sub-acute levels of care and to discharge patients to the appropriate lower acuity setting when they no longer require these levels of care. Commenters stated that keeping patients until they are ready to be discharged to the community is not a goal of LTCHs.

Response: We appreciate the commenters' concerns. We understand that patient populations and goals of care differ across PAC settings, and that LTCHs care for higher acuity patients when compared with other PAC settings. Nonetheless, successful discharge to community, when appropriate, is an important goal many PAC patients share, regardless of the provider from which they are receiving services. We would like to note that in order to account for differences in case-mix across settings, this measure is risk-adjusted.

We understand that discharge to community rates for LTCHs, on average, are expected to be lower compared with rates for other PAC settings, given the higher acuity case-mix in LTCHs. Our analysis has shown that approximately 26 percent of LTCH patients are discharged to the community. This measure will allow us to compare discharge to community rates across LTCHs, and monitor facilities with unexpectedly low rates given their case-mix. It is not our intention to attribute lower discharge to community rates of LTCHs to lower quality of care compared with other PAC settings. Further, we do not expect facilities to achieve a 100 percent discharge to community rate for this measure.

Comment: Several commenters emphasized that a lower acuity PAC setting is often an appropriate and successful discharge destination for LTCH patients. Some commenters recommended that discharges to lower acuity PAC settings, such as IRF or SNF, be considered successful discharges to community, while others recommended that discharges to lower acuity PAC settings be excluded from the measure because otherwise they would be wrongly treated as unfavorable outcomes. One commenter specifically recommended that patients who move from SNF to hospital to LTCH and back to SNF be considered an appropriate discharge outcome for this measure; this commenter also recommended that patients with such a trajectory be excluded from the measure. Another commenter specifically recommended that discharges from an LTCH to an IRF be considered successful discharges to community.

Response: We appreciate that for several LTCH patients, discharge to lower acuity PAC settings such as IRF or SNF represents a successful and positive discharge outcome. However, we would like to clarify that this measure is intended to specifically capture discharge to community settings, namely home or self care, with or without home health services, based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS claim.[276] This measure is not intended to capture discharges to all lower levels of care. Since IRFs and SNFs are not community settings, including IRF and SNF discharges in the definition of discharge to community would reduce the validity of our measure. Nonetheless, we recognize that discharge to a community setting is not an expected outcome for every PAC patient. Therefore, we risk adjust for baseline patient characteristics in this measure to adjust for case-mix in each setting. In addition to adjusting for variables such as principal diagnosis and comorbidities, in the LTCH setting we adjust for ventilator use. We believe it is important to track discharge destination outcomes of all LTCH patients. Therefore, we have not excluded discharges to lower acuity PAC settings from the measure, nor have we excluded patients who were in a SNF prior to their acute or LTCH stay. As stated above, this measure will allow us to compare discharge to community rates across LTCHs, and monitor facilities with unexpectedly low rates given their case-mix. We believe that successful discharge to community, when appropriate, is an important goal many LTCH patients share.

Comment: Several commenters, including MedPAC, were concerned about the reliability and/or validity of the Patient Discharge Status Code on the PAC claim, some referencing MedPAC and other studies that questioned the accuracy of this code. They strongly recommended that CMS address inconsistencies in reporting of the Patient Discharge Status Code, and confirm its accuracy through additional testing. MedPAC recommended that CMS confirm discharge to a community

[276] National Uniform Billing Committee Official UB–04 Data Specifications Manual 2017, Version 11, July 2016, Copyright 2016, American Hospital Association.

setting with the absence of a subsequent claim to a hospital, IRF, SNF, or LTCH, in order to ensure that discharge to community rates reflect actual facility performance; other commenters supported this recommendation. One commenter shared its analysis that between 3.7 percent and 7.4 percent of those successfully discharged to the community as identified by the discharge status on the LTCH, IRF, or SNF claim had a subsequent short-term care hospital (STCH), LTCH, IRF, or SNF claim in the 31-day post-discharge window.

Response: We are committed to developing measures based on reliable and valid data. This measure does confirm the absence of hospital or LTCH claims following discharge to a community setting. Unplanned acute or LTCH readmissions following the discharge to community, including those on the day of LTCH discharge, are considered unfavorable outcomes. We will consider verifying the absence of IRF and SNF claims following discharge to a community setting as we continue to refine this measure. Nonetheless, we would like to note an ASPE report on PAC relationships found that, following discharge to community settings from IRFs, LTCHs, or SNFs in a 5 percent Medicare sample, IRFs or SNFs were very infrequently reported as the next site of PAC.[277] We would also like to clarify that an institutional claim that does not immediately follow a discharge to community would, in most instances, be indicative of a discharge to a community setting followed by a readmission. It should not be interpreted as evidence of an inaccurate discharge to community code on the PAC claim.

Because the discharge to community measure is a measure of discharge destination from the PAC setting, we have chosen to use the PAC-reported discharge destination (from the Medicare FFS claims) to determine whether a patient/resident was discharged to the community (based on discharge status codes 01, 06, 81, 86). We assessed the reliability of the claims discharge status code(s) by examining agreement between discharge status on claims and assessment instruments for the same stay in all four PAC settings. We found between 94 and 99 percent agreement in coding of community discharges on matched claims and assessments in each of the PAC settings. We also assessed how frequently discharges to acute care, as indicated on the PAC claim, were confirmed by follow-up acute care claims, and found that 88 percent to 91 percent of IRF, LTCH, and SNF claims indicating acute care discharge were followed by an acute care claim on the day of, or day after, PAC discharge. We believe that these data support the use of the ''Patient Discharge Status Code'' from the PAC claim for determining discharge to a community setting for this measure.

The use of the claims discharge status code to identify discharges to the community was discussed at length with the TEP convened by our measure development contractor. TEP members did not express significant concerns regarding the accuracy of the claims discharge status code in coding community discharges, nor about our use of the discharge status code for defining this quality measure. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Comment: A few commenters recommended that baseline long-stay nursing facility residents be excluded from the measure, as they could not be reasonably expected to discharge to the community after their PAC stay. One commenter expressed concern that the discharge to community measure fails to consider when a patient's ''home'' is a custodial nursing facility and the patient's post-acute episode involves a discharge back to his or her ''home.'' The commenter encouraged CMS to modify the discharge to community measure so it is able to distinguish baseline custodial nursing facility residents who are discharged back to their nursing facility. One commenter cited data that discharge to community rates were much lower for LTCH patients who had an indication of a prior nursing home stay compared with those who did not. Another commenter noted that these residents have a very different discharge process back to the nursing facility compared with patients discharged to the community. This commenter recommended that different measures be developed for this population, such as return to prior level of function, improvement in function, prevention of further functional decline, development of pressure ulcers, or accidental falls. This commenter also recognized CMS' current efforts in monitoring transitions of care and quality requirements in long-term care facilities. One commenter suggested that CMS use the Minimum Data Set to identify and exclude baseline nursing facility residents.

Similar to the above comments, other commenters emphasized the importance of risk adjustment for pre-hospitalization living setting, noting that some patients could reasonably never be expected to return to the community based on their permanent living setting prior to their acute care hospital stay. These commenters conveyed that it was unreasonable to expect PAC providers to discharge to the community those patients who may have permanently lived in a non-community setting prior to the acute hospital stay, and that risk adjustment should account for this.

Response: We appreciate the commenters' concerns and their recommendations to exclude baseline nursing facility residents from the discharge to community measure, to distinguish baseline custodial nursing facility residents who are discharged back to the nursing facility after their LTCH stay, and to risk adjust for pre-hospitalization living setting when assessing discharge to community outcomes. We recognize that patients/residents who permanently lived in a nursing facility or other long-term care facility at baseline may not be expected to discharge back to a home and community based setting after their PAC stay. We also recognize that, for baseline nursing facility residents, a discharge back to their nursing facility represents a discharge to their baseline residence. We agree with the commenter about the differences in discharge planning processes when discharging a patient/resident to the community compared with discharging them to a long-term nursing facility. However, using Medicare FFS claims alone, we are unable to accurately identify baseline nursing facility residents. In addition, there are no claims data on pre-hospital living setting that we could use for risk adjustment. Potential future modifications of the measure could include the assessment of the feasibility and impact of excluding baseline nursing facility residents from the measure or risk adjusting for pre-hospital living setting, through the addition of patient assessment-based data. However, we note that, currently, the IRF-Patient Assessment Instrument (IRF–PAI) is the only PAC assessment that contains an item related to pre-hospital baseline living setting.

Comment: One commenter recommended that the measure exclude patients who have been discharged to

[277] Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System Final Report. RTI International; 2009.

the community and expire within the post-discharge observation window. The commenter supported this recommendation by explaining that the types of patients treated in each PAC setting varied greatly and that including post-discharge death in the measure could lead to an inaccurate reflection of the quality of care furnished by the PAC. The commenter further cited MedPAC data indicating that, compared with other Medicare beneficiaries, the LTCH patient population is disproportionately more disabled, elderly, and frail.

Response: Including 31-day post-discharge mortality outcomes is intended to identify successful discharges to community, and to avoid the potential unintended consequence of inappropriate community discharges. We have found, through our analyses on our measure development sample, that death in the 31 days following discharge to community is an infrequent event; 2.73 percent of LTCH Medicare FFS beneficiaries discharged to community died in the 31 days following discharge. We do not expect facilities to achieve a 0 percent death rate in the measure's postdischarge observation window; one focus of the measure is to identify facilities with unexpectedly high rates of death for quality monitoring purposes.

We agree with the commenter about the differences in case-mix across the PAC settings. Therefore, we risk adjust this measure for several case-mix variables, such as age, diagnoses from the prior acute stay, comorbidities in the year preceding PAC admission, length of prior acute stay, number of prior hospitalizations in the past year, and ventilator use.

Comment: Several commenters suggested that the discharge to community measure adjust for sociodemographic and socioeconomic factors. Commenters were concerned that provider performance on the measure will depend on patient-related sociodemographic and socioeconomic factors such as availability of home and community supports, financial resources, race, and dual eligibility, which are outside of the provider's control.

Response: We understand the importance of home and community supports, sociodemographic, and socioeconomic factors for ensuring a successful discharge to community outcome. The discharge to community measure is a claims-based measure, and note that currently, there are no standardized data on variables such as living status or home and community supports across the four PAC settings. As we refine the measure in the future, we will consider testing and adding additional relevant data sources and standardized items for risk adjustment of this measure. With regard to the suggestions pertaining to risk adjustment for sociodemographic and socioeconomic factors, we refer the readers to section VIII.C.6. of the preamble of this final rule for a more detailed discussion of the role of SES/SDS factors in risk adjustment of our measures.

Comment: Some commenters emphasized the relationship between functional gains made by patients during their LTCH stay and their ability to discharge to the community. One commenter stated that return to one's previous home represents part of the goal of care; in addition, it is also important that the patient is able to function to the greatest possible extent in the home and community setting and achieve the highest quality of life possible. The commenter recommended that CMS delay its proposal to adopt this measure until it incorporated metrics that assess whether patients achieved their functional and independence goals based on their plan of care and their specific condition.

Other commenters suggested that the measure include risk adjustment for functional status. One commenter noted that functional status is associated with increased risk of 30-day all-cause hospital readmissions, and since readmissions and discharge to community are closely related, functional status risk adjustment is also important for this measure. Another commenter suggested that, for cross-setting standardization, the SNF and LTCH measures should also include risk adjustment that is similar to the risk adjustment for Case-Mix Groups (CMGs) in the IRF setting and Activities of Daily Living in the HHA setting.

Response: We agree that it is important to assess various aspects of patient outcomes that are indicative of successful discharge from the LTCH setting. We also agree that functional status may be related to discharge to community outcomes, and that it is important to test admission functional status risk adjustment when assessing discharge to community outcomes. The discharge to community measure does include functional status risk adjustment in the IRF setting using CMGs from claims, and in the home health setting using Activities of Daily Living from claims. There are no data related to functional status in LTCH claims. Nevertheless, we would like to note that, in other work, we have found admission functional status to not be as strong a predictor of resource use [278] or functional outcomes [279] in LTCHs relative to other PAC settings.

As mandated by the IMPACT Act, we are moving toward the goal of collecting standardized patient assessment data for functional status across PAC settings. The LTCH QRP includes three NQF endorsed functional status quality measures: Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632); Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).

Once standardized functional status data become available across settings, it is our intent to use these data to assess patients' functional gains during their PAC stay, and to examine the relationship between functional status, discharge destination, and patients' ability to discharge to the community. As we examine these relationships between functional outcomes and discharge to community outcomes in the future, we will assess the feasibility of leveraging these standardized patient assessment data to incorporate functional outcomes into the discharge to community measure. Standardized cross-setting patient assessment data will also allow us to examine interrelationships between the quality and resource use measures in each PAC setting, and to understand how these measures are correlated.

Comment: One commenter suggested that CMS risk adjust for additional variables for the LTCH discharge to community measure, including principal diagnosis associated with the LTCH stay, multiple organ failure, do not resuscitate (DNR) status in the LTCH and prior short-term acute care hospital stay, and prior nursing home stay. The commenter noted that, in their analyses, they found that principal diagnosis groups such as cancer diagnoses, adult respiratory failure, and aspiration pneumonia based on the LTCH stay

[278] Post-Acute Care Payment Reform Demonstration: Final Report, Volume 4 of 4. March 2012. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/PAC-PRD_FinalRpt_Vol4of4.pdf.*

[279] Long-Term Care Hospital (LTCH) Functional Outcome Measure: Change in Mobility Among Patients Requiring Ventilator Support (NQF #2632). *http://www.qualityforum.org/QPS/2632.*

were associated with significantly lower discharge to community rates.

Response: We thank the commenter for their suggestions. With regard to using principal diagnosis from the prior acute claim, our approach is consistent with that of claims-based NQF-endorsed readmissions measures for PAC settings. We are adjusting for the medical condition that was the precursor to the LTCH admission. Using surgical categories, we also adjust for whether the patient had surgery in the prior acute stay. Our risk adjustment models are comprehensive, and adjust for all diagnoses and procedures on the prior acute claim, as well as several comorbidities based on the year preceding PAC admission. We adjust for the principal diagnosis groups mentioned by the commenter including cancer diagnoses, adult respiratory failure, and aspiration pneumonia, all of which are significant predictors of lower discharge to community rates.

With regard to risk adjustment for prior nursing home stay, we plan to assess the feasibility and impact of identifying and excluding baseline long-stay nursing facility residents in future measure modifications. We will also consider other risk adjustment suggestions made by the commenters, as we refine the measure.

Comment: One commenter stated that ventilator use is included as a risk adjuster in the LTCH setting only, but should be used across all settings. This commenter also requested information on the hierarchical logistic regression modeling and variables that will be used for risk adjustment.

Response: We would like to clarify that risk adjustment for ventilator use is included in both LTCH and SNF settings. We investigated the need for risk adjustment for ventilator use in IRFs, but found that less than 0.01 percent of the IRF population (19 patient stays in 2012, and 9 patient stays in 2013) had ventilator use in the IRF. Given the low frequency of ventilator use in IRFs, any associated estimates would not be reliable, and therefore, ventilator use is not included as a risk adjuster in the IRF setting measure. However, we will continue to assess this risk adjuster for inclusion in the IRF model for this measure.

For details on measure specifications, modeling, and calculations, we refer readers to the Measure Specifications for Measures Adopted in the FY 2017 LTCH QRP Final Rule, posted on the CMS LTCH QRP Web page at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

Comment: One commenter noted that requiring a maximum of a 30-day gap between an acute care discharge and a PAC admission can, in some cases, result in selection on severity in the PAC stay. If a long intervening stay in an LTCH delays an admission to a lower intensity level of care, such as a SNF, that admission would be excluded from the SNF measure if the gap between acute discharge and SNF admission is more than 30 days. The commenter stated that such a patient would have a higher unobserved severity than a patient admitted within 30 days of acute discharge, and that excluding such a patient would lower the case-mix of SNF cases to their advantage, when comparing discharge to community rates between LTCHs and SNFs. The commenter recommended that the 30-day maximum gap between acute discharge and PAC admission be limited only to the first PAC stay in a PAC sequence. The commenter also asked whether the qualifying acute care stay in the 30 days preceding PAC admission had to immediately precede the PAC admission, or whether it was acceptable to have another intervening PAC stay between the acute discharge and index PAC admission.

Response: We thank the commenter for their comment, which touches on a number of measure aspects that interact. First, the preference expressed in expert panels has been to limit the time lag between the acute discharge and the provider being evaluated. Second, the presence of a long intervening PAC stay could either indicate a more severe patient, or alternatively a more recovered patient when the next PAC provider admits the patient; the bias cannot be assumed to be unidirectional. That said, the purpose of the commenter's recommendation is to capture, in a limited way, some of the unmeasured severity distinguishing beneficiaries across different PAC settings. We agree with the commenter's intent, but do not believe this would have a substantive effect when comparing settings, or improve comparisons of providers of the same type. Nonetheless, in future years, we will consider evaluating the impact of the commenter's suggestion on measure performance.

To address the commenter's question, the qualifying acute care stay within the past 30 days does not need to immediately precede the index PAC admission. For example, if a patient has an acute care stay, an LTCH stay, and a SNF stay within a 30-day window, the SNF stay is a candidate to for measure inclusion even though the acute care stay did not immediately precede SNF admission.

Comment: One commenter requested information about how the surgical procedure categories in the risk adjustment variables are grouped from the Agency for Healthcare Research and Quality (AHRQ) Clinical Classifications Software (CCS) procedure categories listed in the Hospital-Wide All-Cause Unplanned Readmission Measure specifications.

Response: We appreciate the commenter's request for information. The surgical indicators are based on those developed for the Hospital-Wide All-Cause Unplanned Readmission (CMS/Yale) measure (NQF #1789).[280] Further information about the AHRQ CCS procedure categories is available in the Measure Specifications for Measures Adopted in the FY 2017 LTCH QRP Final Rule, posted on the CMS LTCH QRP Web page at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

Comment: One commenter requested information on how planned discharges to an acute care hospital or LTCH were identified and excluded from the discharge to community measure. Specifically, the commenter asked whether discharges were considered planned if the discharge status code on the acute care claim preceding the PAC stay was ''91'' for LTCHs, ''90'' for IRFs, and ''83'' for SNFs, where code ''91'' indicates ''Discharged/transferred to a Medicare certified long term care hospital (LTCH) with a planned acute care hospital inpatient readmission,'' ''90'' indicates ''Discharged/transferred to an inpatient rehabilitation facility (IRF) including rehabilitation distinct part units of a hospital with a planned acute care hospital inpatient readmission'' and ''83'' indicates ''Discharged/transferred to a skilled nursing facility (SNF) with Medicare certification with a planned acute care hospital inpatient readmission.''

Response: We would like to clarify that the determination of planned discharge is not based on the discharge status code on the prior acute care claim indicating a planned acute care readmission (that is, codes 81 through 95). These discharge status codes are not associated with a time frame for planned readmission, and are not used to determine whether a discharge was planned or unplanned. We determine

[280] Hospital-Wide All-Cause Readmission Measure (HWR) (CMS/Yale). *www.qualityforum.org/QPS/1789* (NQF #1789).

whether an observed discharge was planned based on diagnosis and procedure codes reported on inpatient acute or LTCH claims following discharge to community. We identify planned admissions using the planned readmissions algorithm used in the following PAC readmission measures: (1) Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510); (2) All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities (NQF #2502); and (3) All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Long Term Care Hospitals (NQF #2512).

For the IRF and SNF settings, we exclude stays with planned discharges to an acute care hospital or LTCH that occur on the day of, or day after, PAC discharge. For the LTCH setting, we exclude planned discharges to an acute care hospital on the day, of or day after, LTCH discharge. We note that PAC claims indicating discharge to a community are not excluded if they are followed by a subsequent planned acute care or LTCH admission; rather these stays are treated as successful discharge to community outcomes.

Comment: One commenter asked whether an unplanned readmission that follows a planned readmission in the post-discharge observation window would be considered an unfavorable outcome for the discharge to the community measure.

Response: An unplanned readmission that follows a planned readmission in the post-discharge observation window is not considered an unfavorable outcome for the discharge to the community measure. For this measure, we examine the first readmission that falls within the observation window following discharge to community. If the first readmission is unplanned, it is considered an unsuccessful discharge to community outcome. If the first readmission is planned, it is considered a successful discharge to community outcome. Any unplanned readmissions following the first planned readmission do not impact the discharge to community outcome.

Comment: One commenter requested information on the mapping of ICD–9 codes to the CMS-Hierarchical Condition Categories (HCCs) used as risk adjustment variables in the model.

Response: We appreciate the commenter's request for information. We used Version 21 of the HCCs based on ICD–9 codes, but will transition to Version 22 with ICD–10 codes.

Comment: One commenter noted that the various PAC settings served patients with different levels of clinical severity, and the resulting standardized rates thus varied by patient mix as well as by care quality.

Response: We agree with the commenter that the different PAC settings serve patients with different levels of clinical severity. Using risk adjustment, it is not possible to capture the full clinical complexity of patients and the stage of their medical conditions across PAC settings. Therefore, the most appropriate way to capture the differences in the clinical complexity of patients is to separate the provider types and compare like providers to each other. Though there are occasions in which a beneficiary will be choosing the type of PAC provider, those choices are often limited by availability of providers and personal circumstances with regard to availability of caregivers. There is no implication in the measures that care in an LTCH is of lower quality than care in other PAC settings, because the average discharge to community rate for LTCH patients is lower than that of other PAC settings. It is fairer, at present, to capture case-mix differences that are unobservable by doing measure comparisons within provider type.

Comment: One commenter encouraged CMS to provide PAC settings with access to measure performance data as early as possible so providers have time to adequately review these data, and implement strategies to decrease readmissions where necessary.

Response: We intend to provide initial confidential feedback to PAC providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and 2016.

Comment: Several commenters were concerned that the measure may result in unintended consequences such as increased LTCH length of stay to get the patient ready for discharge to community, or inappropriate discharges to community for patients who may benefit from lower acuity PAC services.

Response: We thank the commenters for sharing their concerns about potential unintended consequences of increased LTCH length of stay or inappropriate community discharges for this measure. To avoid the unintended consequence of inappropriate discharges to community, we monitor unplanned acute and LTCH readmissions and death in the 31-day post-discharge observation window. We will consider monitoring IRF, SNF, and nursing facility admissions following discharge to a community setting as we continue to refine this measure. As with all our measures, we will monitor for unintended consequences as part of measure monitoring and evaluation to ensure that measures do not reduce quality of care or access for patients, result in disparities for patient sub-groups, or adversely affect healthcare spending.

Comment: One commenter expressed that use of data preceding measure implementation date to determine a baseline rate of discharge to community could be problematic because they expected changes in data following measure implementation and efforts to improve coding. The commenter recommended measure reporting using data collected after measure implementation.

Response: As stated in section VIII.C.6.b. of the preamble of the proposed rule, data from CY 2015–2016 will be used as the basis for initial confidential feedback reports, and data from CY 2016–2017 will be used for public reporting. We appreciate the recommendation to align the baseline period with the implementation date; however, in order to ensure the reliability of the measure we need two consecutive years of data, which requires us to use data from CY 2016–2017 for public reporting. We believe the reliability of the measure is more important than aligning the baseline and implementation dates.

Comment: Several commenters were concerned that the LTCH discharge to community measure was not NQF-endorsed before being adopted for the LTCH QRP. Some commenters noted that the LTCH patient population is different from those of other settings, making NQF endorsement particularly important. The commenters asked CMS to refrain from implementing the discharge to community measure for the LTCH QRP until it has been endorsed by NQF.

Response: We thank the commenters for their comments regarding NQF endorsement. We would like to clarify that the discharge to community measure has been fully developed and tested. We plan to submit the Discharge to Community-PAC LTCH QRP measure to the NQF for consideration for endorsement.

After consideration of the public comments we received, we are finalizing our proposal to adopt the measure, Discharge to Community-PAC LTCH QRP as a Medicare FFS claims-based measure for the FY 2018 payment determination and subsequent years, with the added exclusion of patients with a hospice benefit in the 31-day postdischarge observation window. For measure specifications, we refer readers to the Measure Specifications for

Measures Adopted in the FY 2017 LTCH QRP Final Rule, posted on the CMS LTCH QRP Web page at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*..

c. Measure To Address the IMPACT Act Domain of Resource Use and Other Measures: Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital Quality Reporting Program

Sections 1899B(a)(2)(E)(ii) and 1899B(d)(1)(C) of the Act require the Secretary to specify measures to address the domain of all-condition risk-adjusted potentially preventable hospital readmission rates by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25223 through 25225), we proposed the measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP as a Medicare FFS claims-based measure to meet this requirement for the FY 2018 payment determination and subsequent years.

The measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries in the 30 days post-LTCH discharge. The LTCH admission must have occurred within up to 30 days of discharge from a prior proximal hospital stay which is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Hospital readmissions include readmissions to a short-stay acute care hospital or an LTCH, with a diagnosis considered to be unplanned and potentially preventable. This measure is claims-based, requiring no additional data collection or submission burden for LTCHs. Because the measure denominator is based on LTCH admissions, each Medicare beneficiary may be included in the measure multiple times within the measurement period. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) or LTCHs that occur during a 30-day window beginning two days after LTCH discharge. This measure is conceptualized uniformly across the PAC settings, in terms of the measure definition, the approach to risk adjustment, and the measure calculation. Our approach for defining potentially preventable hospital readmissions is described in more detail below.

Hospital readmissions among the Medicare population, including beneficiaries that utilize PAC, are common, costly, and often preventable.[281] [282] MedPAC and a study by Jencks et al. estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered ''potentially preventable.'' [283] In addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions would be $12 billion for 30-day, $8 billion for 15-day, and $5 billion for 7-day readmissions in 2005.[284] For hospital readmissions from one PAC setting, SNFs, MedPAC deemed 76 percent of readmissions as ''potentially avoidable''–associated with $12 billion in Medicare expenditures.[285] Mor et al. analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission rate from SNFs, associated with $4.3 billion in expenditures.[286] Fewer studies have investigated potentially preventable readmission rates from the remaining PAC settings.

We have addressed the high rates of hospital readmissions in the acute care setting as well as in PAC. For example, we developed the following measure: All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), as well as similar measures for other PAC providers (NQF #2502 for IRFs and NQF #2510 for SNFs).[287] These measures are endorsed by the NQF, and the NQF endorsed LTCH measure (NQF #2512) was adopted into the LTCH QRP in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49730 through 49731). Note that these NQF endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the Agency for Healthcare Research and Quality's (AHRQ's) Prevention Quality Indicators, approaches developed by MedPAC, and proprietary approaches, such as the 3M™ algorithm for Potentially Preventable Readmissions.[288] [289] [290] Recent work led by Kramer et al. for MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations.[291] [292] Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care, these findings are relevant to the development of potentially preventable readmission measures for PAC.[293] [294] [295]

[281] Friedman, B., and Basu, J.: The rate and cost of hospital readmissions for preventable conditions. *Med. Care Res. Rev.* 61(2):225–240, 2004. doi:10.1177/1077558704263799.

[282] Jencks, S.F., Williams, M.V., and Coleman, E.A.: Rehospitalizations among patients in the Medicare Fee-for-Service Program. *N. Engl. J. Med.* 360(14):1418–1428, 2009. doi:10.1016/j.jvs.2009.05.045

[283] MedPAC: Payment policy for inpatient readmissions, in *Report to the Congress: Promoting Greater Efficiency in Medicare.* Washington, DC, pp. 103–120, 2007. Available from: *http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf*.

[284] Ibid.

[285] Ibid.

[286] Mor, V., Intrator, O., Feng, Z., et al.: The revolving door of rehospitalization from skilled nursing facilities. *Health Aff.* 29(1):57–64, 2010. doi:10.1377/hlthaff.2009.0629.

[287] National Quality Forum: *All-Cause Admissions and Readmissions Measures.* pp. 1–319, April 2015. Available from *http://www.qualityforum.org/Publications/2015/04/All-Cause_Admissions_and_Readmissions_Measures_-_Final_Report.aspx*.

[288] Goldfield, N.I., McCullough, E.C., Hughes, J.S., et al.: Identifying potentially preventable readmissions. *Health Care Finan. Rev.* 30(1):75–91, 2008. Available from *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195042/*.

[289] Agency for Healthcare Research and Quality: *Prevention Quality Indicators Overview.* 2008.

[290] MedPAC: *Online Appendix C: Medicare Ambulatory Care Indicators for the Elderly.* pp. 1–12, prepared for Chapter 4, 2011. Available from: *http://www.medpac.gov/documents/reports/Mar11_Ch04_APPENDIX.pdf?sfvrsn=0*.

[291] Kramer, A., Lin, M., Fish, R., et al.: *Development of Inpatient Rehabilitation Facility Quality Measures: Potentially Avoidable Readmissions, Community Discharge, and Functional Improvement.* pp. 1–42, 2015. Available from *http://www.medpac.gov/documents/contractor-reports/development-of-inpatient-rehabilitation-facility-quality-measures-potentially-avoidable-readmissions-community-discharge-and-functional-improvement.pdf?sfvrsn=0*.

[292] Kramer, A., Lin, M., Fish, R., et al.: *Development of Potentially Avoidable Readmission and Functional Outcome SNF Quality Measures.* pp. 1–75, 2014. Available from *http://www.medpac.gov/documents/contractor-reports/mar14_snfqualitymeasures_contractor.pdf?sfvrsn=0*.

[293] Allaudeen, N., Vidyarthi, A., Maselli, J., et al.: Redefining readmission risk factors for general medicine patients. *J. Hosp. Med.* 6(2):54–60, 2011. doi:10.1002/jhm.805.

[294] Gao, J., Moran, E., Li, Y.-F., et al.: Predicting potentially avoidable hospitalizations. *Med. Care* 52(2):164–171, 2014. doi:10.1097/MLR.0000000000000041.

[295] Walsh, E.G., Wiener, J.M., Haber, S., et al.: Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and home- and community-based services waiver programs. *J. Am. Geriatr. Soc.* 60(5):821–829, 2012. doi:10.1111/j.1532-5415.2012.03920.x.

Potentially Preventable Readmission Measure Definition: We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a TEP to develop a definition and list of conditions for which hospital readmissions are potentially preventable. The Ambulatory Care Sensitive Conditions and Prevention Quality Indicators, developed by AHRQ, served as the starting point in this work. For patients in the 30-day post-PAC discharge period, a potentially preventable readmission (PPR) refers to a readmission for which the probability of occurrence could be minimized with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR conditions is categorized by 3 clinical rationale groupings:

- Inadequate management of chronic conditions;
- Inadequate management of infections; and
- Inadequate management of other unplanned events.

Additional details regarding the definition for potentially preventable readmissions are available in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

This measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), this measure uses the current version of the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. In addition to the CMS Planned Readmission Algorithm, this measure incorporates procedures that are considered planned in PAC settings, as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the CMS Planned Readmission Algorithm and additional procedures considered planned for PAC, can be found in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

The measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, assesses potentially preventable readmission rates while accounting for patient demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates a facility-specific effect, common to patients treated in each facility. This measure is calculated for each LTCH based on the ratio of the predicted number of risk-adjusted, unplanned, potentially preventable hospital readmissions that occur within 30 days after an LTCH discharge, including the estimated facility effect, to the estimated predicted number of risk-adjusted, unplanned inpatient hospital readmissions for the same patients treated at the average LTCH. A ratio above 1.0 indicates a higher than expected readmission rate (worse) while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio (SRR). The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all LTCH stays. The resulting rate is the risk-standardized readmission rate (RSRR) of potentially preventable readmissions.

An eligible LTCH stay is followed until: (1) The 30-day post-discharge period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH) or LTCH. If the readmission is unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned, the readmission is not counted in the measure rate.

This measure is risk adjusted. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of readmission. More specifically, the risk-adjustment model for LTCHs accounts for demographic characteristics (age, sex, original reason for Medicare entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, prolonged mechanical ventilation indicator, comorbidities, length of stay during the patient's prior proximal hospital stay, length of stay in the intensive care and coronary care unit (ICU and CCU), and number of acute care hospitalizations in the preceding 365 days.

The measure is calculated using 2 consecutive calendar years of FFS claims data, to ensure the statistical reliability of this measure for facilities. In addition, we proposed a minimum of 25 eligible stays for public reporting of the measure.

A TEP convened by our measure contractor provided recommendations on the technical specifications of this measure, including the development of an approach to define potentially preventable hospital readmission for PAC. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP summary report available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*. We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The MAP encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*. At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as identified in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting

and value-based purchasing programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) adopted into the LTCH QRP.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF endorsed measures focused on potentially preventable hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we proposed the Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, under the Secretary's authority to specify non-NQF endorsed measures under section 1899B(e)(2)(B) of the Act, for the LTCH QRP for the FY 2018 payment determination and subsequent years, given the evidence previously discussed above.

We plan to submit the measure to the NQF for consideration of endorsement. We stated in the proposed rule that we intended to provide initial confidential feedback to LTCHs, prior to public reporting of this measure, based on 2 calendar years of data from discharges in CY 2015 and 2016. We also stated that we intended to publicly report this measure using data from CY 2016 and 2017.

We invited public comment on our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP. We received several comments, which are summarized with our responses below.

Comment: MedPAC supported this measure and believes that LTCHs should be held accountable for readmissions in the post-discharge readmission window.

Response: We thank commenters for their support of this measure.

Comment: One commenter specifically supported the inclusion of infectious conditions in the ''inadequate management of infections'' and ''inadequate management of other unplanned events'' categories in the measure's definition of potentially preventable hospital readmissions, noting that many of these conditions are preventable using appropriate infection prevention interventions. Another commenter recommended the removal of several PPR conditions including influenza, dehydration/electrolyte imbalance, C. *difficile* infection, and urinary tract infection/kidney infection, and expressed concern that these conditions rely too heavily on patient and caretaker responsibility or may be caused by unforeseen circumstances after LTCH discharge.

One commenter stated that this measure will be particularly important for Medicare beneficiaries with chronic conditions, including diabetes, chronic obstructive pulmonary disorder, asthma, atrial fibrillation, and hypertension. Another commenter expressed concern over being ''penalized'' for readmissions that are clinically unrelated to a patient's original reason for LTCH admission. Another commenter recommended that only readmissions associated with active diagnoses being treated in the LTCH should be considered potentially preventable. Commenters also encouraged CMS to undertake additional empirical testing to ensure that the codes for readmissions are associated with the identified categories.

Response: We appreciate the comments in support of this measure domain and the list of PPR conditions developed for this measure. In response to the comment that suggested several conditions be removed from the definition, we note that as described in the proposed rule, the definition for potentially preventable readmissions for this measure was developed based on existing evidence and was reviewed by a TEP, which included clinicians and PAC experts. We also conducted a comprehensive environmental scan to identify conditions for which readmissions may be considered potentially preventable. Results of this environmental scan and details of the TEP input received were made available in the PPR TEP summary report available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*. We also made revisions to this list of conditions for which readmissions may be considered potentially preventable based on stakeholder feedback received during the public comment period. A summary of the public comments is also available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Though readmissions may be considered potentially preventable even if they may not appear to be clinically related to the patient's original reason for LTCH admission, there is substantial evidence that the conditions included in the definition may be preventable with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. Furthermore, this measure is based on Medicare FFS claims data and it may not always be feasible to determine whether a subsequent readmission is or is not clinically related to the reason why the patient was receiving LTCH care. We intend to conduct ongoing evaluation and monitoring, and will assess the appropriateness and consequences of all PPR conditions, including infections and dehydration as mentioned specifically by one commenter.

Comment: MedPAC commented that the measure definition and risk adjustment should be identical across PAC settings so that potentially preventable readmission rates can be compared across settings. One commenter recommended that a measure for potentially preventable readmission post-discharge from an acute care hospital, regardless of PAC setting, would allow for better alignment across settings and clarity of potentially preventable readmissions. Another commenter recommended the measure be adjusted for patient clinical differences between PAC settings to allow for cross-setting quality comparisons. Other commenters expressed concern over adapting standards from other settings for LTCH, and recommended that the measure be tailored to LTCH patients.

Response: The PPR definition (that is, list of conditions for which readmissions would be considered potentially preventable) is aligned for measures with the same readmission window, regardless of PAC setting. Specifically, the post-PAC discharge PPR measures that were developed for each of the PAC settings contain the same list of PPR conditions. Although there are some minor differences in the specifications across these potentially preventable readmissions measures (for example, years of data used to calculate the measures to ensure reliability and some of the measure exclusions necessary to attribute responsibility to the individual settings), the IMPACT Act PPR measures are standardized. As described for all IMPACT Act measures in section VIII.C.2. of the preamble of this final rule, above, the statistical approach for risk adjustment is also aligned across the measures; however, there is variation in the exact risk adjusters. The risk adjustment models are empirically driven and differ between measures as a consequence of case mix differences, which is necessary to ensure that the estimates are valid.

Comment: Some commenters expressed concern over the overlap

between the proposed PPR measure and the existing all-cause readmission measure adopted for the LTCH QRP. Commenters expressed concern that public reporting of more than one hospital readmission measure for LTCHs may result in confusion among the public and that this could potentially pose challenges for quality improvement for LTCHs. Some commenters believed that CMS should use one readmission measure in the LTCH QRP, rather than multiple readmission measures.

Response: The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) was adopted for the LTCH QRP prior to the IMPACT Act. With regard to overlap with the existing LTCH QRP readmission measure, retaining the all-cause measure will allow us to monitor trends in both all-cause and PPR rates in order to assess the extent to which changes in facility performance for one measure are reflected in the other. We are committed to ensuring that measures in the LTCH QRP are useful in assessing quality and will evaluate the readmission measures in the future.

Comment: One commenter supported the risk adjustment methodology but several expressed concerns over the risk adjustment approach for the proposed PPR measure. Several commenters proposed additional clinical characteristics as risk adjusters including the LTCH primary diagnosis, presence of multiple chronic conditions, being ''hospital dependent,'' having multiple organ failure, and dialysis. Additional patient characteristics that commenters recommended for testing were patients identified as ''do not resuscitate'' during the prior acute stay, availability of home resources and supports, and functional status.

One commenter requested that CMS clarify whether patients with an artificial airway and no mechanical ventilation are included in the mechanical ventilation risk adjustment category. Another commenter requested detail on the AHRQ CCS groups included in the surgical procedure categories and also inquired about which version of the HCCs were used in the risk adjustment model.

Several commenters expressed concern that the measure is not adjusted for sociodemographic factors that may affect utilization. One commenter supported testing the measure for SDS, and cited research they conducted showing variation in race across PAC settings; they also found that dually eligible LTCH patients had significantly higher odds of PPRs.

Response: We appreciate the comments regarding the risk adjustment approach and suggestions for specific risk adjusters for the PPR measure. We wish to clarify that this measure is based on claims data and not all suggested risk adjusters are available. However, our measure development contractor (RTI International) conducted additional testing on some of the suggested risk adjusters and did not find strong evidence supporting the inclusion of these as risk adjusters in a potentially preventable readmission model. With regard to dialysis, this factor has been shown to be a significant predictor for PPR and the measure risk-adjusts for patients' dialysis using the HCC. We intend to evaluate the feasibility of including functional and cognitive status when standardized assessment data become available.

LTCH patients with an artificial airway that are not on mechanical ventilation are not included in the prolonged mechanical ventilation risk adjuster, which is based on the procedure code 96.72 on the LTCH claim.

In response to specific technical questions on the risk adjustment approach, we wish to clarify that the surgical procedure indicators are based on those surgical/gynecological AHRQ CCS group categories developed for the Hospital-Wide All-Cause Unplanned Readmission measure and are available in the SAS programs that are maintained and available by request. This measure was developed using version 21 of the HCCs; however, when the measure is calculated using data post ICD–10 transition, we intend to use version 22 of the HCCs.

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures and, as previously discussed, NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. We refer readers to section VIII.C.6. of the preamble of this final rule, where we also discuss this topic.

Comment: One commenter asked for clarification on whether a qualifying LTCH stay could be preceded by a PAC stay in the 30 days within discharge from the acute hospital. The commenter also asked if an unplanned readmission following a planned readmission in the 30-days post-discharge from the LTCH would be a counted as a readmission in this measure.

Response: We thank the commenter for their question regarding the verification of the measure exclusions. The commenter was correct in its interpretation of the measure exclusion of no short-term acute care hospital stay within the 30 days preceding a PAC admission. The exclusion does not require the short-term acute care hospital stay immediately precede the PAC admission. For example, if a patient had a short-term acute care hospital stay, a SNF stay, and an LTCH stay within a 30-day window, the LTCH stay is a candidate to be an index admission even though it was immediately preceded by a SNF stay and not a short-term acute care hospital stay.

In response to the unplanned readmission question, we would like to reiterate that only the first readmission in the post-discharge window is examined in this measure. Since the second readmission was not captured for analysis, an unplanned readmission following a planned readmission would not count as an unfavorable outcome.

Comment: Several commenters expressed concern that the measure is not NQF-endorsed, and some commenters had additional concerns over measure testing and development. Some commenters recommended that CMS should only adopt measures endorsed by the NQF in quality reporting programs or urged CMS to submit the measures through the NQF endorsement process as soon as feasible and prior to LTCH reporting.

Response: With regard to NQF endorsement, as noted in the proposed rule, we intend to submit this measure to NQF for consideration of endorsement. In addition, we noted that we reviewed the NQF's consensus endorsed measures and were unable to identify any NQF endorsed measures focused on potentially preventable hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we proposed the Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, under the Secretary's authority to specify non-NQF endorsed measures under section 1899B(e)(2)(B) of the Act, for the LTCH QRP.

We would like to clarify that the MAP encouraged continued development of the proposed measure. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_*

for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.

We also wish to note that we conducted additional testing since the MAP meeting. We developed the risk adjustment model and evaluated facilities' PPR rates. Results of these analyses were provided in the appendix of the measure specification made available at the time of the proposed rule. We found that testing results were similar to the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512). The finalized risk-adjustment models and coefficients are included in the final measure specifications available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*. We will make additional testing results available in the future.

Comment: A few commenters questioned the accuracy of claims data being used for this measure. One commenter suggested a baseline period concurrent with measure implementation to mitigate this concern. Another commenter recommended that CMS supplement claims data with validated administrative data.

Response: We appreciate the comment about the baseline period and implementation for the measure. As stated in section VIII.C.6.c. of the preamble of the proposed rule, data from CY 2015–2016 will be used as the basis for initial confidential feedback reports and data from CY 2016–2017 would be used for public reporting. We appreciate the recommendation to align the baseline period with the implementation date; however, in order to ensure the reliability of the measure we need 2 consecutive years of data, which requires us to use data from CY 2016–2017 for public reporting. We believe the reliability of the measure is more important than aligning the baseline and implementation dates.

We appreciate the commenter's concern over the accuracy of claims data. However, we wish to clarify that claims data have been validated for the purposes of assessing hospital readmissions and are used for several NQF-endorsed measures adopted for CMS programs, including the LTCH QRP. Several studies have been conducted to examine the validity of using Medicare hospital claims to calculate several NQF-endorsed quality measures for public reporting.[296] [297] [298] In addition, although assessment and other data sources may be valuable for risk adjustment, we are not aware of another data source aside from Medicare claims data that could be used to reliably assess potentially preventable hospital readmissions for this measure.

Comment: One commenter recommended that CMS use the potentially preventable readmission measure in order to determine best practices for LTCHs and inform LTCHs of their patient population. The commenter also urged CMS to review the impact of readmission measures used across PAC programs to ensure they create consistent improvement incentives across the system.

Response: We thank commenters for their comments related to the usability of the measure. We agree that this measure will be valuable in developing best practices and as a feedback mechanism assessing PPR outcomes for LTCHs. As we continually evaluate and monitor the PAC quality reporting programs, we will take the commenter's suggestion in consideration to ensure that this and other readmission measures are creating consistent incentives for PAC providers.

After consideration of the public comments we received, we are finalizing our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP. For measure specifications, we refer readers to the Measure Specifications for Measures Adopted in the FY 2017 LTCH QRP Final Rule document available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html.*

7. LTCH QRP Quality Measure Finalized for the FY 2020 Payment Determination and Subsequent Years

a. Background

We also proposed to adopt one new quality measure to meet the requirements of the IMPACT Act for the FY 2020 payment determination and subsequent years. The measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, addresses the IMPACT Act quality domain of Medication Reconciliation.

b. Quality Measure To Address the IMPACT Act Domain of Medication Reconciliation: Drug Regimen Review Conducted With Follow-Up for Identified Issues-Post Acute Care Long-Term Care Hospital Quality Reporting Program

Sections 1899B(a)(2)(E)(i)(III) and 1899B(c)(1)(C) of the Act require the Secretary to specify a quality measure to address the domain of medication reconciliation by October 1, 2018 for IRFs, LTCHs, and SNFs, and by January 1, 2017 for HHAs. We proposed to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, for the LTCH QRP as a patient-assessment based, cross-setting quality measure to meet the IMPACT Act requirements with data collection beginning April 1, 2018 for the FY 2020 payment determination and subsequent years.

This measure assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. Specifically, the quality measure reports the percentage of patient stays in which a drug regimen review was conducted at the time of admission and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that stay. For this quality measure, drug regimen review is defined as the review of all medications or drugs the patient is taking to identify any potential clinically significant medication issues. The quality measure utilizes both the processes of medication reconciliation and a drug regimen review, in the event an actual or potential medication issue occurred. The measure informs whether the PAC facility identified and addressed each clinically significant medication issue and if the facility responded or addressed the medication issue in a timely manner. Of note, drug regimen review in PAC settings is generally considered to include medication reconciliation and review of the patient's drug regimen to identify potential clinically significant medication issues.[299] This measure is applied uniformly across the PAC settings.

Medication reconciliation is a process of reviewing an individual's complete

[296] Bratzler DW, Normand SL, Wang Y, et al. An administrative claims model for profiling hospital 30-day mortality rates for pneumonia patients. PLoS One 2011;6(4):e17401.

[297] Keenan PS, Normand SL, Lin Z, et al. An administrative claims measure suitable for profiling hospital performance on the basis of 30-day all-cause readmission rates among patients with heart failure. Circulation 2008;1(1):29–37.

[298] Krumholz HM, Wang Y, Mattera JA, et al. An administrative claims model suitable for profiling hospital performance based on 30-day mortality rates among patients with heart failure. Circulation 2006;113:1693–1701.

[299] Institute of Medicine. Preventing Medication Errors. Washington DC: National Academies Press; 2006.

and current medication list. Medication reconciliation is a recognized process for reducing the occurrence of medication discrepancies that may lead to Adverse Drug Events (ADEs).[300] Medication discrepancies occur when there is conflicting information documented in the medical records. The World Health Organization regards medication reconciliation as a standard operating protocol necessary to reduce the potential for ADEs that cause harm to patients. Medication reconciliation is an important patient safety process that addresses medication accuracy during transitions in patient care and in identifying preventable ADEs.[301] The Joint Commission added medication reconciliation to its list of National Patient Safety Goals (2005), suggesting that medication reconciliation is an integral component of medication safety.[302] The Society of Hospital Medicine published a statement in agreement of the Joint Commission's emphasis and value of medication reconciliation as a patient safety goal.[303] There is universal agreement that medication reconciliation directly addresses patient safety issues that can result from medication miscommunication and unavailable or incorrect information.[304] [305] [306]

The performance of timely medication reconciliation is valuable to the process of drug regimen review. Preventing and responding to ADEs is of critical importance as ADEs account for significant increases in health services utilization and costs,[307] [308] [309] including subsequent emergency room visits and re-hospitalizations.[310] Annual health care costs from ADEs in the United States are estimated at $3.5 billion, resulting in 7,000 deaths annually.[311] [312]

Medication errors include the duplication of medications, delivery of an incorrect drug, inappropriate drug omissions, or errors in the dosage, route, frequency, and duration of medications. Medication errors are one of the most common types of medical errors and can occur at any point in the process of ordering and delivering a medication. Medication errors have the potential to result in an ADE.[313] [314] [315] [316] [317] [318] Inappropriately prescribed medications are also considered a major healthcare concern in the United States for the elderly population, with costs of roughly $7.2 billion annually.[319]

There is strong evidence that medication discrepancies occur during transfers from acute care facilities to PAC facilities. Discrepancies occur when there is conflicting information documented in the medical records. Almost one-third of medication discrepancies have the potential to cause patient harm.[320] An estimated 50 percent of patients experienced a clinically important medication error after hospital discharge in an analysis of two tertiary care academic hospitals.[321]

Medication reconciliation has been identified as an area for improvement during transfer from the acute care facility to the receiving PAC facility. PAC facilities report gaps in medication information between the acute care hospital and the receiving PAC setting when performing medication reconciliation.[322] [323] Hospital discharge has been identified as a particularly high risk time point, with evidence that medication reconciliation identifies high levels of discrepancy.[324] [325] [326] [327] [328] [329] Also, there is evidence that medication reconciliation discrepancies occur throughout the patient stay.[330] [331] For older patients, who may have multiple comorbid conditions and thus multiple medications, transitions between acute and PAC settings can be further

[300] *Ibid*

[301] Leotsakos A., et al. Standardization in patient safety: The WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

[302] The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

[303] Greenwald, J. L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: a consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

[304] Leotsakos A., et al. Standardization in patient safety: The WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

[305] The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

[306] IHI. Medication Reconciliation to Prevent Adverse Drug Events [Internet]. Cambridge, MA: Institute for Healthcare Improvement; [cited 2016 Jan 11]. Available from: *http://www.ihi.org/topics/adesmedicationreconciliation/Pages/default.aspx*.

[307] Institute of Medicine. Preventing Medication Errors. Washington DC: National Academies Press; 2006.

[308] Jha AK, Kuperman GJ, Rittenberg E, et al. Identifying hospital admissions due to adverse drug events using a computer-based monitor. Pharmacoepidemiol Drug Saf. 2001;10(2):113–119.

[309] Hohl CM, Nosyk B, Kuramoto L, et al. Outcomes of emergency department patients presenting with adverse drug events. Ann Emerg Med. 2011;58:270–279.

[310] Kohn LT, Corrigan JM, Donaldson MS. To Err Is Human: Building a Safer Health System Washington, DC: National Academies Press; 1999.

[311] Greenwald, J. L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: a consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

[312] Phillips, David P.; Christenfeld, Nicholas; and Glynn, Laura M. Increase in US Medication-Error Deaths between 1983 and 1993. The Lancet. 351:643–644, 1998.

[313] Institute of Medicine. To err is human: Building a safer health system. Washington, DC: National Academies Press; 2000.

[314] Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. JAMA. 1997:277(4): 312–317.

[315] Bond CA, Raehl CL, & Franke T. Clinical pharmacy services, hospital pharmacy staffing, and medication errors in United States hospitals. Pharmacotherapy. 2002:22(2): 134–147.

[316] Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. JAMA. 1995:274(1): 29–34.

[317] Barker KN, Flynn EA, Pepper GA, Bates DW, & Mikeal RL. Medication errors observed in 36 health care facilities. JAMA. 2002: 162(16):1897–1903.

[318] Bates DW, Boyle DL, Vander Vliet MB, Schneider J, & Leape L. Relationship between medication errors and adverse drug events. J Gen Intern Med. 1995:10(4): 199–205.

[319] Fu, Alex Z., et al. ''Potentially inappropriate medication use and healthcare expenditures in the US community-dwelling elderly.'' Medical care 45.5 (2007): 472–476.

[320] Wong, Jacqueline D., et al. ''Medication reconciliation at hospital discharge: evaluating discrepancies.'' Annals of Pharmacotherapy 42.10 (2008): 1373–1379.

[321] Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: A randomized controlled trial. Ann Intern Med. 2012:157(1):1–10.

[322] Gandara, Esteban, et al. ''Communication and information deficits in patients discharged to rehabilitation facilities: an evaluation of five acute care hospitals.'' Journal of Hospital Medicine 4.8 (2009): E28–E33.

[323] Gandara, Esteban, et al. ''Deficits in discharge documentation in patients transferred to rehabilitation facilities on anticoagulation: results of a system wide evaluation.'' Joint Commission Journal on Quality and Patient Safety 34.8 (2008): 460–463.

[324] Coleman EA, Smith JD, Raha D, Min SJ. Post hospital medication discrepancies: Prevalence and contributing factors. Arch Intern Med. 2005 165(16):1842–1847.

[325] Wong JD, Bajcar JM, Wong GG, et al. Medication reconciliation at hospital discharge: Evaluating discrepancies. Ann Pharmacother. 2008 42(10):1373–1379.

[326] Hawes EM, Maxwell WD, White SF, Mangun J, Lin FC. Impact of an outpatient pharmacist intervention on medication discrepancies and health care resource utilization in post hospitalization care transitions. Journal of Primary Care & Community Health. 2014; 5(1):14–18.

[327] Foust JB, Naylor MD, Bixby MB, Ratcliffe SJ. Medication problems occurring at hospital discharge among older adults with heart failure. Research in Gerontological Nursing. 2012, 5(1): 25–33.

[328] Pherson EC, Shermock KM, Efird LE, et al. Development and implementation of a post discharge home-based medication management service. Am J Health Syst Pharm. 2014; 71(18): 1576–1583.

[329] Pronovosta P, Weasta B, Scwarza M, et al. Medication reconciliation: A practical tool to reduce the risk of medication errors. J Crit Care. 2003; 18(4): 201–205.

[330] Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. JAMA. 1995:274(1): 29–34.

[331] Himmel, W., M. Tabache, and M. M. Kochen. ''What happens to long-term medication when general practice patients are referred to hospital?.'' European journal of clinical pharmacology 50.4 (1996): 253–257.

complicated,[332] and medication reconciliation and patient knowledge (medication literacy) can be inadequate post-discharge.[333] The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, provides an important component of care coordination for PAC settings and would affect a large proportion of the Medicare population who transfer from hospitals into PAC services each year. For example, in 2013, 1.7 million Medicare FFS beneficiaries had SNF stays, 338,000 beneficiaries had IRF stays, and 122,000 beneficiaries had LTCH stays.[334]

A TEP convened by our measure development contractor provided input on the technical specifications of this quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The TEP supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We solicited stakeholder feedback on the development of this measure by means of a public comment period held from September 18 through October 6, 2015. Through public comments submitted by several stakeholders and organizations, we received support for implementation of this measure. The public comment summary report for the measure is available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The NQF-convened MAP met on December 14 and 15, 2015 and provided input on the use of this measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP. The MAP encouraged continued development of the quality measure to meet the mandate added by the IMPACT Act. The MAP agreed with the measure gaps identified by CMS including medication reconciliation and stressed that medication reconciliation be present as an ongoing process. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx*.

Since the MAP's review and recommendation of continued development, we have continued to refine this measure in compliance with the MAP's recommendations. The measure is consistent with the information submitted to the MAP and supports its scientific acceptability for use in quality reporting programs. Therefore, we proposed this measure for implementation in the LTCH QRP as required by the IMPACT Act.

We reviewed the NQF's endorsed measures and identified one NQF-endorsed cross-setting and quality measure related to medication reconciliation, which applies to the SNF, LTCH, IRF, and HHA settings of care: Care for Older Adults (COA), (NQF #0553). The quality measure, Care for Older Adults (COA), (NQF #0553) assesses the percentage of adults 66 years and older who had a medication review. The Care for Older Adults (COA), (NQF #0553) measure requires at least one medication review conducted by a prescribing practitioner or clinical pharmacist during the measurement year and the presence of a medication list in the medical record. This is in contrast to the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, which reports the percentage of patient stays in which a drug regimen review was conducted at the time of admission and that timely follow-up with a physician occurred each time one or more potential clinically significant medication issues were identified throughout that stay.

After review of both quality measures, we decided to propose the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP for the following reasons:

- The IMPACT Act requires the implementation of quality measures, using patient assessment data that are standardized and interoperable across PAC settings. The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, employs three standardized patient-assessment data elements for each of the four PAC settings so that data are standardized, interoperable, and comparable; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure does not contain data elements that are standardized across all four PAC settings.
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, requires the identification of potential clinically significant medication issues at the beginning, during, and at the end of the patient's stay to capture data on each patient's complete PAC stay; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure only requires annual documentation in the form of a medication list in the medical record of the target population.
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, includes identification of the potential clinically significant medication issues and communication with the physician (or physician designee) as well as resolution of the issue(s) within a rapid timeframe (by midnight of the next calendar day); whereas, the Care for Older Adults (COA) (NQF #0553) quality measure does not include any follow-up or timeframe in which the follow-up would need to occur.
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, does not have age exclusions; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure limits the measure's population to patients aged 66 and older.
- The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, would be reported to LTCHs quarterly to facilitate internal quality monitoring and quality improvement in areas such as patient safety, care coordination, and patient satisfaction; whereas the Care for Older Adults (COA) (NQF #0553) quality measure would not enable quarterly quality updates, and thus data comparisons within and across PAC providers would be difficult due to the limited data and scope of the data collected.

Therefore, based on the evidence discussed above, we proposed to adopt the quality measure entitled, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, for the LTCH QRP for the FY 2020 payment determination and subsequent years. We plan to submit the

[332] Chhabra, P. T., et al. (2012). ''Medication reconciliation during the transition to and from long-term care settings: a systematic review.'' Res Social Adm Pharm 8(1): 60–75.

[333] Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: A randomized controlled trial. Ann Intern Med. 2012:157(1):1–10.

[334] March 2015 Report to the Congress: Medicare Payment Policy. Medicare Payment Advisory Commission; 2015.

quality measure to the NQF for consideration for endorsement.

The calculation of the quality measure would be based on the data collection of three standardized items to be included in the LTCH CARE Data Set. The collection of data by means of the standardized items would be obtained at admission and discharge. For more information about the data submission required for this measure, we refer readers to section VIII.C.9. of the preamble of this final rule.

The standardized items used to calculate this quality measure do not duplicate existing items currently used for data collection within the LTCH CARE Data Set. The measure denominator is the number of patient stays with a discharge or expired assessment during the reporting period. The measure numerator is the number of stays in the denominator where the medical record contains documentation of a drug regimen review conducted at: (1) Admission; and (2) discharge with a lookback through the entire patient stay, with all potential clinically significant medication issues identified during the course of care and followed up with a physician or physician designee by midnight of the next calendar day. This measure is not risk adjusted. For technical information about this measure, including information about the measure calculation and discussion pertaining to the standardized items used to calculate this measure, we refer readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

Data for the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, would be collected using the LTCH CARE Data Set with submission through the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system.

We invited public comment on our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP for the LTCH QRP.

Comment: Several commenters, including MedPAC, expressed support for the quality measure. Commenters supported the medication reconciliation concept, and several commenters conveyed that preventing and responding to adverse drug events that account for increases in health service utilization and cost is critically important. Further, several commenters expressed appreciation to CMS for proposing a quality measure to address the IMPACT Act domain, Medication Reconciliation, acknowledging the importance of medication reconciliation for addressing patient safety issues. MedPAC further noted that the medication reconciliation and follow-up process can help reduce medication errors that are especially common among patients who have multiple health care providers and multiple comorbidities. One commenter recommended that CMS consider adopting the measure for FY 2019 payment determination.

Response: We agree that medication reconciliation is an important patient safety process for addressing medication accuracy during transitions in patient care and identifying preventable adverse drug events (ADEs), which may lead to reduced health services utilization and associated costs. We appreciate the commenter's request that CMS adopt the measure for FY 2019 payment determination; however, the adoption of the measure has been proposed for adoption for the LTCH QRP for FY 2020 payment determination and subsequent years.

Comment: Several commenters requested guidance regarding the definition of ''clinically significant medication issues.'' Several commenters were concerned that the phrase could be interpreted differently by the many providers involved in a patient's treatment, and that this could result in a challenge to collect reliable, accurate, and comparable data for this quality measure. One commenter stated that there are likely to be variations in measure performance that are not based on differences in care, but rather on differences in data collection. In addition, one commenter requested that CMS clarify when medication issues are identified, by providing further guidance regarding the definition of the term ''identified.'' Several commenters requested further clarification of the measure and conveyed their concern that there are four measures or sub-measures embedded in the description of the measure and stated that, without additional clarification, it may be difficult for providers to utilize the measure for quality improvement purposes.

Response: For this measure, potential clinically significant medication issues are defined as those issues that, in the clinician's professional judgment, warrant interventions, such as alerting the physician and/or others, and the timely completion of any recommended actions (by midnight of the next calendar day) so as to avoid and mitigate any untoward or adverse outcomes. The definition of ''clinically significant'' in this measure was conceptualized during the measure development process. For purposes of the measure, the decision regarding whether or not a medication issue is ''clinically significant'' will need to be made on a case-by-case basis, but we also intend to provide additional guidance and training on this issue

We would like to clarify that the measure is one measure, comprised of three assessment items used to calculate each LTCH facilities observed score. The items used to calculate the measure are collected by the LTCH CARE Data Set. Items used to calculate the proposed measure include: Items N2001 (Drug Regimen Review Item) and N2003 (Medication Follow-Up Item), collected at admission, and item N2005 (Medication Intervention Item) collected at discharge. Each of the three items are collected in order to report the percentage of patient/resident stays in which a drug regimen review was conducted at the time of admission and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that stay. The measure is collected admission and at discharge to include data collected throughout the entire patient stay. LTCHs are able to use the data collected for this measure at admission, discharge, or at any time point for internal quality improvement purposes.

Comment: Several commenters expressed concern related to burden and expenses related to this measure. Specifically, the commenters expressed concern that the reporting and tracking requirements for the measure items will increase resource use and costs for LTCHs. The commenters also expressed concern that the costs will be cumulative since future PAC measures will be developed to fulfill the mandate of the IMPACT Act. Therefore, the commenters recommended that CMS narrow the scope of the measure to reduce costs for LTCHs.

Response: We are very sensitive to the issue of burden associated with data collection and have proposed only the minimal number of items needed to calculate the quality measure. We emphasize that this measure follows standard clinical practice requirements of ongoing review, documentation, and timely reconciliation of all patient medications, with appropriate follow-up to address all clinically significant medication concerns.

Comment: Several commenters expressed concerns that the measure is not NQF-endorsed and does not have full support from the NQF-convened MAP or the TEP. One commenter noted that the MAP recommended continued development for the measure. Several commenters recommended that CMS obtain NQF endorsement for the measure prior to implementation. Further, commenters requested that the measure be modified to address the specific needs of the LTCH population.

Response: Since the time of the MAP consideration, with our measure contractor, we tested this measure in a pilot test involving twelve PAC facilities (IRF, SNF and LTCH), representing variation across geographic location, size, profit status, and clinical record collection system. Two clinicians in each facility collected data on a sample of 10 to 20 patients for a total of 298 records (147 qualifying pairs). Analysis of agreement between coders within each participating facility indicated a 71 percent agreement for item DRR–01 [335] Drug Regimen Review (admission); 69 percent agreement for item DRR–02 [336] Medication Follow-up (admission); and 61 percent agreement for DRR–03 [337] Medication Intervention (during stay and discharge). Overall, pilot testing enabled CMS to verify feasibility of the measure. Furthermore, measure development included convening a TEP to provide input on the technical specifications of this quality measure, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The TEP included stakeholders from the LTCH setting and supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

As noted above, we plan to conduct further testing on this measure once we have started collecting data from the PAC settings. Once we have completed this additional measure performance testing, we plan to submit to NQF for endorsement.

Comment: Several commenters, including MedPAC, encouraged CMS to develop a measure to evaluate medication reconciliation throughout the care continuum. Commenters, including MedPAC, suggested CMS focus on discharge from the PAC setting and evaluate whether the PAC sends a medication list to the patient's primary care physician or to the next PAC provider. One commenter recommended that CMS add a medication management measure to fully address patients' medication management routine needs in order to prepare patients for discharge to PAC settings or the community.

Response: PAC facilities are expected to document information pertaining to the process of a drug regimen review, which includes medication reconciliation, in the patient's discharge medical record. Further, it is standard practice for patient discharge records to include a medication list to be transferred to the admitting PAC facility. We will take the recommendation into consideration for future measure development in accordance with the IMPACT Act, which emphasizes the transfer of interoperable patient information across the continuum of care.

After consideration of the public comments we received, we are finalizing our proposal to adopt the measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP measure for the LTCH QRP for FY 2020 payment determination and subsequent years, as described in the Measure Specifications for Measures Adopted in the FY 2017 LTCH QRP Final Rule, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

8. LTCH QRP Quality Measures and Measure Concepts Under Consideration for Future Years

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25228), we invited comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in the table below for future years in the LTCH QRP. We are developing a measure related to the IMPACT Act domain, ''Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions.'' We are considering the possibility of adding quality measures that rely on the patient's perspective; that is, measures that include patient-reported experience of care and health status data. We recently posted a ''Request for Information to Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences with Care Received in Long-Term Care Hospitals'' (80 FR 72722 through 72725).

Also, we are considering a measure focused on pain that relies on the collection of patient-reported pain data, and another that documents whether a patient has an Advance Care Plan. Finally, we are considering measures related to patient safety: Venous Thromboembolism Prophylaxis, Ventilator Weaning (Liberation) Rate, Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay, and Patients Who Received an Antipsychotic Medication.

LTCH QRP Quality Measures Under Consideration for Future Years

IMPACT Act Domain	Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions.
• IMPACT Act Measure	• Transfer of health information and care preferences when an individual transitions.
NQS Priority	Patient- and Caregiver-Centered Care.
• Measures	• Patient Experience of Care. • Percent of Patients with Moderate to Severe Pain. • Advance Care Plan.
NQS Priority	Patient Safety.

[335] DRR pilot items DRR–01, DRR–02 and DRR–03 are equivalent to the proposed rule DRR PAC instrument items N. 2001, N. 2003 and N. 2005.

[336] DRR pilot items DRR–01, DRR–02 and DRR–03 are equivalent to the proposed rule DRR PAC instrument items N. 2001, N. 2003 and N. 2005.

[337] DRR pilot items DRR–01, DRR–02 and DRR–03 are equivalent to the proposed rule DRR PAC instrument items N. 2001, N. 2003 and N. 2005.

LTCH QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS—Continued

• Measures	• Ventilator Weaning (Liberation) Rate. • Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay. • Patients Who Received an Antipsychotic Medication. • Venous Thromboembolism Prophylaxis.

We received several comments about LTCH QRP quality measures under consideration for future years which are summarized with our responses below.

Comment: Several commenters recommended that CMS adopt malnutrition-related quality measures in the LTCH QRP to promote early identification of Medicare beneficiaries diagnosed with or at risk for malnutrition, as identification of these conditions is critical to improving outcomes and patient safety by reducing complications such as infections, falls and pressure ulcers. Commenters also recommended that CMS require the inclusion of nutritional status and a nutrition care plan as necessary health information that is transferred to an individual, a caregiver, or provider of services as a component of the Transfer of Health Information for Individuals and Care Preferences quality measure. One commenter recommended that CMS adopt a malnutrition-related composite quality measure in the LTCH QRP and other related care settings and programs. Another commenter acknowledged CMS' past recognition of malnutrition as an important patient safety issue. A commenter recommended that CMS adopt a disease-related malnutrition-related quality measures(s) in the LTCH QRP to reduce the risk of associated adverse outcomes. Specifically, the commenter encouraged the use of the American Society for Parenteral and Enteral Nutrition's publication on malnutrition characteristics and diagnosis.

Response: We will take the suggestions into consideration as we develop future measures for the LTCH QRP and other quality reporting programs. We agree with the commenters' rationale for consideration of adopting malnutrition quality measures, including a malnutrition care composite measure, and for including nutritional status and a nutrition care plan during transitions of care to an individual, a caregiver or provider as they are important components of care for LTCH patients.

Comment: One commenter remarked on the limited number of items in the LTCH CARE Data Set related to communication, cognition, and swallowing and noted that these domains are important in treating individuals with neurological disorders. The commenter encouraged CMS to adopt a specific screening instrument, the Montreal Cognitive Assessment (MoCA), or similar screening tools and assessment tools (CARE–C) to best meet the needs of Medicare beneficiaries and the IMPACT Act. Another commenter requested that CMS add a functional cognition assessment item to the LTCH discharge assessment and that this information be provided to the next provider when a patient is transferred. The commenter also noted the important role that occupational therapists play in such an assessment. The commenter offered to collaborate with CMS to develop future measures in the area of cognitive function.

Response: We agree that future measure development should include other areas of function, such as communication, cognition, and swallowing, and are important components of functional assessment and improvement for patients who receive care in PAC settings, including LTCHs. We will continue to engage stakeholders as we develop and implement quality measures to meet the requirements of the IMPACT Act, and we will take these suggested quality measure concepts and recommendations into consideration in our ongoing measure development and testing efforts.

Comment: One commenter did not support the Venous Thromboembolism (VTE) Prophylaxis measure, since it was previously adopted by LTCHs and would add burden without adding usefulness.

Response: We thank the commenter for their comments on the Venous Thromboembolism (VTE) Prophylaxis measure under consideration for future implementation in the LTCH QRP and will take into consideration the commenter's recommendations.

Comment: One commenter supported the Ventilator Weaning (Liberation) Rate and Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay quality measures for implementation in LTCHs. The commenter emphasized the importance of specifying inclusion and exclusion criteria and risk adjustment.

Response: We will take the suggestions into consideration to inform our ongoing measure development efforts. Our measure development contractor, RTI International, will continue to engage members of a TEP originally convened in April 2014. This TEP is providing ongoing advisement to our measure development contractor on all aspects, including the measures denominator, numerator, inclusion and exclusion criteria, risk adjustment, as well as development and feasibility of data elements.

Comment: One commenter recognized the importance of advance care planning in LTCHs to establish patient preferences regarding medical treatment, as many LTCH patients are unable to make medical care decisions on their own.

Response: We thank the commenter for the comment and agree with the importance of advanced care plans as they relate to the critically chronically ill and vulnerable patient population in LTCHs. We will take this comment into consideration as we develop future measures for the LTCH QRP.

Comment: One commenter expressed support for the inclusion of a patient-reported experience of care measure in the LTCH QRP. The commenter supported accepting proxy responses from family members and caregivers to support accurate and reliable results at the facility level due to the acuity of the patients in LTCHs. The commenter also recommended that CMS continue their efforts to develop a patient experience survey to collect this valuable data and incorporate voluntary reporting into the LTCH QRP as quickly as possible. Another commenter believes that data collection for the Patient Experience of Care quality measure would be difficult if the measure were dependent on collecting data from a patient satisfaction survey, such as the HCAHPS survey. The commenter stated that it would be difficult to assess patient experience by requiring LTCHs to collect data from these severely ill patients, since they are less likely to be satisfied with their care. In addition, the commenter stated that a patient satisfaction survey would create a significant cost burden for providers

and require significant resources for data collection.

Response: While we recognize the difficulty in surveying this patient population, we also believe that patient experience of care is an important element of quality in the LTCH setting. We will continue to take these and future stakeholder inputs under advisement to inform our ongoing quality measure development.

Comment: One commenter supported the future proposal of the IMPACT Act Transfer of Health Information and Care Preferences measure. Another commenter encouraged the inclusion of measures that capture the role of family caregivers in supporting care transitions, quality outcomes, and individual care preferences. The commenter also emphasized the importance of acknowledging and measuring the unique needs of family members when making difficult care decisions, noting the particular importance in the LTCH setting due to the high acuity of LTCH patients. One commenter requested more information about the measure specifications before proposing the measure for the LTCH QRP.

Response: As we move through the development of this measure concept, we will consider the inclusion of the role of family caregivers in supporting care transitions, quality outcomes, and individual care preferences. In addition, we will take these recommendations regarding measure specifications into consideration in our ongoing measure development and testing efforts.

Comment: One commenter supported the inclusion of the antipsychotic quality measure in the LTCH QRP (measure listed on the Nursing Home Compare Web site). However, the commenter cautioned against adapting the pre-existing, non-NQF endorsed antipsychotic measures currently used in nursing homes, indicating that these process measures do not provide a linkage to clinical outcomes or intermediate outcomes. Another commenter also expressed concern about this measure not being appropriate for the LTCH setting.

Response: We appreciate commenters' feedback on this potential measure development area. We acknowledge that measuring the use of antipsychotic medication is important for the aging Medicare population. However, as LTCH patients may differ from the general Medicare population, we recognize the importance of engaging stakeholders if we do adopt/develop such a measure for use in the LTCH setting. We will take the commenters' recommendations into consideration in our measure development and testing efforts, as well as in our ongoing efforts to identify and propose appropriate measures for the LTCH QRP in the future.

Comment: One commenter encouraged CMS to consider new measures in the context of the measurement gap areas identified by the Core Quality Measures Collaborative (CQMC).

Response: We will take the comment and suggestion into consideration as we develop future measures for the LTCH QRP.

9. Form, Manner, and Timing of Quality Data Submission for the FY 2018 Payment Determination and Subsequent Years

a. Background

Section 1886(m)(5)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each LTCH submit to the Secretary data on quality measures specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires that, for the fiscal year beginning on the specified application date, as defined in section 1899B(a)(2)(E) of the Act, and each subsequent year, each LTCH submit to the Secretary data on measures specified by the Secretary under section 1899B of the Act. The data required under sections 1886(m)(5)(C) and (F) of the Act must be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(m)(5)(A)(i) of the Act, for any LTCH that does not submit data in accordance with sections 1886(m)(5)(C) and (F) of the Act for a given fiscal year, the annual payment for discharges occurring during the fiscal year must be reduced by 2 percentage points.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49749 through 49752), we:

- Adopted timing for new LTCHs to begin reporting quality data under the LTCH QRP for the FY 2017 payment determination and subsequent years; and
- Adopted new deadlines that allow 4.5 months (approximately 135 days) after the end of each calendar year quarter for quality data submission, beginning with quarter 4 of 2015 (October 2015 through December 2015). The new deadlines apply to all LTCH QRP quality measures (except Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)) for the FY 2017 and FY 2018 payment determinations and subsequent years.

b. Timeline for Data Submission under the LTCH QRP for the FY 2018 Payment Determination and Subsequent Years

The table below presents the data collection period, data submission (for the LTCH CARE Data Set-assessment based and CDC measures) and data correction timelines for quality measures affecting the FY 2018 and subsequent years' payment determinations.

SUMMARY DETAILS ON THE LTCH CARE DATA SET AND CDC NHSN DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS *

Quality measure	Submission method	Data Collection/submission quarterly reporting period(s)	Quarterly review and correction period and data submission deadlines for payment determination	First APU determination affected
NQF #0678: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (76 FR 51748 through 51750).	LTCH CARE Data Set/QIES ASAP.	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #0138: NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (76 FR 51745 through 51747).	CDC NHSN	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.

SUMMARY DETAILS ON THE LTCH CARE DATA SET AND CDC NHSN DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS *—Continued

Quality measure	Submission method	Data Collection/submission quarterly reporting period(s)	Quarterly review and correction period and data submission deadlines for payment determination	First APU determination affected
NQF #0139: NHSN Central-Line Associated Bloodstream Infection (CLABSI) Outcome Measure (76 FR 51747 through 51748).	CDC NHSN	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #1716: NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (78 FR 50863 through 50865).	CDC NHSN	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #1717: NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (78 FR 50865 through 50868).	CDC NHSN	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NHSN Ventilator-Associated Event (VAE) Outcome Measure (79 FR 50301 through 50305).	CDC NHSN	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (77 FR 53624 through 53627).	LTCH CARE Data Set/QIES ASAP.	10/1/15–12/31/15, 1/1/16–3/31/16**.	5/15/16, 8/15/16**	FY 2018
NQF #0431: Influenza Vaccination Coverage Among Healthcare Personnel (77 FR 53630 through 53631).	CDC NHSN	10/1/16–3/31/17, 10/1–3/31 for subsequent years.	5/15/17, 5/15 for subsequent years.	FY 2018.
NQF #2512: All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from Long-Term Care Hospitals (78 FR 50868 through 50874).	Medicare FFS Claims Data.	N/A	N/A	FY 2018.
NQF #0674: Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (80 FR 49736 through 49739).	LTCH CARE Data Set/QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018.
NQF #2631: Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (79 FR 50298 through 50301).	LTCH CARE Data Set/QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year..	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018.
NQF #2631: Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (80 FR 49739 through 49747).	LTCH CARE Data Set/QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018.
NQF #2632: Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (79 FR 50298 through 50301).	LTCH CARE Data Set/QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018.

* We refer readers to the table below for an illustration of the CY quarterly data collection/submission quarterly reporting periods and correction and submission deadlines for all APU years.

** For this measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, we refer readers to the proposals on data submission for this measure, which we are finalizing, in section VIII.C.9.d. of the preamble of this final rule. These proposals for the FY 2019 payment determination and for FY 2020 payment determination and subsequent years are illustrated in the tables in that section.

Further, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49749 through 49752), we established that the LTCH CARE Data Set-based and CDC NHSN measures finalized for adoption into the LTCH QRP would follow a calendar year schedule with quarterly reporting periods, followed by quarterly review and correction periods and submission deadlines. This pattern is illustrated in the table below and is in place for all APU years unless otherwise specified. We also wish to illustrate that for the measures finalized for use in the LTCH QRP that use the LTCH CARE Data Set or CDC NHSN data sources, payment determination would subsequently use the data collection and deadlines shown below unless otherwise specified.

ANNUAL CY LTCH CARE DATA SET AND CDC NHSN DATA COLLECTION/SUBMISSION REPORTING PERIODS AND DATA SUBMISSION/CORRECTION DEADLINES FOR PAYMENT DETERMINATIONS

Proposed CY data collection quarter	Data collection/submission quarterly reporting period.	Quarterly review and correction periods and data submission deadlines for payment determination	
Quarter 1	January 1–March 31*, **	April 1–August 15*	Deadline: August 15.*, **
Quarter 2	April 1–June 30	July 1–November 15	Deadline: November 15.
Quarter 3	July 1–September 30	October 1–February 15	Deadline: February 15
Quarter 4	October 1–December 31*, **	January 1–May 15*	Deadline: May 15.*, **

*The annual data submission time frame for the measure, Influenza Vaccination Coverage among Healthcare Personnel, is October 1 through March 31 of the subsequent year with a reporting deadline of May 15 in that subsequent year.

**For the measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, we refer readers to the proposals on data submission for this measure, which we are finalizing in section VIII.C.9.d. of the preamble of this final rule. These proposals for the FY 2019 payment determination and for FY 2020 payment determination and subsequent years are illustrated in the tables in that section.

c. Timeline and Data Submission Mechanisms for the FY 2018 Payment Determination and Subsequent Years for the LTCH QRP Resource Use and Other Measures—Claims-Based Measures

The MSPB–PAC LTCH QRP measure; Discharge to Community-PAC LTCH QRP measure and Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, which we are finalizing in this final rule, are Medicare FFS claims-based measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, no additional information collection would be required from LTCHs. As discussed in section VIII.C.6. of the preamble of this final rule, these measures would use 2 years of claims-based data beginning with CY 2015 and CY 2016 claims to inform confidential feedback reports for LTCHs, and CYs 2016 and 2017 claims data for public reporting.

We invited public comments on this proposal. We did not receive comments related to data submission mechanisms for these measures. For comments related to the measures, we refer readers to section VIII.C.6. of the preamble of this final rule, above. For comments related to the future public display of these measures, we refer readers to section VIII.C.14. of the preamble of this final rule.

We are finalizing the timeline and data submission mechanisms for FY 2018 payment determination and subsequent years as proposed.

d. Revisions to the Previously Adopted Data Collection Period and Submission Deadlines for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) for the FY 2019 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627), we adopted the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure for the FY 2016 payment determination and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50858 through 50861), we finalized the data submission timelines and submission deadlines for the measures for FY 2016 and FY 2017 payment determinations. We refer readers to the FY 2013 and FY 2014 IPPS/LTCH PPS final rules for a more detailed discussion of the measure, timelines and deadlines.

In these previous rules, we finalized that LTCHs were required to perform data collection in alignment with the influenza vaccination season (IVS); that is, obtaining the vaccination status of patients who are in an LTCH for one or more days between the dates of October 1 of a given year through March 31 of the subsequent year, or what the CDC terms the Influenza Vaccination Season (IVS), but for only those patients whose corresponding admissions and discharges occurred during the IVS. Through analysis of the quality data submitted for this measure, we discovered that only requiring LTCHs to submit patient influenza vaccination data during the IVS (October 1 of a given year through March 31 of the subsequent year) inadvertently limits the data collection to only a subset of patients whose stays at an LTCH qualify for inclusion in the measure calculation. This measure is structured in such a way that all patients in an LTCH for one or more days during the IVS are included in the measure. For those patients, an LTCH should have the opportunity to demonstrate the Influenza vaccination status of these patients on either their LTCH CARE Data Set admission assessment or on their discharge assessment (planned, unplanned, or expired). By limiting data collection to only those assessments obtained during the IVS, per our previously finalized policy, CMS inadvertently excluded the collection of Influenza vaccination status data on those patients who were in an LTCH for at least one day during the IVS, but for whom the associated LTCH CARE Data Set admission and/or discharge assessments occurred outside of the IVS (prior to October 1 or after March 31).

For these reasons, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25230 through 25232), we proposed that beginning with the FY 2019 payment determination and subsequent years, which includes the CY 2016/2017 IVS, data collection and submission for the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) will be required year-round, thus including all patients in the LTCH one or more days during the IVS (October 1 of any given CY through March 31 of the subsequent CY), regardless of the associated LTCH

CARE Data Set admission and discharge dates. This includes, for example, a patient that is admitted September 15 of a given year, and discharged April 1 of the subsequent year (thus, in the LTCH during the IVS). This policy will enable the important data collection necessary to indicate that a patient who had an admission or a discharge outside of the IVS, but was in the facility during the vaccination season, ensuring that the data collected and submitted to CMS is representative of the status of all patients within the IVS, rather than only a subset of those who had both admissions and discharges within the IVS.

Further, our proposal effectively changes the data collection and submission timeline for this measure to include 4 calendar quarters, that is based on the influenza *season* (July 1 of any given year through June 30 of the subsequent year), rather than on the calendar year. For the purposes of APU determination and for public reporting, data calculation and analysis uses data from an influenza vaccination season, which takes place within the *influenza season* itself. While the influenza vaccination season is October 1 of a given year (or when the vaccine becomes available) through March 31 of the subsequent year, this timeframe rests within a greater time period of the *influenza season,* which spans 12 months—that is, July 1 of a given year through June 30 of the subsequent year, as defined by the CDC. Thus, for this measure, we utilize data from a timeframe of 12 months that mirrors the influenza season which is July 1 of a given year through June 30 of the subsequent year. In addition, for the APU determination, we review data submitted beginning on July 1 of the calendar year 2 years prior to the calendar year of the APU effective date and ending June 30 of the subsequent calendar year, one year prior to the calendar year of the APU effective date. For example, and as provided in the below for the FY 2020 (October 1, 2019) APU determination, we review data submission beginning July 1, 2017 through June 30, 2018 for the 2017/2018 influenza vaccination season (October 1, 2017 [or when the vaccine becomes available] through March 31, 2018), so as to capture all data that an LTCH will have submitted with regard to the 2017/2018 influenza vaccination season itself, which resides within the associated influenza season. We will use assessment data from the influenza season so as to ensure full capture of vaccination status in the IVS that resides within the influenza season period, as well for public reporting. Further, because we enable the opportunity to review and correct data for all assessment based LTCH CARE Data Set measures within the LTCH QRP, we continue to follow quarterly data collection/submission reporting period(s) and their subsequent quarterly review and correction periods with data submission deadlines for public reporting and payment determinations. However, rather than using a standard CY timeframe, these quarterly data collection/submission periods and their subsequent quarterly review and correction periods and submission deadlines begin with CY quarter 3, July 1, of a given year and end CY quarter 2, June 30, of the following year.

The revisions to the data collection period for the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), will ultimately have the effect of helping LTCHs capture Influenza vaccination data on any LTCH patients that were in their hospital for one or more days during the IVS, by ensuring that such patient's admission and discharge assessments, regardless of the date of those assessments, capture potential influenza vaccination data, and allow the appropriate inclusion of patients and thus the accurate calculation of data for this measure. Lastly, this clarification will also remove any ambiguity and ensure that LTCHs are receiving credit for recording the vaccination status of all patients that were in their hospital for at least one day during any given IVS, regardless of the date(s) of their admission and/or discharge.

We would like to note that in order to implement the newly proposed revision to the data collection timeframes and submission deadlines for this measure, the FY 2019 payment determination will only be based on three CY quarters, as this policy will not go into effect until October 1, 2016, which is the start of the 2016/2017 IVS. Because of this, we are not requiring LTCHs to respond to the Influenza vaccination items on the LTCH CARE Data Set admission or discharge assessments that take place during Q3 2016 (7/1/16–9/30/16), as this quarter will occur prior to the effective date of this policy, if finalized. This is illustrated in the table for the FY 2019 payment determination, below. All subsequent payment determinations will be based on four CY quarters, as discussed above, beginning with Q3 of CY 2017 for the FY 2020 payment determination. This is illustrated in table for the FY 2020 payment determination and subsequent years, below.

FY 2019 PAYMENT DETERMINATION: * SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURE, NQF #0680 PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE

Finalized Measure:

- Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) (77 FR 53624 through 53627)

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination *	APU determination affected
LTCH CARE Data Set/QIES ASAP System.	CY 16 Q4 ..... 10/1/16–12/31/16.	1/1/2017–5/15/17 deadline.	
	CY 17 Q1 ..... 1/1/17–3/31/17.	4/1/2017–8/15/17 deadline.	
	CY 17 Q2 ..... 4/1/17–6/30/17.	7/1/17–11/15/17 deadline	FY 2019.

* This table refers to the FY 2019 payment determination only. We refer readers to the table below for all subsequent FY payment determinations for this measure.

FY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS: SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURE, PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE (SHORT STAY) (NQF #0680)

Finalized Measure:

- NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (77 FR 53624 through 53627)

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination *	APU determination affected
LTCH CARE Data Set/QIES ASAP System.	CY 17 Q3 ..... 7/1/17–9/30/17	10/1/17–2/15/18 deadline.	
	Q3 (7/1–9/30)	10/1–2/15.	
	CY 17 Q4 ..... 10/1/17–12/31/17.	1/1/2018–5/15/18 deadline.	
	Q4 (10/1–12/31)	1/1–5/15	FY 2020.
	CY 18 Q1 ..... 1/1/18–3/31/18.	4/1/2018–8/15/18 deadline	Subsequent Years.
	Q1 (1/1–3/31)	4/1–8/15.	
	CY 18 Q2 ..... 4/1/18–6/30/18.	7/1/18–11/15/18 deadline.	
	Q2 (4/1–6/30)	7/1/18–11/15/18 deadline.	

We invited comment on our proposal to revise the data collection and submission timeframe for the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), beginning with the FY 2019 payment determination and subsequent years.

Comment: One commenter supported the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure and the proposed revisions to data collection.

Response: We appreciate the commenter's support for this measure and its continued inclusion in the LTCH QRP, and the proposed revisions to data collection.

After consideration of the public comment we received, we are finalizing our proposal to revise the data collection period and submission deadlines for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) for the FY 2019 payment determination and subsequent years.

e. Timeline and Data Submission Mechanisms for the Newly Finalized LTCH QRP Quality Measure for the FY 2020 Payment Determination and Subsequent Years

As discussed in section VIII.C.7. of the preamble of this final rule, we proposed that the data for the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, affecting the FY 2020 payment determination and subsequent years be collected by completing data elements that would be added to the LTCH CARE Data Set with submission through the QIES ASAP system. Data collection would begin on April 1, 2018. More information on LTCH reporting using the QIES ASAP system is located at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Technical-Information.html.*

For the FY 2020 payment determination, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25232 through 25233), we proposed to collect CY 2018 Q2 through Q4 data, that is, beginning with admissions on April 1, 2018 through discharges on December 31, 2018, to remain consistent with the usual April release schedule for the LTCH CARE Data Set, to give LTCHs sufficient time to update their systems so that they can comply with the new data reporting requirements, and to give us sufficient time to determine compliance for the FY 2020 payment determination. The proposed use of 3 quarters of data for the initial year of assessment data reporting in the LTCH QRP, to make compliance determinations related to the applicable FY APU, is consistent with the approach we used previously for the SNF, IRF, and Hospice QRPs.

The table below presents the proposed data collection period and data submission timelines for the new proposed LTCH QRP quality measure for the FY 2020 payment determination. We invited public comments on this proposal.

DETAILS ON THE PROPOSED DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR RESOURCE USE AND OTHER MEASURES AFFECTING THE FY 2020 PAYMENT DETERMINATION

Quality measure	Submission method	Data collection/submission quarterly reporting period	Quarterly review and correction periods and data submission deadlines for payment determination	APU determination affected
Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP.	LTCH CARE Data Set/QIES ASAP.	4/1/18–6/30/18 (Q2), 7/1/18–9/30/18 (Q3), 10/1/18–12/31/18 (Q4).	11/15/18 (Q2), 2/15/19 (Q3), 5/15/19 (Q4).	FY 2020.

Following the close of the reporting quarters for the FY 2020 payment determination, LTCHs would have the already established additional 4.5 months to correct their quality data and that the final deadline for correcting data for the FY 2020 payment determination would be May 15, 2019 for these measures. We also proposed that for the FY 2021 payment determination and subsequent years, we would collect data using the calendar year reporting cycle as described in section VIII.C.9.c. of the preamble of this final rule, and illustrated in the table below. We invited public comments on this proposal.

PROPOSED DATA COLLECTION PERIOD AND DATA CORRECTION DEADLINES AFFECTING THE FY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	Submission method	Proposed CY data collection quarter	Proposed data collection/ submission quarterly reporting period	Proposed quarterly review and correction periods and data submission deadlines for payment determination
Drug Regimen Review Conducted with Follow-Up for Identified Issues PAC LTCH QRP.	LTCH CARE Data Set/QIES ASAP.	Quarter 1	January 1–March 31	April 1–August 15.
		Quarter 2	April 1–June 30	July 1–September 30.
		Quarter 3	July 1–November 15	October 1–February 15.
		Quarter 4	October 1–December 31	January 1–May 15.

We did not receive any public comments on the proposed data collection periods and data submission timelines for the new proposed LTCH QRP quality measure for the FY 2020 and FY 2021 payment determinations and subsequent years.

We are finalizing the timeline and data submission mechanisms for FY 2020 and FY 2021 payment determination and subsequent years as proposed. For comments related to the measure, we refer readers to section VIII.C.7. of the preamble of this final rule, above.

10. LTCH QRP Data Completion Thresholds for the FY 2016 Payment Determination and Subsequent Years

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50311 through 50314), we finalized LTCH QRP thresholds for completeness of LTCH data submissions. To ensure that LTCHs are meeting an acceptable standard for completeness of submitted data, we finalized the policy that, beginning with the FY 2016 payment determination and for each subsequent year, LTCHs must meet or exceed two separate data completeness thresholds: One threshold set at 80 percent for completion of quality measures data collected using the LTCH CARE Data Set submitted through the QIES and a second threshold set at 100 percent for quality measures data collected and submitted using the CDC's NHSN.

In addition, we stated that we would apply the same thresholds to all measures adopted as the LTCH QRP expands and LTCHs begin reporting data on previously finalized measure sets. That is, as we finalize new measures through the regulatory process, LTCHs will be held accountable for meeting the previously finalized data completion threshold requirements for each measure until such time that updated threshold requirements are proposed and finalized through a subsequent regulatory cycle.

Further, we finalized the requirement that an LTCH must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates. For a detailed discussion of the finalized LTCH QRP data completion requirements, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50311 through 50314). In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25233), we did not propose any changes to these policies.

11. LTCH QRP Data Validation Process for the FY 2016 Payment Determination and Subsequent Years

Validation is intended to provide added assurance of the accuracy of the data that will be reported to the public as required by sections 1886(m)(5)(E) and 1899B(g) of the Act. In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28275 through 28276), we proposed, for the FY 2016 payment determination and subsequent years, a process to validate the data submitted for quality purposes. However, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50314 through 50316), we did not finalize the proposal; instead we decided to further explore suggestions from commenters before finalizing the LTCH data validation process that we proposed. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49752 through 49753), we did not propose any new policies related to data accuracy validation. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25233), we did not propose a data validation policy because we are developing a policy that could be applied to several PAC quality reporting programs. We intend to propose a data validation policy through future rulemaking.

Although we did not solicit feedback specifically regarding data validation, we received one comment which is summarized and discussed below.

Comment: One commenter supported CMS' determination that it was not necessary to propose a data validation policy because there is a policy under development that could be applied to several PAC QRPs.

Response: We appreciate the commenter's support. We intend to propose a data validation policy through the notice and comment process in the **Federal Register** through future rulemaking.

12. Change to Previously Codified LTCH QRP Submission Exception and Extension Policies

We refer readers to § 412.560(c) for requirements pertaining to submission exception and extension for the FY 2017 payment determination and subsequent years. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25233 through 25234), we proposed to revise § 412.560(c) to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an LTCH from submitting their quality data for the LTCH QRP. We proposed the increased time allotted for the submission of the requests from 30 to 90 days to be consistent with other quality reporting programs; for example, the Hospital IQR Program also proposed to extend the deadline to 90 days in section VIII.C.15.a. of the preamble of the proposed rule (81 FR 25205). We believe that this increased time will assist providers experiencing an event in having the time needed to submit such a request. With the exception of this one change, we did not propose any

additional changes to the exception and extension policies for the LTCH QRP at this time.

We invited public comments on the proposal to revise § 412.560(c) to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an LTCH from submitting their quality data for the LTCH QRP.

Comment: Several commenters supported changing the timing for submission of exception and extension requests from 30 to 90 days from the date of the qualifying event preventing an LTCH from submitting their LTCH QRP data. One commenter stated that it helps to align the LTCH QRP with other quality reporting programs, and allows LTCHs to better cope with unforeseeable events.

Response: We thank the commenter for their support.

After consideration of the public comments we received, we are finalizing our proposal to revise § 412.560(c) to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an LTCH from submitting their quality data for the LTCH QRP.

13. Previously Finalized LTCH QRP Reconsideration and Appeals Procedures

We refer readers to § 412.560(d) for a summary of our finalized reconsideration and appeals procedures for the LTCH QRP for FY 2017 payment determination and subsequent years. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25234), we did not propose any changes to this policy. However, we wish to clarify that in order to notify LTCHs found to be noncompliant with the reporting requirements set forth for a given payment determination, we may include the QIES mechanism in addition to U.S. mail, and we may elect to utilize the MACs to administer such notifications.

14. Policies Regarding Public Display of Measure Data for the LTCH QRP and Procedures for the Opportunity To Review and Correct Data and Information

a. Public Display of Measures

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making the LTCH QRP data available to the public. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755), we finalized our proposals to display performance data for the LTCH QRP quality measures by fall 2016 on a CMS Web site, such as the *Hospital Compare,* after a 30-day preview period, and to give providers an opportunity to review and correct data submitted to the QIES ASAP system or to the CDC NHSN. The procedures for the opportunity to review and correct data are provided in the section VIII.C.14.b. of the preamble of this final rule, below. In addition, we finalized the proposal to publish a list of LTCHs that successfully meet the reporting requirements for the applicable payment determination on the LTCH QRP Web site at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/ltch-quality-reporting/*. In the FY 2016 IPPS/LTCH PPS final rule, we also finalized that we would update the list after the reconsideration requests are processed on an annual basis.

Also, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755), we finalized that the display of information for fall 2016 contains performance data on four quality measures:

- Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678);
- NHSN CAUTI Outcome Measure (NQF #0138);
- NHSN CLABSI Outcome Measure (NQF #0139); and
- All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512).

The measures Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), NHSN CAUTI Outcome Measure (NQF #0138), and NHSN CLABSI Outcome Measure (NQF #0139) are based on data collected beginning with the first quarter of 2015 or discharges beginning on January 1, 2015. With the exception of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), rates are displayed based on 4 rolling quarters of data and would initially use discharges from January 1, 2015 through December 31, 2015 (CY 2015) for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and data collected from January 1, 2015 through December 31, 2015 for NHSN CAUTI Outcome Measure (NQF #0138) and NHSN CLABSI Outcome Measure (NQF #0139). For the readmissions measure, data will be publicly reported beginning with data collected for discharges beginning January 1, 2013, and rates would be displayed based on 2 consecutive years of data. For LTCHs with fewer than 25 eligible cases, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25234 through 25235), we proposed to assign the LTCH to a separate category: ''The number of cases is too small (fewer than 25) to reliably tell how well the LTCH is performing.'' If an LTCH has fewer than 25 eligible cases, the LTCH's readmission rates and interval estimates would not be publicly reported for the measure.

Calculations for all four measures are discussed in detail in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755).

Comment: Several commenters, including MedPAC, supported public reporting of quality measures. MedPAC encouraged ongoing development and public reporting for cross-cutting measures for all provider settings.

Response: We appreciate MedPAC's and other commenters' support for the public reporting of LTCH quality measures. We will continue to move forward with cross-cutting measure and public reporting of these measures to meet the mandate of the IMPACT Act.

Comment: A few commenters discussed the requirements of the Affordable Care Act and the IMPACT Act for publicly reporting the measures that are implemented into the LTCH QRP and expressed concern-regarding such public reporting. The commenters suggested that previously finalized measures are not suited for cross-PAC provider comparison, as opposed to LTCH-to-LTCH comparison using comparable data that are risk adjusted, for example, as in the case with the use of the Standardized Infection Ratio, and that using such data for cross-comparison purposes could be misleading to those who use the publicly reported data.

Response: We appreciate commenters' concern about the use of cross-setting quality measures and provider comparability in satisfaction of our requirements to publicly report the data and information. We interpret the commenters' comments to suggest that the measures previously finalized in FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755), such as the CDC Healthcare Associated Infection (HAI) measures (which use the Standardized Infection Ratio) that is, NHSN CAUTI Outcome Measure (NQF #0138), NHSN CLABSI Outcome Measure (NQF #0139) and the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) are appropriate for LTCH-to-LTCH quality comparison. We wish to clarify that such comparison is their intended application at this time rather than across PAC provider comparison.

We further interpret the commenters to be expressing concern surrounding the other measure that we also finalized for public reporting, ''The Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678),'' inferring that the measure, which satisfies the IMPACT Act quality measure domain of Skin Integrity, would not be appropriate for cross-PAC comparison because it is not further risk adjusted for LTCHs. We note that this measure is risk adjusted uniformly across the PAC providers (LTCHs, IRFs, SNFs and HHAs) and, given that the measure's risk adjustment factors take into account frailty and comorbidities, we did not believe that further setting-specific risk adjustment was warranted. The measure was finalized for use to satisfy the domain described; however as of fall 2016, the measure will initially be publicly reported for LTCH-based public reporting only. With regard to cross-PAC provider comparability, we will continue to examine risk adjustment and other factors as part of our ongoing measure development work and continue to monitor for additional factors that would take into account greater risk as we continue to collect the data.

Pending the availability of data, we proposed to publicly report data in CY 2017 on 4 additional measures beginning with data collected on these measures for the first quarter of 2015, or discharges beginning on January 1, 2015: (1) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); (2) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717); and beginning with the 2015–16 influenza vaccination season these two measures; (3) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and (4) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).

Standardized infection ratios (SIRs) for the Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716) and Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717) will be displayed based on 4 rolling quarters of data and will initially use MRSA Bacteremia and CDI events that occurred from January 1, 2015 through December 31, 2015 (CY 2015), for calculations. We proposed that the display of these ratios will be updated quarterly.

Rates for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) will initially be displayed for personnel working in the reporting facility October 1, 2015 through March 31, 2016. Rates for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) will also initially be displayed for patients in the LTCH during the influenza vaccination season, from October 1, 2015, through March 31, 2016. We proposed that the display of these rates will be updated annually for subsequent influenza vaccination seasons.

Calculations for the MRSA Bacteremia and CDI Healthcare Associated Infection (HAI) measures adjust for differences in the characteristics of hospitals and patients using a Standardized Infection Ratio (SIR). The SIR is a summary measure that takes into account differences in the types of patients that a hospital treats. For a more detailed discussion about SIR, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753). The MRSA Bacteremia and CDI SIRs may take into account the laboratory methods, bed size of the hospital, and other facility-level factors. It compares the actual number of HAIs in a facility or State to a national benchmark based on previous years of reported data and adjusts the data based on several factors. A confidence interval with a lower and upper limit is displayed around each SIR to indicate that there is a high degree of confidence that the true value of the SIR lies within that interval. A SIR with a lower limit that is greater than 1.0 means that there were more HAIs in a facility or State than were predicted, and the facility is classified as ''Worse than the U.S. National Benchmark.'' If the SIR has an upper limit that is less than 1, the facility had fewer HAIs than were predicted and is classified as ''Better than the U.S. National Benchmark.'' If the confidence interval includes the value of 1, there is no statistical difference between the actual number of HAIs and the number predicted, and the facility is classified as ''No Different than U.S. National Benchmark.'' If the number of predicted infections is less than 1.0, the SIR and confidence interval are not calculated by CDC.

Calculations for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) are based on reported numbers of personnel who received an influenza vaccine at the reporting facility or who provided written documentation of influenza vaccination outside the reporting facility. The sum of these two numbers is divided by the total number of personnel working at the facility for at least 1 day from October 1 through March 31 of the following year, and the result is multiplied by 100 to produce a compliance percentage (vaccination coverage). No risk adjustment is applicable to these calculations. More information on these calculations and measure specifications is available at: *http://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/4-hcp-vaccination-module.pdf*. We proposed that this data will be displayed on an annual basis and would include data submitted by LTCHs for a specific, annual influenza vaccination season. A single compliance (vaccination coverage) percentage for all eligible healthcare personnel will be displayed for each facility.

We invited public comment on our proposal to begin publicly reporting in CY 2017 pending the availability of data on Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716); Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1717); and Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

Comment: Several commenters specifically supported the public reporting of the CDC NHSN measures.

Response: We appreciate the commenters' support for public reporting of healthcare-associated infections and shared commitment towards improving quality and promoting patient safety.

After consideration of the public comments we received, we are finalizing our proposal to begin publicly reporting in CY 2017 pending the availability of data on: The Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716); the Facility-wide Inpatient Hospital-onset CDI Outcome Measure (NQF #1716); and the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431).

For the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), we proposed to display rates annually based on the influenza season to avoid reporting for more than one influenza vaccination within a CY. For example, in 2017 we would display rates for the patient vaccination measure based on discharges starting on July 1, 2015, to June 30, 2016. We proposed this approach because it includes the entire influenza vaccination season (October 1, 2015, to March 31, 2016).

Calculations for Percent of Residents or Patients Who Were Assessed and

Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) will be based on patients meeting any one of the following criteria: patients who received the influenza vaccine during the influenza season; patients who were offered and declined the influenza vaccine; and patients who were ineligible for the influenza vaccine due to contraindication(s). The facility's summary observed score will be calculated by combining the observed counts of all the criteria. This is consistent with the publicly reported patient influenza vaccination measure for *Nursing Home Compare.* In addition, for the patient influenza measure, we will exclude LTCHs with fewer than 20 stays in the measure denominator. For additional information on the specifications for this measure, we refer readers to the LTCH Quality Reporting Measures Information Web page at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We invited public comments on our proposal to begin publicly reporting the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure on discharges from July 1 of the previous calendar year to June 30 of the current calendar year. We invited comments on the public display of the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) in 2017 pending the availability of data.

Comment: Several commenters supported the public reporting of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) and Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) across settings. Commenters believed that surveillance is a key component in the prevention and management of influenza outbreaks and the need for a multi-faceted approach.

Response: We appreciate the commenters' support for public reporting of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) and Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) across settings.

After consideration of the public comments we received, we are finalizing our proposal to begin publicly reporting the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure on discharges from July 1st of the previous calendar year to June 30th of the current calendar year in 2017 pending the availability of data.

In addition, we requested public comments on whether to include in the future, public display comparison rates based on CMS regions or U.S. census regions for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678); All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512); and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) for CY 2017 public display.

Comment: One commenter supported regional comparison for the LTCH quality measures. The commenter had no preference for the type of region and encouraged more granular evaluation such as State comparison.

Response: We appreciate the commenter's support for publicly displaying regional comparison rates for these quality indicators and their encouragement on providing state comparison rates. We are currently determining the feasibility of including State comparison rates for these quality indicators.

b. Procedures for the Opportunity To Review and Correct Data and Information

Section 1899B(g) of the Act requires the Secretary to establish procedures for public reporting of LTCHs' performance, including the performance of individual LTCHs, on quality measures specified under section 1899B(c)(1) of the Act and resource use and other measures specified under section 1899B(d)(1) of the Act (collectively, IMPACT Act measures) beginning not later than 2 years after the applicable specified application date under section 1899B(a)(2)(E) of the Act. Under section 1899B(g)(2) of the Act, the procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, which refers to public display and review requirements in the Hospital IQR Program, that each LTCH has the opportunity to review and submit corrections to its data and information that are to be made public prior to the information being made public.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49754), and as illustrated in the second table in section VIII.C.9.e. of the preamble of this final rule, we finalized that once the provider has an opportunity to review and correct quarterly data related to measures submitted via the QIES ASAP system or CDC NHSN, we would consider the provider to have been given the opportunity to review and correct this data. We wish to clarify that although the correction of data (including claims) can occur after the submission deadline, if such corrections are made after a particular quarter's submission and correction deadline, such corrections will not be captured in the file that contains data for calculation of measures for public reporting purposes. To have publicly displayed performance data that is based on accurate underlying data, it will be necessary for LTCHs to review and correct this data before the quarterly submission and correction deadline.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25235 through 25237), we restated and proposed additional details surrounding procedures that would allow individual LTCHs to review and correct their data and information on measures that are to be made public before those measure data are made public.

For assessment-based measures, we proposed a process by which we will provide each LTCH with a confidential feedback report that will allow the LTCH to review its performance on such measures and, during a review and correction period, to review and correct the data the LTCH submitted to CMS via the CMS QIES ASAP system for each such measure. In addition, during the review and correction period, the LTCH will be able to request correction of any errors in the assessment-based measure rate calculations.

We proposed that these confidential feedback reports will be available to each LTCH using the Certification and Survey Provider Enhanced Reports (CASPER) system. We refer to these reports as the LTCH Quality Measure (QM) Reports. We proposed to provide monthly updates to the data contained in these reports as data become available. We proposed to provide the reports so that providers will be able to view their data and information at both the facility and patient level for its quality measures. The CASPER facility level QM Reports may contain information such as the numerator, denominator, facility rate, and national rate. The CASPER patient-level QM Reports may contain individual patient information which will provide information related to which patients were included in the quality measures

to identify any potential errors for those measures in which we receive patient-level data. Currently, we do not receive patient-level data on the CDC measure data received via the NHSN system. In addition, we would make other reports available in the CASPER system, such as LTCH CARE Data Set assessment data submission reports and provider validation reports, which will disclose the LTCH's data submission status providing details on all items submitted for a selected assessment and the status of records submitted.

We refer LTCHs to the CDC NHSN system Web site for information on obtaining reports specific to NHSN submitted data at: *http://www.cdc.gov/nhsn/ltach/index.html.* Additional information regarding the content and availability of these confidential feedback reports would be provided on an ongoing basis on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html.*

As previously finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49750 through 49752) and illustrated in the second table in section VIII.C.9.c. of the preamble of this final rule, LTCHs will have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data (that appear on the CASPER-generated QM reports) and NHSN data used to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, LTCHs can review and perform corrections to errors in the assessment data used to calculate the measures and can request correction of measure calculations. However, as already established, once the quarterly submission deadline occurs, the data is ''frozen'' and calculated for public reporting and providers can no longer submit any corrections. We encourage LTCHs to submit timely assessment data during a given quarterly reporting period and review their data and information early during the review and correction period so that they can identify errors and resubmit data before the data submission deadline.

As noted above, the assessment data will be populated into the confidential feedback reports, and we intend to update the reports monthly with all data that have been submitted and are available. We believe that the data collection/submission quarterly reporting periods plus 4.5 months to review and correct the data is sufficient time for LTCHs to submit, review and, where necessary, correct their data and information. These timeframes and deadlines for review and correction of such measures and data satisfy the statutory requirement that LTCHs be provided the opportunity to review and correct their data and information and are consistent with the informal process hospitals follow in the Hospital IQR Program.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755), we finalized the data submission/correction and review period. Also, we afford LTCHs a 30-day preview period prior to public display during which LTCHs may preview the performance information on their measures that will be made public. We would like to clarify that we will provide the *preview* report using the CASPER system, with which LTCHs are familiar. The CASPER preview reports inform providers of their performance on each measure which will be publicly reported. Please note that the CASPER preview reports for the reporting quarter will be available after the 4.5 month correction period and the applicable data submission/correction deadline have passed and are refreshed on a quarterly basis for those measures publicly reported quarterly, and annually for those measure publicly reported annually. We proposed to give LTCHs 30 days to review the preview report beginning from the date on which they can access the report.

As already finalized, corrections to the underlying data will not be permitted during this time; however, LTCHs may ask for a correction to their measure calculations during the 30-day preview period. We proposed that if CMS determines that the measure, as it is displayed in the preview report, contains a calculation error, we can suppress the data on the public reporting Web site, recalculate the measure and publish it at the time of the next scheduled public display date. This process is consistent with informal processes used in the Hospital IQR Program. We stated that, if finalized, we intend to utilize a subregulatory mechanism, such as our LTCH QRP Web site, to provide more information about the preview reports, such as when they will be made available and explain the process for how and when providers may ask for a correction to their measure calculations. We invited public comment on these proposals to provide preview reports using the CASPER system, giving LTCHs 30 days review the preview report and ask for a correction, and to use a subregulatory mechanism to explain the process for how and when providers may ask for a correction.

In addition to assessment-based measures and CDC measure data received via the NHSN system, we have also proposed claims-based measures for the LTCH QRP. The claims-based measures include those proposed to meet the requirements of the IMPACT Act as well as the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) which was finalized for public display in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755). As noted in above, section 1899B(g)(2) of the Act requires prepublication provider review and correction procedures that are consistent with those followed in the Hospital IQR Program. Under the Hospital IQR Program's informal procedures, for claims-based measures, we provide hospitals 30 days to preview their claims-based measures and data in a preview report containing aggregate hospital-level data. We proposed to adopt a similar process for the LTCH QRP.

Prior to the public display of our claims-based measures, in alignment with the Hospital IQR, HAC Reduction and Hospital VBP Programs, we proposed to make available through the CASPER system, a confidential preview report that will contain information pertaining to claims-based measure rate calculations, for example, facility and national rates. The data and information will be for feedback purposes only and could not be corrected. This information will be accompanied by additional confidential information based on the most recent administrative data available at the time we extract the claims data for purposes of calculating the measures. Because the claims-based measures are recalculated on an annual basis, these confidential CASPER QM reports for claims-based measures will be refreshed annually. As previously finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755), LTCHs will have 30 days from the date the preview report is made available in which to review this information.

The 30-day preview period is the only time when LTCHs will be able to see claims-based measures before they are publicly displayed. LTCHs will not be able to make corrections to underlying claims data during this preview period, nor will they be able to add new claims to the data extract. However, LTCHs may request that we correct our measure calculation if the LTCH believes it is incorrect during the 30-day preview period. We proposed that if we agree that the measure, as it is displayed in the preview report, contains a calculation error, we can suppress the

data on the public reporting Web site, recalculate the measure, and publish it at the time of the next scheduled public display date. This process will be consistent with informal policies followed in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our LTCH QRP Web site, to explain the process for how and when providers may contest their measure calculations.

The proposed claims-based measures—The MSPB–PAC LTCH QRP; Discharge to Community-PAC LTCH QRP and Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP—use Medicare administrative data from hospitalizations for Medicare FFS beneficiaries. Public reporting of data will be based on 2 consecutive calendar years of data, which is consistent with the specifications of the proposed measures. We proposed to create data extracts using claims data for the proposed claims based measures—The MSPB–PAC LTCH measure; Discharge to Community-PAC LTCH QRP and Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP—at least 90 days after the last discharge date in the applicable period, which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is December 31, 2017 for data collection January 1, 2016 through December 31, 2017, we will create the data extract on approximately March 31, 2018 at the earliest, and use that data to calculate the claims-based measures for that applicable period. Since LTCHs will not be able to submit corrections to the underlying claims snapshot nor add claims (for those measures that use LTCH claims) to this data set at the conclusion of the at least 90-day period following the last date of discharge used in the applicable period, at that time we will consider LTCH claims data to be complete for purposes of calculating the claims-based measures.

We proposed that beginning with data that will be publicly displayed in 2018, claims-based measures will be calculated using claims data at least 90 days after the last discharge date in the applicable period, at which time we will create a data extract or snapshot of the available claims data to use for the measures calculation. This timeframe allows us to balance the need to provide timely program information to LTCHs with the need to calculate the claims-based measures using as complete a data set as possible. As noted, under this procedure, during the 30-day preview period, LTCHs will not be able to submit corrections to the underlying claims data or to add new claims to the data extract. This is for two reasons: first, for certain measures, the claims data used to calculate the measures may not be derived from the LTCH's claims, but are from the claims of another provider. For example, the measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP uses claims data submitted by the hospital to which the patient was readmitted, which may not be the LTCH. For the claims that are not those of the LTCH, the LTCH cannot make corrections to them. Second, even where the claims used to calculate the measures are those of the LTCH, it will not be not possible to correct the data after it is extracted for the measures calculation. This is because it is necessary to take a static ''snapshot'' of the claims in order to perform the necessary measure calculations.

We seek to have as complete a data set as possible. We recognize that the proposed at least 90 day ''run-out'' period when we would take the data extract to calculate the claims-based measures, is less than the Medicare program's current timely claims filing policy under which providers have up to 1 year from the date of discharge to submit claims. We considered a number of factors in determining that the proposed at least 90 day run-out period is appropriate to calculate the claims-based measures. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted or episode-based measures). We then need to generate and check the calculations. Because several months lead time is necessary after acquiring the data to generate the claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to LTCHs sooner than 18 to 24 months after the last discharge. We believe this would create an unacceptably long delay both for LTCHs and for us to deliver timely calculations to LTCHs for quality improvement.

We invited public comment on these proposals, which are summarized and discussed below.

Comment: One commenter supported CASPER monthly confidential feedback reports.

Response: We appreciate the commenter's support for providing monthly confidential feedback reports.

Comment: Several commenters suggested that LTCHs be able to correct data during the 30-day preview period, and that CMS address any potential issues such as system errors and revise confirmed errors before the calculation results are made public. Commenters further suggested that the 30-day preview period was intended by Congress to enable correction of the data prior to public reporting. In addition, the commenters noted that CMS will be updating the NHSN system to permit changes to the CDC quality data. One commenter recommended that CMS conduct a ''dry run'' in which LTCHs receive confidential preview reports prior to publicly reporting measures so that LTCHs can become familiar with the methodology, understand the measure results, know how well they are performing, and have an opportunity to give CMS feedback on potential technical issues with the measures.

Response: We interpret the commenter to be referring to the preview reports that will be provided prior to public reporting and appreciate their concern about correcting data during the 30-day preview period and addressing any potential issues. Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making the LTCH QRP data available to the public and to ensure that LTCHs have the opportunity to review any such data with respect to the LTCH prior to its release to the public. In addition, section 1899B(g) of the Act, as added by the IMPACT Act, requires the Secretary to establish procedures for making information available to the public regarding the performance of individual PAC providers with respect to IMPACT Act measures beginning no later than two years after the applicable specified application date.

We implemented the 30-day preview period to be consistent with other public reporting programs such as the Hospital IQR Program. We provide opportunity for assessment-based data and NHSN data to be reviewed and corrected prior to their freeze dates, and LTCHs will have up until the run off period ends for ensuring their data used in the claims-based measures are accurate prior to the data file being used to calculate the measures. The 30-day preview period serves as the final opportunity for providers to review their data and alert CMS should they find an error in the measure calculation or any component thereof. While LTCHs will not have the opportunity to correct the underlying data during the 30-day preview period before public display, there will be a process by which LTCHs may request a review of their data should they disagree with quality measure calculations, or the components of such calculations (numerators and denominators), as

displayed on their preview reports. We will also consider suppressing quality reporting data if any systemic issues, such as on the part of the QIES ASAP system or the CDC's NHSN is discovered. We refer readers to the LTCH QRP Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html,* for further information on public reporting, such as the process of accessing reports, and where we will provide an email address should LTCHs have questions regarding any of the above-mentioned reports or processes.

With regard to the commenter's suggestion that we provide a dry run, we wish to convey that we intend to offer providers information related to their measures so that they become familiar with the measure's methodology and can utilize their confidential preview reports which they will receive prior to the public reporting of new LTCH QRP measures. LTCHs will also receive other confidential reports such as the LTCH facility and patient level QM Reports as well as an additional confidential facility-level report to incorporate the quarterly freeze dates, for example, the *Review and Correct* Report. We believe that these various reports will provide an indication on how well the LTCH is performing as well as opportunities to provide CMS feedback on technical issues with the measures. Therefore, no additional dry run period is warranted.

Finally, with regard to the commenter's suggestion that we will be updating the NHSN system to permit changes to the CDC quality data, we interpret the commenter to be suggesting that we are working to update the CDC NHSN submission system, and we wish to clarify that at this time we are not doing so. That said, we also wish to clarify that providers have 4.5 months from the end of a reporting quarter until the freeze date to enter corrections into their CDC HAI measure data prior to the file being transmitted from the CDC to CMS.

Comment: Several commenters recommended that CMS create an *LTCH Compare* Web site to separate LTCH and short-term acute care hospital performance data due to different patient populations and federal requirements. One commenter voiced their concern that LTCHs and short-term acute care hospitals are different venues. LTCHs treat sicker, more medically complex patients and therefore their quality metrics are different. A separate Web page would allow patients, families, and providers to compare quality performance data with other LTCHs and not provide an incorrect impression of the care provided in LTCHs.

Response: We appreciate commenters' suggestion on creating a separate *LTCH Compare* Web site. CMS is currently developing a separate *Compare* Web site for the reporting of LTCH quality measures similar to other PAC provider types. The *LTCH Compare* Web site is scheduled to be publicly available in late fall 2016.

Comment: One commenter suggested providing more frequent updates and requested patient-level data for the claims-based measures.

Response: The decision to update claims-based measures on an annual basis was to ensure that the amount of data received during the reporting period was sufficient to generate reliable measure rates. However, we will explore the feasibility of providing LTCHs with information more frequently. We believe that we are limited in our ability to provide patient-level information that stems from claims submitted by providers other than LTCHs, but we will explore the feasibility of providing patient-level data.

Comment: Several commenters noted that CMS will publish a list of LTCHs that comply with the LTCH QRP each year on its Web site.

Response: We intend to publish a list of LTCHs that comply with the LTCH QRP each year on our Web site, and it will be updated to reflect changes made as a result of appeals.

After consideration of the public comments we received, we are finalizing our proposals related to procedures for the opportunity to review and correct data and information.

15. Mechanism for Providing Feedback Reports to LTCHs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to PAC providers on their performance to the measures specified under sections 1899B(c)(1) and (d)(1) of the Act, beginning 1 year after the specified application date that applies to such measures and PAC providers. As discussed earlier, the reports we proposed to provide for use by LTCHs to review their data and information will be confidential feedback reports that will enable LTCHs to review their performance on the measures required under the LTCH QRP. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25237 through 25238), we proposed that these confidential feedback reports will be available to each LTCH using the CASPER system. Data contained within these CASPER reports will be updated as previously described, on a monthly basis as the data become available except for our claims-based measures which are only updated on an annual basis.

We intend to provide detailed procedures to LTCHs on how to obtain their confidential feedback CASPER reports on the LTCH QRP Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html.*

We proposed to use the CMS QIES ASAP system to provide quality measure reports in a manner consistent with how providers obtain various reports to date. The QIES ASAP system is a confidential and secure system with access granted to providers, or their designees.

We sought public comment on this proposal to satisfy the requirement to provide confidential feedback reports to LTCHs.

Comment: One commenter encouraged CMS to provide instructions on how to obtain CASPER reports and suggestion training for LTCHs on how to improve their measures via these confidential feedback reports.

Response: We will provide LTCHs with detailed instructions and training regarding how to obtain and interpret these reports. For additional information on this and other training opportunities, please refer to the CMS LTCH Quality Reporting Training Web page at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Training.html.*

After consideration of the public comment we received, we are finalizing our proposal to provide confidential feedback reports to LTCHs as proposed.

D. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

1. Background

a. Statutory Authority

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units.

Section 1886(s)(4)(A)(i) of the Act requires that, for FY 2014 [338] and each

[338] The statute uses the term ''rate year'' (RY). However, beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD–9–CM codes, effective on October 1 of each year. This change allowed for

subsequent fiscal year, the Secretary must reduce any annual update to a standard federal rate for discharges occurring during the fiscal year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable fiscal year.

As provided in section 1886(s)(4)(A)(ii) of the Act, the application of the reduction for failure to report under section 1886(s)(4)(A)(i) of the Act may result in an annual update of less than 0.0 percent for a fiscal year, and may result in payment rates under section 1886(s)(1) of the Act being less than the payment rates for the preceding year. In addition, section 1886(s)(4)(B) of the Act requires that the application of the reduction to a standard Federal rate update be noncumulative across fiscal years. Thus, any reduction applied under section 1886(s)(4)(A) of the Act will apply only with respect to the fiscal year rate involved and the Secretary may not take into account the reduction in computing the payment amount under the system described in section 1886(s)(1) of the Act for subsequent years.

Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013 through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit must submit to the Secretary data on quality measures as specified by the Secretary. The data must be submitted in a form and manner and at a time specified by the Secretary. Under section 1886(s)(4)(D)(i) of the Act, unless the exception of subclause (ii) applies, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract.

Section 1886(s)(4)(D)(ii) of the Act provides an exception to the requirement for NQF endorsement of measures: In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making public the data submitted by inpatient psychiatric hospitals and psychiatric units under the IPFQR Program. These procedures must ensure that a facility has the opportunity to review its data prior to the data being made public. The Secretary must report quality measures that relate to services furnished by the psychiatric hospitals and units on the CMS Web site.

b. Covered Entities

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645), we established that the IPFQR Program's quality reporting requirements cover those psychiatric hospitals and psychiatric units paid under Medicare's IPF PPS (42 CFR 412.404(b)). Generally, psychiatric hospitals and psychiatric units within acute care and critical access hospitals that treat Medicare patients are paid under the IPF PPS. Consistent with prior rules, we continue to use the term ''inpatient psychiatric facility'' (IPF) to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology in our IPF PPS regulations at 42 CFR 412.402. For more information on covered entities, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645).

c. Considerations in Selecting Quality Measures

Our objective in selecting quality measures is to balance the need for information on the full spectrum of care delivery and the need to minimize the burden of data collection and reporting. We have focused on measures that evaluate critical processes of care that have significant impact on patient outcomes and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. We refer readers to section VIII.F.4.a. of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645 through 53646) for a detailed discussion of the considerations taken into account in selecting quality measures.

Before being proposed for inclusion in the IPFQR Program, measures are placed on a list of measures under consideration, which is published annually by December 1 on behalf of CMS by the NQF. In compliance with section 1890A(a)(2) of the Act, measures that we proposed for the IPFQR Program in the proposed rule were included in a publicly available document: ''List of Measures under Consideration for December 1, 2015'' (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81172*). The Measure Applications Partnership (MAP), a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the IPFQR Program, among other Federal programs, and provides input on those measures to the Secretary. The MAP's 2016 recommendations for quality measures under consideration are captured in the following document: ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015–2016—Final Report, February 2016'' (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81599*). We considered the input and recommendations provided by the MAP in selecting all measures for the IPFQR Program, including those discussed below.

2. Retention of IPFQR Program Measures Adopted in Previous Payment Determinations

The current IPFQR Program includes 16 mandatory measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53646 through 53652), we adopted 6 measures for the FY 2014 payment determination and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50889 through 50895), we added 2 measures for the FY 2016 payment determination and subsequent years. In the FY 2015 IPF PPS final rule (79 FR 45963 through 45974), we adopted another 2 measures for the FY 2016 payment determination and subsequent years, and finalized 4 measures for the FY 2017 payment determination and subsequent years. In the FY 2016 IPF PPS final rule (80 FR 46694 through 46714), we removed 1 measure beginning with the FY 2017 payment determination; we also adopted 5 measures and removed 2 measures beginning with the FY 2018 payment determination. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25239), we indicated that we are retaining 15 of these previously adopted measures and proposed to update one measure, as discussed below.

Comment: Many commenters expressed concerns about implementation of the Screening for Metabolic Disorders Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or

annual payment updates and the ICD–9–CM coding update to occur on the same schedule and appear in the same **Federal Register** document, promoting administrative efficiency. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the RY update period would be the 12-month period from October 1 through September 30, which we refer to as a ''fiscal year'' (FY) (76 FR 26435). Therefore, with respect to the IPFQR Program, the terms ''rate year,'' as used in the statute, and ''fiscal year'' as used in the regulation, both refer to the period from October 1 through September 30. For more information regarding this terminology change, we refer readers to section III. of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435).

Any Other Site of Care) (NQF #0647), and Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647). Commenters were primarily concerned with the increased burden of data collection associated with these measures. Some commenters were unsure of how to abstract the Transition Record measures and referred to having unanswered questions regarding the technical specifications of these measures, even following CMS Webinars.

Response: The Screening for Metabolic Disorders, Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647), and Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0648) measures were finalized in the FY 2016 IPF PPS final rule (80 FR 46706, 46709 and 46713) for the FY 2018 payment determination and subsequent years with one modification from the proposals. This modification was to only require reporting on the last two quarters of the reporting period (July 1, 2016–December 1, 2016) for the first year these measures were in the IPFQR Program (that is, for the FY 2018 payment determination). In other words, data collection for these measures was scheduled to begin on July 1, 2016.

However, as discussed in the previous comment, we continued to receive stakeholder concerns in response to this proposed rule. In addition, we received many questions regarding how to operationalize these measures during our Webinar on these measures on January 21, 2016. Specifically, during the Webinar there were questions regarding the data elements required for the Transition Record measure, questions regarding what tests would be sufficient, and questions about when the tests should be administered to meet the requirements of the Screening for Metabolic Disorders measure.[339] Following this Webinar, we continued to receive questions directly from stakeholders regarding the operationalization of these measures. These questions continued to focus on uncertainty around data elements required for the Transition Record measures and uncertainty around the specific tests required and associated timeline for the Screening for Metabolic Disorders measure. On June 8, 2016, we provided updated technical specifications for the implementation of Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647) and Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0648). These updated technical specifications are available in the IPFQR Program Manual at: *http://www.qualityreportingcenter.com/wp-content/uploads/2016/06/IPF_CY2016_IPFQRManual_Guide_20160607_FINAL.pdf1_.pdf*. In addition, CMS provided an updated tool for collection of all three measures to assist facilities in data collection and submission.

Due to these updates, we postponed data collection and implementation of these three measures until January 1, 2017 for the FY 2019 payment determination and subsequent years via an IPFQR Program listserv announcement sent on June 9, 2016. This delay is intended to provide IPFs with sufficient time to understand the updated specifications and train personnel to appropriately abstract data based on these updated specifications and use the updated data collection tool for submission. To summarize, we delayed data collection and are not requiring submission of Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647), Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0648) and Screening for Metabolic Disorders for the FY 2018 payment determination. We refer readers to the chart in section VIII.D.5. of the preamble of this final rule for an updated list of measures for the FY 2018 payment determination.

Comment: Several commenters thanked CMS for delaying implementation of Screening for Metabolic Disorders, Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647), and Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0648) until January 1, 2017.

Response: We thank the commenters for their support.

3. Update to Previously Finalized Measure: Screening for Metabolic Disorders

In the FY 2016 IPF PPS final rule (80 FR 46709 through 46713), we finalized our proposal to include the Screening for Metabolic Disorders measure in the IPFQR Program for the FY 2018 payment determination and subsequent years. In that final rule, we described the denominator as IPF patients discharged with one or more routinely scheduled antipsychotic medications during the measurement period. We also listed the following denominator exclusions: (1) Patients for whom a screening could not be completed within the stay due to the patient's enduring unstable medical or psychological condition; and (2) patients with a length of stay equal to or greater than 365 days, or less than 3 days.

In the FY 2016 IPF PPS final rule (80 FR 46717 through 46718), we finalized the CMS global sample methodology for 10 IPFQR Program measures eligible for sampling, including the Screening for Metabolic Disorders measure. Seven of these 10 measures have denominator exclusions for patients with short length of stay within an IPF. Of these 7 measures, the Screening for Metabolic Disorders measure is the only one with an exclusion for less than 3 days; the other 6 all have denominator exclusions for length of stay less than or equal to 3 days. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25239), we proposed to update the length of stay exclusion for the Screening for Metabolic Disorders measure to exclude patients with a length of stay equal to or greater than 365 days, or less than or equal to 3 days. We anticipate that this update will reduce burden on IPFs because it will allow IPFs to use the same sample for as many measures as possible, by aligning the denominator exclusions.

We welcomed public comments on this proposed denominator exclusion.

Comment: Many commenters supported the proposal to change the length of stay exclusion for the ''Screening for Metabolic Disorders'' measure. Several of these commenters noted that this supports the goal of the global sample to reduce provider burden.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to change the length of stay exclusion for the ''Screening for Metabolic Disorders'' measure to exclude patients with a

[339] Slides from and a Q&A transcript from this Webinar are available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228773668169*.

length of stay equal to or greater than 365 days, or less than or equal to 3 days. As discussed above, we note that we have delayed measure implementation until January 1, 2017 for the FY 2019 payment determination and subsequent years.

4. New Quality Measures for the FY 2019 Payment Determination and Subsequent Years

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25239 through 25243), we proposed two new measures for the FY 2019 payment determination and subsequent years:

- SUB–3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and the subset measure SUB–3a Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664) (SUB3 and SUB–3a); and
- 30-day all-cause unplanned readmission following psychiatric hospitalization in an IPF.

The sections below outline our rationale for proposing these measures.

a. SUB–3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and the Subset Measure SUB–3a Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664) (SUB–3 and SUB3a)

Individuals with mental illness experience substance use disorders (SUDs) at a much higher rate than the general population.[340] Nearly 18 percent of the 43.6 million adults aged 18 years and older who had a mental illness in 2013 met the criteria for a SUD. Of those who met the criteria for a SUD, 26.7 percent used illicit drugs.[341] Illicit drug use is particularly high among adults with serious mental illnesses.[342] Misuse and abuse of prescription drugs among individuals with mental illnesses, in particular opioids, are also of growing concern.

Individuals with co-occurring mental disorders and SUDs, the combination of one or more mental disorders and one or more SUDs, experience far more physical illnesses and episodes of care than individuals with a single diagnosis.[343] These co-occurring disorders tend to go undetected and untreated, especially among the elderly population, which experiences more adverse effects than the non-elderly adult population.[344] Treatment of only one disorder for individuals who have two or more mental and SUDs often leads to poor functioning and poor treatment compliance that inhibits full recovery, increases the risk of relapse, and can lead to other high-risk illnesses, such as coronary heart disease, diabetes, infections, and respiratory disease.[345] [346] Furthermore, individuals with undetected, untreated or undertreated co-occurring disorders are more likely to experience homelessness, incarceration, additional medical illness, suicide, and early death.[347]

Due to the prevalence of substance abuse among individuals with mental illness, and the negative effects therefrom, we believe it is imperative to assess IPFs' efforts to offer treatment options for patients who screen positive for drug and alcohol use. As described under the Measure Description section of the NQF Web page regarding this measure, the SUB–3 measure includes hospitalized patients age 18 years and older ''who are identified with an alcohol or drug use disorder who receive or refuse at discharge a prescription for FDA-approved medications for alcohol or drug use disorder, OR who receive or refuse a referral for addictions treatment.'' [348] The SUB–3a subset measure includes hospitalized patients age 18 years and older ''who receive a prescription for FDA-approved medications for alcohol or drug use disorder OR a referral for addictions treatment.'' [349] The numerator of the SUB–3 measure includes ''patients who received or refused at discharge a prescription for medication for treatment of alcohol or drug use disorder OR received or refused a referral for addictions treatment.'' [350] The numerator of the SUB–3a subset measure includes ''patients who received a prescription at discharge for medication for treatment of alcohol or drug use disorder OR a referral for addictions treatment.'' [351] The denominators of both the SUB–3 measure and SUB–3a subset measure include ''hospitalized inpatients 18 years of age and older identified with an alcohol or drug use disorder'' subject to a list of exclusions.[352] Further information on this measure, including the denominator exclusions, can be found in the measure detail sheet on the NQF's Web site (*http://www.qualityforum.org/QPS/1664*) or in the section of the Specifications Manual for National Hospital Inpatient Quality Measures on Substance Use Measures at: *http://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890516540&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D2.6.2_SUB_v5_1.pdf&blobcol=urldata&blobtable=MungoBlobs*.

We previously adopted the SUB–1 measure (Alcohol Use Screening (NQF #1661)) (78 FR 50890 through 50892) and the SUB–2 (Alcohol Use Brief Intervention Provided or Offered) and the subset measure SUB–2a (Alcohol Use Brief Intervention (NQF #1663)) measure (80 FR 46699 through 46701). While the SUB–1 measure assesses ''hospitalized patients 18 years of age and older who are screened during the hospital stay using a validated screening questionnaire for unhealthy alcohol use,'' [353] the SUB–2 and SUB–2a measure assesses ''hospitalized patients who screened positive for unhealthy alcohol use who received or refused a brief intervention during the hospital stay'' [354] and ''hospitalized patients 18 years and older who received the brief intervention during the hospital stay,'' [355] respectively. The SUB–1 measure and the SUB–2 and SUB–2a measure combined provide a greater understanding of the rate at which patients are screened for potential alcohol abuse and the rate at which those who screen positive accept the offered interventions.

Despite the value created by the inclusion of the SUB–1 measure and the SUB–2 and SUB–2a measure in the IPFQR Program measure set, neither fully captures hospitalized patients 18 years of age and older with other SUDs because these measures focus on alcohol use only. In the past, commenters have urged CMS to include measures related to illicit and opioid drugs in our measure set (80 FR 46701) stating that co-occurring substance use disorders are prevalent in many patients with psychiatric diagnoses and the SUB–3

[340] National Institute on Drug Abuse (NIDA). ''Comorbidity: Addiction and Other Mental Illnesses.''

[341] SAMHSA. *Results from the 2014 National Survey on Drug Use and Health: Mental Health Findings.*

[342] Ibid.

[343] SAMHSA. ''Mental and Substance Use Disorders.''

[344] Robert Drake. ''Dual Diagnosis and Integrated Treatment of Mental Illness and Substance Abuse Disorder.''

[345] SAMHSA. ''Mental and Substance Use Disorders.''

[346] Mental Health Foundation. ''Physical Health and Mental Health.''

[347] SAMHSA. ''Mental and Substance Use Disorders.''

[348] NQF SUB–3 and SUB–3a Measure Specifications. Available at: *http://www.qualityforum.org/QPS/1664*.

[349] Ibid.

[350] Ibid.

[351] Ibid.

[352] Ibid.

[353] NQF SUB–1 Measure Specifications.

[354] NQF SUB–2 and SUB–2a Measure Specifications.

[355] Ibid.

and SUB–3a measure will ensure that patients continue to receive treatment after discharge.[356] While the SUB–3 and SUB–3a measure does not guarantee that patients would continue to receive treatment for substance use disorders after discharge, the addition of the SUB–3 and SUB–3a measure to the existing measure set would encourage IPFs to offer and provide FDA-approved medication OR a referral for addictions treatment to patients with co-occurring drug or alcohol use disorders at discharge. This measure would also provide information regarding the rate at which these treatment options are accepted by patients. The SUB–3 and SUB–3a measure also provides a fuller picture of the entire episode of care. In addition, aggregated data from the SUB–1 measure, SUB–2 and SUB–2a measure, and the SUB–3 and SUB–3a measure from each IPF would help provide patients with adequate consumer information to guide their decision-making process in selecting a treatment facility, specifically for patients that are diagnosed with a substance use disorder.

Furthermore, we believe that this measure set promotes the National Quality Strategy priority of Effective Prevention and Treatment for leading causes of mortality, starting with cardiovascular disease. It is notable that the high prevalence of SUDs among adults age 65 years and older contributes to serious medical conditions, including cardiovascular disease and liver disease. The proposed measure also supports HHS' Opioid Abuse Reduction Initiative to reduce prescription opioid and heroin related overdose, death, and dependence.[357] We also note that the addition of SUB–3 and SUB–3a in the measure set could encourage interventions and promote prevention of conditions that are associated with alcohol and drug use disorders, including disorders associated with the misuse of prescription drugs.

For these reasons, we included the SUB–3 and SUB–3a measure in our ''List of Measures under Consideration for December 1, 2015'' (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81172*). The MAP provided input on the measure and supported its inclusion in the IPFQR Program in its report ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015–2016—Final Report, February 2016'' available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81599*. Moreover, this measure is NQF-endorsed for the IPF setting, in conformity with the statutory criteria for measure selection under section 1886(s)(4)(D)(i) of the Act.

Therefore, we proposed to adopt the SUB–3 and SUB–3a measure for the FY 2019 payment determination and subsequent years. We welcomed public comment on this proposal.

Comment: Several commenters supported the inclusion of the SUB–3/3a measure in the IPFQR Program citing reasons including: Encouraging IPFs to offer and provide addiction treatment for patients with co-occurring drug or alcohol disorders; helping to ensure patients continue to receive treatment after discharge; and complementing the SUB–1, SUB–2/2a measure set. One commenter observed that the requirements for this measure, as outlined in the proposed rule, seem reasonable for IPFs.

Response: We thank the commenters for their support.

Comment: Several commenters recommended enhancing the SUB–3a measure. For example, commenters suggested referral to evidence-based behavioral therapies which complement Medication Assisted Therapy (MAT) or discharge to counties for assessment for care evaluation be included in the numerator of this measure.

Response: We thank these commenters for their suggestions. When feasible and practicable, we consider that it is important to implement measures as they are specified, especially after measures are NQF-endorsed. We encourage commenters to suggest these changes to the measure's steward, The Joint Commission, so that any changes to the measure can be properly specified, tested, and endorsed for these changes as part of the measure maintenance process.

Comment: Many commenters recommended that CMS not adopt SUB–3 and SUB–3a for the IPFQR Program, citing concerns that these measures are not specified for IPFs, they are not related to the primary reason patients seek IPF care, they evaluate patient compliance rather than quality of care, and they do not provide useful public information as they are not based on evidence-based practices.

Response: As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50891), although the SUB measures were developed using all hospitalizations in general acute care, the SUB–3/3a measure is equally applicable to freestanding IPFs and psychiatric units within acute care hospitals because substance use disorders (SUDs) are a common comorbidity for populations hospitalized in these settings and offering SUD treatment at discharge when a comorbid SUD has been identified is a part of high quality care regardless of the treatment setting. In addition, we note that the NQF has endorsed this measure for both the Hospital/Acute Care Facility setting and the Behavioral Health/Psychiatric: Inpatient setting. Furthermore, we maintain that it is important that providers understand gaps in patient compliance so they can modify their discharge processes to influence and encourage compliance. We believe that this measure will provide information regarding the rate at which these treatment options are offered to and accepted by patients who screened positive for drug and alcohol use disorders and may present an opportunity to improve treatment rates. In addition, the aggregated data from the SUB–1 measure, SUB–2 and SUB–2a measure, and the SUB–3 and SUB–3a measure from each IPF will provide patients with important consumer information to guide their decision-making process in selecting a treatment facility. Furthermore, we note that the MAP supported this measure for the IPFQR Program and refer readers to their final recommendations at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*.

Comment: Several commenters recommended that CMS not adopt SUB–3 and SUB–3a for the IPFQR Program, citing concerns that these measures are not consistent with the screening and treatment provided by IPFs. These commenters observed that IPFs provide a more comprehensive screening than required by the SUB measures, and that treatment is more intensive than that required by the measure.

Response: We note that the SUB–3/3a measure is focused on a facility's discharge procedures for patients who screened positive for an SUD during their stay in the IPF. This measure does not address inpatient treatment provided by the IPF during the patient's stay. We believe that offering patients who have screened positive for SUD a prescription for medication for treatment of alcohol or drug use disorder or a referral for addictions treatment represents a minimum standard for discharge and we expect that IPFs which provide more intensive interventions than described in the measure will meet the criteria for this measure.

[356] 80 FR 46701.

[357] ASPE. ''Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths.''

Comment: One commenter recommended that CMS not adopt SUB–3 and SUB–3a for the IPFQR Program, citing concerns that treatment for SUD is more appropriate for the non-acute setting. This commenter acknowledged that screening for these disorders is appropriate for the acute setting.

Response: We thank the commenter for the support of screening for SUD in the inpatient setting. We would like to clarify that the numerator for SUB–3 is ''The number of patients who received or refused at discharge a prescription for medication for treatment of alcohol or drug use disorder OR received or refused a referral for addictions treatment;'' and the numerator for SUB–3a is ''The number of patients who received a prescription at discharge for medication for treatment of alcohol or drug use disorder OR a referral for addictions treatment.'' We note that this measure is focused on inpatient facilities providing patients with the appropriate tools for continuing or beginning treatment for SUD after discharge in the non-acute setting. Furthermore, as stated above, we note that the MAP supported this measure for the IPFQR Program and we refer readers to their final recommendations at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*. We also note that the NQF endorsed this measure for the following care settings: Behavioral Health/Psychiatric: Inpatient, Hospital/Acute Care Facility.[358]

Comment: Several commenters recommended that CMS not adopt SUB–3 and SUB–3a for the IPFQR Program until CMS has demonstrated that this is an area with variation across IPFs, as all IPFs should already be meeting the criteria for this measure, and therefore the measure will not demonstrate meaningful variation across providers.

Response: We agree with the commenters that SUB–3 and SUB–3a represent the standard of care for SUD treatment and referral within the IPF setting. However, based on the data published on *Hospital Compare* for the 2016 Program year, there is significant variation in facility performance on the SUB–1 measure (Alcohol Use Screening), the only SUB measure for which data are currently available for the IPFQR Program. Facility performance ranges between 0.0 percent and 100.0 percent, with a mean performance of 77.4 percent and a coefficient of variance of 0.35. Because the SUB–3/3a measure depends on the identification of alcohol and substance abuse disorders, IPF performance on the SUB–1 measure indicates that there is likely variation in performance across providers on the SUB–3/3a measure as well.

Comment: One commenter expressed concern that this measure may create an incentive for hospitals to refer patients to treatment for which the patients do not have coverage, such as Partial Hospitalization Programs and Intensive Outpatient Programs.

Response: We understand the commenter's concern regarding affordability of treatment. We agree that IPFs should consider patient's insurance coverage and cost of care when providing referrals.

Comment: One commenter expressed concern that addition of a chart-abstracted measure to the IPFQR Program is too burdensome for IPFs because they are already updating processes for other measures.

Response: We appreciate the commenter sharing its thoughts on the burden of data collection. We believe that the requirements associated with reporting on this measures strike a reasonable balance between IPF burden and providing useful information to IPFs, CMS, and the public on the quality of care provided in IPFs.

After consideration of the public comments we received, we are finalizing our proposal to adopt both SUB–3: Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and subset measure SUB–3a: Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664) for the FY 2019 payment determination and subsequent years as proposed.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658) and FY 2014 IPPS/LTCH PPS final rule (78 FR 50901 through 50902), we finalized policies for population, sampling, and minimum case thresholds. In the FY 2016 IPF PPS final rule, we made one change to these requirements (80 FR 46717 through 46719) in finalizing a policy in which IPFs may take one, global, sample for all measures for which sampling is permitted. This policy was adopted to decrease burden on IPFs and streamline policies and procedures. We also refer readers to section VIII.D.8.c. of the preamble of this final rule for additional information about population and sampling requirements.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25240), we proposed to allow sampling for the SUB–3 and SUB–3a measure and proposed to include the SUB–3 and SUB–3a measure in the list of measures covered by the global sample. We welcomed public comment on this proposal.

We did not receive any public comments on this proposal. Therefore, for the reasons discussed above, we are finalizing our proposal to include SUB–3: Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and subset measure SUB–3a: Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664) in the list of measures covered by the global sample for the FY 2019 payment determination and subsequent years as proposed.

b. 30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF

The MAP, composed of national stakeholders, identified readmissions as a key gap area in the IPFQR Program in a January 2015 report.[359] A goal of the CMS Quality Strategy is to ''promote effective communication and coordination of care'' across different care settings and providers. In addition, readmission following discharge from IPFs is undesirable for patients because readmissions represent a deterioration in patients' mental and/or physical health status. Furthermore, an analysis of Medicare claims data for calendar years 2012 and 2013 showed that among the 716,174 IPF admissions for Medicare beneficiaries, more than 20 percent resulted in readmission to an IPF or a short-stay acute care hospital within 30 days of discharge.[360] Risk-standardized readmission rates ranged from 11 percent to 35 percent, indicating wide variation across IPFs and clear opportunity for improvement. Finally, MedPAC estimates of Medicare payments to IPFs in 2012 indicated that the average payment per discharge was nearly $10,000.[361] Therefore, reducing readmissions would substantially reduce costs. For these reasons, we developed a facility-level outcome measure of all-cause, unplanned

[358] For detailed measure information, we refer readers to: *http://www.qualityforum.org/QPS/1664*.

[359] Process and Approach for MAP Pre-Rulemaking Deliberations. *Measure Applications Partnership*. 2015. Available at: *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

[360] Inpatient Psychiatric Facility All-Cause Unplanned Readmission Measure: Draft Technical Report, November 23, 2015. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#17*. (On this page, the file is listed as ''Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance'' under ''Downloads.'')

[361] Inpatient Psychiatric Facility Services Payment System. *MedPAC*. 2014. Available at: *http://www.medpac.gov/documents/payment-basics/inpatient-psychiatric-facility-services-payment-system-14.pdf*.

readmissions following discharge from a qualifying IPF admission. This measure would provide an important indicator of the quality of care patients receive in the IPF setting.

Although not all readmissions are preventable, there is evidence that improvements in the quality of care for patients in the IPF setting can reduce readmission rates which, in turn, would reduce costs to Medicare and the burden to patients and their caregivers. For example, a study of 30-day behavioral health readmissions using a multistate Medicaid database found that connecting patients to services they will need post-discharge can help prevent readmissions. A 1-percent increase in the percentage of patients receiving follow-up care within 7 days of discharge was associated with a 5 percent reduction in the probability of being readmitted.[362] Other studies have also found that transitional interventions such as pre- and post-discharge patient education, structured needs assessments, medication reconciliation/education, transition managers, and inpatient/outpatient provider communication have been effective in reducing early psychiatric readmissions. A systematic review of such interventions observed reductions of 13.6 percent to 37.0 percent of readmissions.[363]

The proposed readmission measure would complement the portfolio of facility-level, risk-standardized readmission measures in the acute care setting that CMS quality reporting and pay-for-performance programs currently use. These programs include, among others, the Hospital IQR Program, which requires facilities to report on condition-specific risk-standardized readmission measures (including Acute Myocardial Infarction (AMI), Heart Failure (HF), Pneumonia, and elective Hip/Knee replacements, among others).[364] In addition, the Hospital IQR Program requires reporting on a Hospital-Wide All-Cause Unplanned Readmissions measure (READM–30–HWR) as finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528). The Hospital Readmissions Reduction Program, a pay-for-performance program for subsection (d) hospitals or hospitals paid under section 1814(b)(3) of the Act, also uses risk-standardized condition-specific readmission measures (including AMI, HF, and Pneumonia, among others).[365]

The proposed IPF readmission measure, 30-day all-cause unplanned readmission following psychiatric hospitalization in an IPF, estimates a facility-level, risk-standardized readmission rate for unplanned, all-cause readmissions within 30 days of discharge from an IPF. Detailed information about the development of this measure as well as final measure specifications can be downloaded from the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#17* (on this page, the file is listed as ''Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance'' under ''Downloads.'') The denominator for this measure includes Medicare FFS beneficiaries aged 18 years and older who are admitted to and discharged alive from an IPF with a principal diagnosis of a psychiatric disorder. Admissions to IPFs for nonpsychiatric disorders, which account for only 1.1 percent of admissions, were not included in the measure cohort because IPFs are expected to admit patients who need inpatient care for psychiatric causes.[366] Therefore, nonpsychiatric admissions could represent either admissions that were initiated for presumed or preliminary psychiatric diagnoses but later were changed to nonpsychiatric primary diagnoses during the admission or admissions with unreliable data.

Eligible index admissions require enrollment in Medicare Parts A and B for 12 months prior to the index admission, the month of admission, and at least 30 days post-discharge. Admissions to IPFs are excluded from the denominator if any of the following apply:

- Subsequent admission on day of discharge (Day 0) or within 2 days post-discharge (Day 1-Day 2) due to transfers to another inpatient facility on Day 0 or 1 or billing procedures for interrupted stays, which do not allow for identification of readmissions to the same IPF within 3 days;
- Patient discharged against medical advice (AMA) because the provider would not have an opportunity to provide optimal care; and
- Unreliable patient data (for example, has a death date but also admission afterwards).

The numerator for the IPF readmission measure is defined as any admission to an IPF or acute care hospital that occurs on or between days 3 and 30 post-discharge, except those considered planned by the CMS Planned Readmission Algorithm, Version 3.0.[367] The all-cause, unplanned, 30-day readmission rate is harmonized with other readmission measures that are endorsed by NQF and in use by CMS programs. For the timeframe for measurement, literature supports the connection between 30-day readmissions and the quality of care provided during the index admission.[368] [369] [370] [371] [372] This timeframe also supports interventions that have been developed on a wide range of patient populations that focus on reducing 30-day readmission rates.[373] [374] [375] [376] [377] Finally, a

[362] Mark TL, Mark T, Tomic KS, et al. Hospital readmission among Medicaid patients with an index hospitalization for mental and/or substance use disorder. *J Behav Health Serv Res.* 2013; 40(2):207–221.

[363] Vigod SN, Kurdyak PA, Dennis CL, et al. Transitional interventions to reduce early psychiatric readmissions in adults: systematic review. *Br J Psychiatry.* 2013; 202(3):187–194.

[364] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/OutcomeMeasures.html.*

[365] 76 FR 51660 through 51676.

[366] Prospective Payment System for Inpatient Hospital Services. In: Services DoHaH, Ed. 42, Vol. 412, U.S. Government Publishing Office 2011:535–537.

[367] Horwitz LI, Grady JN, Zhang W, et al. 2015 Measure Updates and Specifications Report: Hospital-Wide All-Cause Unplanned Readmission Measure—Version 4.0. Centers for Medicare & Medicaid Services; 2015. Available in the Hospital Wide All Cause Readmission Updates folder at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[368] Hyland M. National Mental Health Benchmarking Project. In: Wendy Hoey, Whitecross MFaF, eds. Reducing 28 Day Readmission. Australian Mental Health Outcomes and Classification Network 2008:38.

[369] Boaz TL, Becker MA, Andel R, Van Dorn RA, Choi J, Sikirica M. Risk factors for early readmission to acute care for persons with schizophrenia taking antipsychotic medications. Psychiatric services (Washington, DC). 2013; 64(12):1225–1229.

[370] Zilber N, Hornik-Lurie T, Lerner Y. Predictors of early psychiatric rehospitalization: a national case register study. Isr J Psychiatry Relat Sci. 2011; 48(1):49–53.

[371] Lutterman T, Ganju V, Schacht L, Shaw R, Monihan K, et al. Sixteen State Study on Mental Health Performance Measures. 2003.

[372] Carr VJ, Lewin TJ, Sly KA, et al. Adverse incidents in acute psychiatric inpatient units: rates, correlates and pressures. Aust N Z J Psychiatry. 2008; 42(4):267–282.

[373] Naylor M, Brooten D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. Annals of internal medicine. 1994; 120(12):999–1006.

[374] Naylor MD, Brooten D, Campbell R, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. JAMA. 1999; 281(7):613–620.

[375] van Walraven C, Seth R, Austin PC, Laupacis A. Effect of discharge summary availability during post-discharge visits on hospital readmission. J Gen Intern Med. 2002; 17(3):186–192.

[376] Zhang J, Harvey C, Andrew C. Factors associated with length of stay and the risk of readmission in an acute psychiatric inpatient facility: a retrospective study. Aust N Z J Psychiatry. 2011; 45(7):578–585.

[377] Silva NC, Bassani DG, Palazzo LS. A case-control study of factors associated with multiple psychiatric readmissions. Psychiatric services (Washington, DC). 2009; 60(6):786–791.

workgroup of relevant clinical experts agreed that the 30-day time period captures complications that may be attributable to the IPF.

An all-cause readmission rate was selected because it promotes a holistic approach to the treatment of patients with psychiatric disorders, who often have comorbid medical conditions. From the patient and caregiver perspective, these readmissions indicate a deterioration in the patient's condition. In addition, the relationship between principal discharge diagnosis of the index admission and the principal discharge diagnosis of the readmission may be complex and difficult to determine based only on principal diagnosis codes. For example, a patient discharged with bipolar disorder may be readmitted because of a suicide attempt or self-harm due to poorly controlled symptoms of bipolar disorder. A measure that looks only for readmissions with principal discharge diagnoses of bipolar disorder would miss these readmissions.

The IPF readmission measure uses Medicare FFS claims and enrollment data over a 24-month measurement period to calculate the measure results. Twenty-four months was determined to provide an adequate number of cases and reliable results. Because this measure is not limited to a single diagnosis, a 24-month measurement period gives sufficient sample size. The IPF measure had 4.2 percent of IPFs with fewer than 25 cases in the 24-month measurement period from January 2012 to December 2013. For comparison, the HWR measure had 3.8 percent of hospitals with fewer than 25 cases in the 12-month measurement period from July 2013 to June 2014.

We recognize that the risk of readmission is influenced by patient factors, so the measure is risk-adjusted to account for differences in the patients served across IPFs. Hierarchical logistic regression is used to estimate a risk standardized readmission rate for each facility. Factors considered in the risk-adjustment model include patient demographics, principal discharge diagnoses of the index admission, comorbidities in claims during the 12 months prior to the index admission or during the index admission with the exception of complications of care, and several risk variables specific to the IPF patient population. Risk factors were selected for inclusion in the final risk model if they were positively selected at least 70 percent of the time in a stepwise backward elimination process. The final risk model includes age, gender, 13 principal discharge diagnosis Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (CCS) categories, 38 comorbidity CMS Hierarchical Condition Categories (CC), history of discharge against medical advice, history of suicide or self-harm, history of aggression, and the hospital as a random effect. For more information about factors used in calculating the risk-standardized readmission rate, we refer readers to the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#17*. (On this page, the file is listed as ''Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance'' under ''Downloads.'')

We understand the importance of the role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations, as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measure. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the effect of sociodemographic status on quality measures, resource use, and other measures under the Medicare program, as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

As part of the measure development process for this measure, we solicited public comments on the measure via the CMS Public Comment Web page. As part of our comment solicitation, we provided the Measure Information Form (MIF), Data Dictionary, and the Measure Technical Report to the public to inform their review of the measure. We accepted public comments from November 25, 2015 through December 11, 2015. The significant majority of stakeholders who provided comments on the measure design supported this measure because of the importance of measuring readmissions in this population. Commenters who provided input on the methodology agreed that it appears to be scientifically acceptable, and those who provided input on the feasibility agreed with our belief that the measure is feasible as designed. After review and evaluation of all the public comments received, we did not identify any areas in which the measure needed to be modified. For specific information regarding the comments we received, we refer readers to the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#17*. (On this page, the file is listed as ''Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance'' under ''Downloads.'')

While section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by NQF, the proposed IPF readmission measure was submitted to NQF for endorsement on January 29, 2016, and we anticipate the measure will receive endorsement prior to the release of the final rule. However, the exception to the requirement to specify an endorsed measure states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization. We have reviewed NQF-endorsed and other consensus-endorsed measures related to all-cause unplanned readmissions and believe that none are

appropriate to the inpatient psychiatric setting. Therefore, no equivalent readmission measure that is endorsed by a consensus organization is available for use in the IPFQR Program.

For the reasons stated above, we proposed the IPF readmission measure described in this section for the FY 2019 payment determination and subsequent years. We welcomed public comment on this proposal.

Comment: A few commenters supported inclusion of the Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF measure in the IPFQR Program.

Response: We thank the commenters for their support.

Comment: Many commenters recommended that CMS postpone adoption of the 30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF measure until it has been NQF endorsed and risk-adjusted for sociodemographic factors. Several commenters observed that some IPFs treat a disproportionate share of disadvantaged patients, and that sociodemographic factors influence the IPF's ability to manage chronic psychiatric conditions. Other commenters observed that this measure may reflect on community resources, such as availability of outpatient treatment, rather than IPF quality. One commenter asked that CMS provide additional detail on the variables included in the risk-adjustment algorithm for this measure.

Response: We appreciate the commenters' concern for appropriate risk adjustment and NQF endorsement. We note that this measure (MUC15–1082) was included on the ''List of Measures Under Consideration for December 1, 2015'' (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81172*) that is used by the MAP to consider measures for use in CMS programs. The MAP noted the importance of addressing readmissions for patients admitted for psychiatric disorders and conditionally supported this measure for use in the IPFQR Program, pending NQF review, including the examination of SDS risk factors, and endorsement. We refer readers to *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367* (on this site download ''MAP 2015–2016 Preliminary Recommendations'' or ''MAP 2016 Considerations for Implementing Measures Draft Report'') for additional information on the MAP consideration and recommendations.

The 30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF measure was submitted to NQF for consideration on January 29, 2016. As part of the submission, we evaluated the impact and appropriateness of including sociodemographic status (SDS) factors in the risk model; as part of the NQF SDS 2-year trial described earlier. The domains of SDS risk factors that were considered for inclusion in the risk model were income, education, and access to care.

While most SDS risk factors had an association with readmission in the univariate models, it is worth noting that SDS risk factors indicating that a patient resides in a mental health or primary care shortage area were associated with lower risk of readmission, contrary to the commenters concern that readmissions would be increased in these settings. Another noteworthy finding was that the association between readmission and all of the SDS risk factors was attenuated once clinical variables were added to the risk model. Therefore, when we compared the results of a model with both SDS risk factors and clinical risk factors to one with only clinical risk factors we found that the inclusion of SDS risk factors did not improve model performance. Because of the negligible impact on model performance, the complexity of operationalizing variables that utilize census-level data, and concerns about the potential to partially mask a quality signal, these factors were not included in the final risk model for the measure as submitted to the NQF. For more detail about the SDS risk factors that were considered and the results of the analyses we refer readers to the NQF Supplemental Document for this measure, available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2860*.

The NQF Committee met on June 9, 2016 to consider the measure for endorsement. During this meeting, the committee reviewed the measure testing results, which included the SDS evaluation as discussed above, and final measure specifications with adjustment for clinical risk factors. Ninety-five percent of the committee members voted in support of the measure as specified in the final technical report without inclusion of SDS factors in the risk model.[378] Review for a final NQF endorsement decision is anticipated in the fall of 2016. The complete NQF submission with the results of the SDS testing and final technical report is located at the following link: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2860*.

Comment: A few commenters expressed concerns because the measure is not risk-adjusted for involuntary admissions. One commenter recommended that CMS evaluate stratification by IPFs that are designated for involuntary patients and those that are not.

Response: We appreciate the commenters' concerns relating to the impact of involuntary admissions on readmission rates and evaluated this as a risk factor during measure development. Patients admitted involuntarily, as assessed by an indication in the claims data, accounted for 3 percent of all IPF admissions and had a lower unadjusted readmission rate than the general IPF patient population (17 percent compared to 19 percent, respectively). Based on these findings, the measure development expert workgroup,[379] convened by the measure development team, concluded that the ''involuntary'' admission indicator in the claims data does not capture all incidences of involuntary admissions and might, therefore, result in erroneous associations. However, we will take the suggestion to stratify the measure results by IPFs that are and are not designated for involuntary admission into consideration for the future.

Comment: Many commenters recommended that CMS not adopt the 30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF measure citing concerns that inclusion of all-cause readmissions in this measure may unfairly reflect on IPFs for unrelated readmissions and that the inclusion of these readmissions may impact the ability of IPFs to use the measure results for quality improvement. One commenter expressed concern that CMS has not appropriately studied the link between psychiatric admissions and acute care readmissions.

Response: We appreciate the commenters' views. This measure evaluates an all-cause, unplanned readmission rate in order to capture adverse events experienced by patients following discharge from an IPF. There are several reasons to measure both psychiatric and nonpsychiatric readmissions following psychiatric admissions: (1) The measure will encourage improved integration of

[378] The transcript from this discussion is available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=80625*. For information on this measure, see Day 2 of the transcript.

[379] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. (The Technical Report can be downloaded from the ''Inpatient Psychiatric Facility Readmission Measure'' folder).

physical and behavioral health care, which is important for adults living with serious mental illness because they die on average 25 years earlier than the general population, largely due to preventable conditions, such as cardiovascular disease, diabetes, and infectious diseases;[380] (2) readmissions, regardless of cause, are disruptive to patients and their families or caregivers;[381] (3) readmission due to medical conditions may actually be related to the previous psychiatric index admission (for example, a patient may be readmitted for a hip fracture that was caused by adverse effects of psychotropic medications prescribed by the IPF, or a patient with poorly managed depression may neglect management of his/her comorbid diabetes);[382] and (4) the designation of the principal versus secondary diagnosis may be somewhat arbitrary making it difficult to determine if the readmission is related to the previous psychiatric treatment, especially if patients present with complex problems that involve both mental and physical issues (for example, using 2012–2013 Medicare fee-for-service claims data, 93 percent of readmissions to an acute care hospital with a non-psychiatric diagnosis following discharge from an IPF had a secondary diagnosis of mental illness).

Reporting an all-cause readmission rate will provide quality improvement teams within IPFs with a more complete picture of their patients' recovery than if the readmission rate included a more limited set of post-discharge admission events (for example, only psychiatric readmissions). We believe this information would help IPFs improve quality at their facilities.

We also note that we have aligned and harmonized this measure with the Hospital-Wide Readmission measure previously adopted in the Hospital IQR Program to measure all-cause readmissions.[383] This will allow for easier interpretation of measure rates, especially among IPFs that are part of larger hospital systems.

Comment: Several commenters recommended against adoption of the 30-Day All-Cause Unplanned Readmissions Following Psychiatric Hospitalization in an IPF measure citing concerns with the validity of the evidence for this measure. Specifically, they expressed concern that the chronic nature of some psychiatric and substance use disorders may necessitate readmissions within 30 days in some instances. Furthermore, many of these commenters noted that not all strategies to reduce readmissions in Medicare patients are available to this disabled subset of Medicare patients.

Response: We appreciate the commenters' concerns and recognize that some readmissions are unavoidable. However, we note that there have been improvements in all-cause readmission rates among patients admitted to the hospital setting for conditions evaluated by readmission measures adopted by CMS.[384]

While not all interventions to reduce readmissions in the hospital setting may be applicable to this disabled patient population, the evidence supporting processes that can be adopted by IPFs to influence readmission rates in this population is robust and valid. Specifically, we noted several interventions cited in the technical report that were identified from clinical guidelines and systematic reviews of multiple studies[385] involving patients with chronic psychiatric conditions (for example, administering evidence-based treatments to patients with bipolar disorder and discharge planning in mental health). Many of the interventions, such as connecting patients to intensive case management, are specifically targeted toward patients with severe mental disability.

Furthermore, the NQF committee that reviewed this measure in June 2016 agreed that the evidence sufficiently supported this measure with 95 percent of steering committee members in agreement that it passed the ''importance'' criterion, which includes a review of the validity of the evidence.[386]

Comment: One commenter's support for the adoption of the Thirty-Day All-Cause Unplanned Readmissions Following Psychiatric Hospitalization in an IPF measure was contingent on the measure having been tested for validity and reliability.

Response: We tested for validity and reliability as part of the measure development process. We refer readers to the technical report for this measure, which includes a detailed description of the validity and reliability testing. This report can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* (The Technical Report can be downloaded from the ''Inpatient Psychiatric Facility Readmission Measure'' folder.)

Comment: Several commenters requested information about the sample size for the measure and recommended reducing the lag between claims being generated by facilities and public reporting.

Response: Public reporting of claims-based measures requires some lag time to ensure that the measure is calculated on final action claims and includes a long enough timeframe to ensure most facilities have enough cases to calculate reliable measure rates. The readmission measure for the IPFQR Program uses a measurement period of 24 months. Consistent with readmissions measures for other programs, the 30-Day All-Cause Readmission Following Psychiatric Hospitalization in an IPF will be publicly reported on *Hospital Compare* for IPFs that meet a case threshold of 25 cases per measurement period. With a 2-year measurement period, 96 percent of IPFs would have enough cases for public reporting. For comparison, the Hospital-Wide Readmission measure in the Hospital IQR Program, is able to report rates for 96 percent of hospitals with a one-year measurement period.[387]

Comment: Many commenters requested that CMS address how the planned readmission algorithm was adapted for psychiatric patients.

Response: We carefully considered how to identify appropriate planned

[380] Parks J, Svendsen D, Singer P, Foti ME. Morbidity and mortality in people with serious mental illness. 2006 available at: *http://www.nasmhpd.org/sites/default/files/Mortality%20and%20Morbidity%20Final%20Report%208.18.08.pdf.*

[381] Based on evidence provided by patients and caregivers during the measure development process.

[382] Based on evidence provided by technical experts during the measure development process.

[383] This measure was adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528). Technical specifications for this measure are available at: *http://altarum.org/sites/default/files/uploaded-publication-files/Rdmsn_Msr_Updts_HWR_0714_0.pdf.*

[384] Barrett ML, Wier LM, Jiang J, Steiner CA. All-Cause Readmissions by Payer and Age, 2009–2013. HCUP Statistical Brief #199. Rockville, MD: Agency for Healthcare Research and Quality; 2015. *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb199-Readmissions-Payer-Age.pdf.*

[385] For more information on the clinical guidelines and studies, we refer readers to the technical report at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* (The Technical Report can be downloaded from the ''Inpatient Psychiatric Facility Readmission Measure'' folder).

[386] The transcript from this discussion is available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=80625.* For information on this measure, see Day 2 of the transcript.

[387] This measure was adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528). Technical specifications for this measure are available at: *http://altarum.org/sites/default/files/uploaded-publication-files/Rdmsn_Msr_Updts_HWR_0714_0.pdf.*

readmissions following discharge from an IPF. We convened a workgroup of clinical experts to review the existing planned readmission algorithm, which is used by the Hospital-Wide Readmission measure in the acute care setting,[388] which excludes planned procedures and select diagnoses from the readmission outcome, in the context of patients discharged with psychiatric illness. The expert workgroup convened to inform measure development confirmed that the algorithm was appropriate for use in the IPF setting because readmissions for the planned procedures and select diagnoses would also be considered planned among patients discharged with a psychiatric diagnosis in the previous 30 days. The workgroup carefully evaluated electroconvulsive therapy (ECT) (ICD–9–CM 94.26 and 94.27), which is the only potentially planned procedure in the algorithm that is specifically to treat psychiatric conditions and confirmed that it was appropriately categorized as potentially planned by the algorithm. This therapy accounts for over 40 percent of all potentially planned procedures in this patient population.[389] Information on the planned readmission algorithm specifications and testing for use in this measure is located in the technical report at the following link: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Comment: Several commenters expressed concern that CMS would impose a penalty based on performance on the 30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF while not providing adequate financial resources to improve and expand outpatient services.

Response: We understand the commenter's concerns regarding payment policies for treatment of psychiatric illness in the outpatient setting; however, outpatient payment is beyond the scope of this proposed rule. Moreover, the IPFQR Program does not penalize IPFs based on performance; it is a pay for reporting program.

After consideration of the public comments we received, we are finalizing the 30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF measure for the FY 2019 payment determination and subsequent years as proposed.

5. Summary of Finalized Measures for the FY 2018 Payment Determination and Subsequent Years and for the FY 2019 Payment Determination and Subsequent Years

The measures that we have previously finalized for the FY 2018 payment determination and subsequent years are set forth in the table below. We note that this table does not include Screening for Metabolic Disorders, Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647), and Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0648) because we have postponed these measures until the FY 2019 payment determination and subsequent years, as discussed in section VIII.D.2. of the preamble of this final rule.

FINALIZED MEASURES FOR FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure ID	Measure
0640	HBIPS–2	Hours of physical restraint use.
0641	HBIPS–3	Hours of seclusion use.
0560	HBIPS–5	Patients discharged on multiple antipsychotic medications with appropriate justification.
0576	FUH	Follow-Up After Hospitalization for Mental Illness.
1661	SUB–1	Alcohol Use Screening.
1663	SUB–2 and SUB–2a	Alcohol Use Brief Intervention Provided or Offered and the subset measure Alcohol Use Brief Intervention.
1651	TOB–1	Tobacco Use Screening.
1654	TOB–2 and TOB–2a	Tobacco Use Treatment Provided or Offered and the subset measure Tobacco Use Treatment.
1656	TOB–3 and TOB–3a	Tobacco Use Treatment Provided or Offered at Discharge and the subset measure Tobacco Use Treatment at Discharge.
1659	IMM–2	Influenza Immunization.
N/A	N/A	Influenza Vaccination Coverage Among Healthcare Personnel.
N/A	N/A	Assessment of Patient Experience of Care.
N/A	N/A	Use of an Electronic Health Record.

The new measures that we are finalizing for the IPFQR Program for the FY 2019 payment determination and subsequent years are set forth in the table below.

FINALIZED NEW IPFQR PROGRAM MEASURES FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

National quality strategy priority	NQF #	Measure ID	Measure
Effective Treatment and Prevention.	1664	SUB–3 and SUB–3a	SUB–3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB–3a Alcohol & Other Drug Use Disorder Treatment at Discharge.
Communication/Care Coordination.	N/A (Under review for endorsement).	N/A	30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF.

[388] Ibid.

[389] Calculated from Medicare fee-for-service administrative claims data from 2012–2013.

For the IPFQR Program, the total number of measures for the FY 2019 payment determination and subsequent years is 18, as set forth in in the table below.

FINALIZED MEASURES FOR FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure ID	Measure
0640	HBIPS–2	Hours of physical restraint use.
0641	HBIPS–3	Hours of seclusion use.
0560	HBIPS–5	Patients discharged on multiple antipsychotic medications with appropriate justification.
0576	FUH	Follow-Up After Hospitalization for Mental Illness.
1661	SUB–1	Alcohol Use Screening.
1663	SUB–2 and SUB–2a	Alcohol Use Brief Intervention Provided or Offered and the subset measure Alcohol Use Brief Intervention.
1651	TOB–1	Tobacco Use Screening.
1654	TOB–2 and TOB–2a	Tobacco Use Treatment Provided or Offered and the subset measure Tobacco Use Treatment.
1656	TOB–3 and TOB–3a	Tobacco Use Treatment Provided or Offered and the subset measure Tobacco Use Treatment.
1659	IMM–2	Influenza Immunization.
0647	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).**
0648	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).**
N/A	N/A	Screening for Metabolic Disorders.**
0431	N/A	Influenza Vaccination Coverage Among Healthcare Personnel.
N/A	N/A	Assessment of Patient Experience of Care.
N/A	N/A	Use of an Electronic Health Record.
1664	SUB–3 and SUB–3a	Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and the subset measure Alcohol & Other Drug Use Disorder Treatment at Discharge.*
N/A (Under review for endorsement).	N/A	30-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF.*

* New measures finalized for the FY 2019 payment determination and future years.
** Measures previously finalized for the FY 2018 payment determination and subsequent years, but postponed to FY 2019 payment determination and subsequent years through a subregulatory process described in section VIII.D.2. of the preamble of this final rule.

6. Possible IPFQR Program Measures and Topics for Future Consideration

As we have indicated in prior rulemaking (79 FR 45974 through 45975), we seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the IPF setting. Therefore, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25243), we stated that through future rulemaking, we intend to propose new measures for adoption that will help further our goals of achieving better health care and improved health for Medicare beneficiaries who obtain inpatient psychiatric services through the widespread dissemination and use of quality information.

We welcomed public comments on possible new measures.

Comment: One commenter recommended moving to electronic clinical quality measures (eCQMs) to reduce burden on providers.

Response: We agree that moving to eCQMs is important and will ultimately reduce burden. At this time, we are not operationally able to implement eCQM reporting, not all of our measures are electronically specified, and not all IPFs have EHRs for collection of eCQM data. However, we continue to work toward transitioning to electronic eCQMs in the future.

Comment: Several commenters recommended that CMS develop and adopt an additional measure for identifying individuals with substance use disorders. Some of these commenters specifically suggested that CMS evaluate HBIPS–1 for adoption in the IPFQR Program.

Response: We thank these commenters for their suggestions and will consider measures for identifying individuals with substance use disorders, such as the HBIPS–1 measure in the future.

Comment: Many commenters recommended that CMS focus on measures that are meaningful to patients. Some commenters recommended that CMS only adopt measures specifically associated with the primary reasons that patients seek care from an IPF.

Response: We agree with the commenters that the IPFQR Program should focus on measures that are meaningful to patients. However, we continue to believe that there also is value in including measures that are not directly tied to the reason that the patient seeks care from an IPF, such as those reflecting professional standards for quality care or evidence-based factors associated with better outcomes. We also believe that limiting the program to measures that specifically apply to psychiatric services creates a false demarcation between non-psychiatric and psychiatric care, and ignores the broader responsibility of the facility for the overall health of the patient.

Comment: Several commenters requested that CMS consider the tradeoff between burden and clinical value, specifically the measure's usefulness in improving care, when proposing new measures for the IPFQR Program.

Response: When proposing measures for the IPFQR Program, our objective is to balance the need for information on the full spectrum of care delivery with the need to minimize the burden of data collection and reporting. To that end, we focus on measures that evaluate critical processes of care that have significant impact on patient outcomes and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. Because we are sensitive to the need to minimize the burden on IPFs, we address this issue during Technical Expert Panels (TEPs) as part of our measure development process. We also refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR

53645 through 53646) for our considerations for the development and selection of measures for the IPFQR Program.

Comment: Several commenters requested that CMS pursue development of a patient and caregiver perception of care measure focused on the psychiatric patient population.

Response: We thank the commenters for their recommendations. We believe that patient and family engagement measures are important, and we will consider this suggestion as we develop future measures.

Comment: One commenter urged CMS to consider the use of psychiatric scales and instruments which are commonly used in IPF settings and specifically suggested the 24 item Behavior and Symptom Identification Scale (Basis 24).

Response: We thank the commenter for its suggestion and will consider measures related to the use of specific diagnostic or assessment tools, such as the Basis-24 tool [390] in the future.

We thank the commenters for their feedback and suggestions and we will consider them as we develop future policy.

7. Public Display and Review Requirements

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25243 through 25244), we proposed to change to how we specify the timeframes for public display of data and the associated preview period for IPFs to review the data that will be made public.

Under section 1886(s)(4)(E) of the Act, we are required to establish procedures for making the data submitted under the IPFQR Program available to the public. Such procedures must ensure that an IPF has the opportunity to review its data that are to be made public prior to such data being made public. Section 1866(s)(4)(E) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS Web site.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898), we stated that we would publicly display the data submitted by IPFs for the IPFQR Program on a CMS Web site in April of each calendar year following the start of the respective payment determination year. For example, we publicly displayed the data for the FY 2015 payment determination in April 2015. We strive to publicly display data as soon as possible on a CMS Web site, as this provides consumers with healthcare information and furthers our goal of transparency. Therefore, we believe it is best to not specify in rulemaking the exact timeframe for publication, as doing so may prevent earlier publication. We proposed, then, to make these data available as soon as it is feasible. We intend to make the data available on *Hospital Compare* on at least a yearly basis.

We also are required to give each IPF an opportunity to review its data before the data are made public. This purpose of this preview period is to ensure that each IPF is informed of the IPF level data that the public will be able to see for its facility, and to submit measure rate errors resulting from CMS calculations of IPF submitted patient-level claims and Web-based measure numerator and denominator data. It is not for the purpose of correcting an IPF's possible submission errors. As finalized in the 2015 IPF PPS final rule (79 FR 45976), IPFs have the entire data submission period to review and correct claims data element and Web-based measure numerator and denominator count data they have submitted to CMS. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898), we stated that the preview period would be 30 days and would begin approximately 12 weeks prior to the public display of the data.

Because we proposed to make the data for the IPFQR Program available as soon as possible, and the timeframe for publication may change from year-to-year, we proposed to no longer specify the dates for review in rulemaking, nor to specify in rulemaking that the preview period will begin approximately 12 weeks prior to publicly displaying the data. Instead, we proposed to announce the exact timeframes through subregulatory guidance, including on a CMS Web site and/or on our applicable listservs. We also proposed to continue our policy that the time period for review will be approximately 30 days in length.

As noted earlier, we wish to publicly display data as early as possible. For the FY 2017 payment determination, it may be technically feasible for us to display the data as early as December 2016. We previously finalized that the preview period would be 30 days and would be approximately 12 weeks prior to the public display date (in the FY 2014 IPPS/LTCH PPS final rule, 78 FR 50897 through 50898). However, in this case (for the FY 2017 payment determination), 12 weeks prior to December 1, 2016 is in mid-September 2016, which is 2 weeks before the usual effective date of the IPPS/LTCH PPS final rule. Therefore, for FY 2017 only, if it is technically feasible to display the data as early as December 2016, we proposed a 2-week preview period that would start on October 1, 2016. However, as a courtesy, and to give IPFs 30 days for review if they so choose, we proposed to provide IPFs with their data as early as mid-September. The actual dates will be dependent on technical feasibility and will ensure that IPFs have 30 days to preview their data. We believe that this proposal complies with prior policies while still allowing us to display data as soon as possible for the FY 2017 payment determination.

We invited public comment on these proposals.

Comment: Many commenters supported the objective of publicly displaying the data as soon as possible to improve transparency, but requested that CMS clarify that IPFs will continue to have a 30-day preview period. These commenters further requested that CMS clarify how it will ensure there is sufficient time between the preview period and public display to correct any inaccuracies in the data since CMS is no longer providing the approximately 30 day preview period beginning 12 weeks prior to publicly posting the data.

Response: We thank the commenters for their support. As noted above, we are not changing the duration of the preview period from the previously finalized ''approximately 30 days'' and as such we will continue to ensure that IPFs have approximately 30 days to preview their data prior to publication on *Hospital Compare.* As we clarified in the proposed rule (81 FR 25244), the purpose of this preview period is to allow each IPF to see its facility level data prior to that data being made public, not to correct an IPF's possible submission errors. In the event that an IPF identifies measure rate errors resulting from CMS calculations of IPF submitted data, we will ensure that these errors are corrected prior to making the data publicly available.

After consideration of the public comments we received, for the FY 2018 payment determination and subsequent years we are finalizing our proposals to: (1) No longer specify the dates of preview period or data publication in rulemaking; (2) make the data for the IPFQR Program available as soon as possible; (3) announce the exact timeframes through subregulatory guidance, including on a CMS Web site and/or on our applicable listservs; and (4) continue our policy that the time period for review will be approximately

[390] For more information on the Basis-24 tool, we refer readers to the following: *http://www.ebasis.org/basis24.php.*

30 days in length as proposed. For the FY 2017 payment determination only, we are also finalizing our proposal that if it is technically feasible to display the data in December 2016, we would provide data to IPFs for a 2-week preview period that would start on October 1, 2016, as proposed. Moreover, we are finalizing as proposed that as a courtesy, for the FY 2017 payment determination only, if we are able to display the data in December 2016, we would ensure that IPFs have approximately 30 days for review if they so choose by providing IPFs with their data as early as mid-September.

8. Form, Manner, and Timing of Quality Data Submission

a. Procedural and Submission Requirements

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25244), we did not propose any changes to the procedural and submission requirements for the FY 2019 payment determination and subsequent years, and we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50898 through 50899) for more information on these previously finalized requirements.

b. Change to the Reporting Periods and Submission Timeframes

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50901), we finalized requirements for reporting periods and submission timeframes for the IPFQR Program measures. In the FY 2016 IPF PPS final rule, we made one change to these requirements (80 FR 46715 and 46716). We refer readers to these rules for further information.

c. Population and Sampling

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658) and FY 2014 IPPS/LTCH PPS final rule (78 FR 50901 through 50902), we finalized policies for population, sampling, and minimum case thresholds. In the FY 2016 IPF PPS final rule, we made one change to these requirements in finalizing a policy in which IPFs may take one, global sample for all measures for which sampling is permitted (80 FR 46717 through 46719). This policy was adopted to decrease burden on IPFs and streamline policies and procedures. We refer readers to these rules for further information.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25240), we proposed to allow sampling for the SUB–3 and SUB–3a measure. In other words, we proposed to include the SUB3 and SUB–3a measure in the list of measures covered by the global sample. We refer readers to section VIII.D.4.a. of the preamble of this final rule where we finalize our proposal to include both SUB–3: Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and subset measure SUB–3a: Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664) in the list of measures covered by the global sample for the FY 2019 payment determination and subsequent years as proposed.

d. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25244), we did not propose any changes to the DACA requirements, and we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658) for more information on these requirements.

9. Reconsideration and Appeals Procedures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53660), we adopted a reconsideration and appeals process, later codified at 42 CFR 412.434, by which an IPF can request a reconsideration of its payment update reduction if an IPF believes that its annual payment update has been incorrectly reduced for failure to meet all IPFQR Program requirements and, if dissatisfied with a decision made by CMS on its reconsideration request, may file an appeal with the Provider Reimbursement Review Board. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25244), we did not propose any changes to the Reconsideration and Appeals Procedure and refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53660) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50953) for further details on the reconsideration process.

10. Exceptions to Quality Reporting Requirements

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25244), we did not propose any changes to the exceptions to quality reporting requirements. For more information, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660), where we initially finalized the policy as ''Waivers from Quality Reporting,'' and the FY 2015 IPF PPS final rule (79 FR 45978), where we renamed the policy as ''Exceptions to Quality Reporting Requirements.''

E. Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals (CAHs) Participating in the EHR Incentive Programs in 2017

1. Background

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record (EHR) technology (CEHRT). Eligible hospitals and CAHs may qualify for these incentive payments under Medicare (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrate meaningful use of CEHRT, which includes reporting on clinical quality measures (CQMs) using CEHRT.

Sections 1886(b)(3)(B) and 1814(l) of the Act also establish downward payment adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Section 1903(a)(3)(F)(i) of the Act establishes 100 percent Federal financial participation (FFP) to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade and meaningfully use CEHRT.

Under sections 1886(n)(3)(A) and 1814(l)(3)(A) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on CQMs selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare EHR Incentive Program. The set of CQMs from which eligible hospitals and CAHs will report under the EHR Incentive Program beginning in FY 2014 is listed in Table 10 of the EHR Incentive Program Stage 2 final rule (77 FR 54083).

In order to further align CMS quality reporting programs for eligible hospitals and CAHs and avoid redundant or duplicative reporting among hospital programs, the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 (hereinafter referred to as the 2015 EHR Incentive Programs Final Rule) [391] (80 FR 62890) indicated our intent to address CQM reporting requirements for the Medicare and

[391] Medicare and Medicaid Programs: Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; final rule (80 FR 62761 through 62955) (''2015 EHR Incentive Programs Final Rule'').

Medicaid EHR Incentive Programs for eligible hospitals and CAHs for 2016, 2017, and future years in the IPPS rulemaking. We believe that receiving and reviewing public comments for various CMS quality programs at one time while simultaneously finalizing the requirements for these programs would provide us with an opportunity to better align these programs for eligible hospitals and CAHs, allow more flexibility within the Medicare and Medicaid EHR Incentive Programs, and add overall value and consistency. To further achieve this goal, the 2015 Edition final rule (80 FR 62652) published by ONC indicated that it would address certification policy regarding the reporting of CQMs for eligible hospitals and CAHs in or in conjunction with the annual IPPS rulemaking to better align with the reporting goals of other CMS programs.

2. CQM Reporting for the Medicare and Medicaid EHR Incentive Programs in 2017

a. Background

In the EHR Incentive Program Stage 2 final rule, we outlined the CQMs available for use in the EHR Incentive Programs beginning in 2014 for eligible hospitals and CAHs in Table 10 at 77 FR 54083 through 54087. In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25245), we proposed to maintain the existing requirements established in earlier rulemaking for the reporting of CQMs under the EHR Incentive Programs in 2017, unless otherwise indicated in the proposed rule. These requirements include reporting on 16 CQMs covering at least 3 NQS domains for eligible hospitals and CAHs (77 FR 54079). We noted in the proposed rule (81 FR 25245) that the proposals would apply to both the Medicare and Medicaid EHR Incentive Programs, with the exception of the submission period proposed policy.

As we expect to expand the current measures to align with the National Quality Strategy and the CMS Quality Strategy [392] and incorporate updated standards and terminology in current CQMs, including updating the electronic specifications for these CQMs, and creating de novo CQMs, we plan to expand the set of CQMs available for reporting under the EHR Incentive Programs in future years. We will continue to engage stakeholders to provide input on future proposals for CQMs as well as request comment on future electronic specifications for new and updated CQMs.

In addition, we are transitioning from the quality data model (QDM) expression language to the clinical quality language (CQL) specification, which defines a representation for the expression of clinical knowledge that can be used within both the clinical decision support (CDS) and CQM domains. The QDM logic expression is tightly coupled to the QDM logic model and based on capabilities of the health level 7 (HL7) reference information model (RIM), an object model which does not have significant ability to express mathematical logic such as addition, subtraction, division, and multiplication. The QDM logic expression requires multiple, often repetitious lines of logic to compare relationships among different activities, usually by indicating the time of one activity with the time of the other activity. Also, software cannot easily parse QDM logic directly from the Healthcare Quality Measures Format (HQMF), the HL7 standard for representing a clinical quality measure as an electronic document. Using QDM logic expression in HQMF often require significant human interaction and interpretation to program or configure software, such as EHRs, to calculate a measure. In general, the CQL is a mathematical expression language that can be parsed by software to calculate results, without needing human interpretation to implement the expressed logic. The CQL includes basic math and allows description of relationship among activities in a simple, direct manner, which significantly reduces the lines of logic. With a modest effort, it represents a change that is straightforward to learn and interpret compared to the existing QDM logic statements.

The CQL specification defines two components: CQL—author-friendly domain specific language; and expression logical model—computable extensible markup language (XML). The CQL leverages best practices and lessons learned from the quality data model, health e-decisions, and electronic CQM and clinical decision support (CDS) communities. The CQL is designed to work with any data model, more expressive and robust than the QDM logic, and is a HL7 draft standard for trial use (DSTU). The CQL includes: Datatypes; data retrieval and queries; timing phrases and operators; variable and function declaration; input parameters with default values; conditional logic, Boolean logic, and value comparison; simple arithmetic and aggregate functions; operations on value sets, lists, intervals, sets and dates/times; and shared libraries. We anticipate the incorporation of the CQL into the CQM electronic specifications as we support the development and testing of this standard. We anticipate starting this work effort in 2016 with the expectation that extensive development and testing will continue, at minimum, through the fall of 2017. We will not implement CQL until the development and testing phases show success for utilization with the CQMs. We are engaging the participation of hospitals and other providers, health IT developer, measure developer, and other stakeholder communities as we undertake this effort at all stages of development and testing. For further information, we refer readers to the eCQI Resource Center Web page (*https://ecqi.healthit.gov/*).

b. CQM Reporting Period for the Medicare and Medicaid EHR Incentive Programs in CY 2017

In the 2015 EHR Incentive Programs Final Rule (80 FR 62892 through 62893), beginning in CY 2017 and for subsequent years, we established a CQM reporting period of one full calendar year (consisting of four quarterly data reporting periods) for CQM reporting for eligible hospitals and CAHs participating in the Medicare and Medicaid EHR Incentive Programs, with a limited exception for providers demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program, for whom the CQM reporting period is any continuous 90-day period within the calendar year. We believe that one full calendar year of data will result in more complete and accurate data. Providers will be able to submit one full calendar year of data for both the EHR Incentive Program and the Hospital IQR Program, thereby reducing the reporting burden. We continue to assess electronically submitted data for accuracy and reliability. If data are determined to be flawed, such data will be identified by CMS in order to preserve the integrity of data used for differentiating performance.

We also established a reporting period for CQMs of any continuous 90-day period within CY 2017 for eligible hospitals and CAHs that are demonstrating meaningful use for the first time in either the Medicare or Medicaid EHR Incentive Programs (80 FR 62892 through 62893). In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25245 through 25246), we proposed the following submission periods for the Medicare EHR Incentive Program, as well as requirements for eligible

[392] Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

hospitals and CAHs reporting CQMs electronically.

• Eligible hospitals and CAHs Reporting CQMs by Attestation:

++ For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2017, the reporting period is any continuous 90-day period within CY 2017. The submission period for attestation is the 2 months following the close of the calendar year, ending February 28, 2018.

++ For eligible hospitals and CAHs that demonstrated meaningful use in any year prior to 2017, the reporting period is the full CY 2017 (consisting of four quarterly data reporting periods). The submission period for attestation is the 2 months following the close of the calendar year, ending February 28, 2018.

• Eligible hospitals and CAHs Reporting CQMs Electronically: For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2017 or that have demonstrated meaningful use in any year prior to 2017, the reporting period is the full CY 2017 (consisting of four quarterly data reporting periods). The submission period for reporting CQMs electronically is the 2 months following the close of the calendar year, ending February 28, 2018.

In regard to the Medicaid EHR Incentive Program, we provide States with the flexibility to determine the submission periods for reporting CQMs.

For the reporting period in CY 2017, we did not propose new CQMs. However, section 1886(n)(3)(B)(iii) of the Act requires that, in selecting measures for eligible hospitals and CAHs for the Medicare EHR Incentive Program, and establishing the form and manner for reporting measures, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under section 1886(b)(3)(B)(viii) of the Act, the Hospital IQR Program. In the interest of avoiding redundant or duplicative reporting with the Hospital IQR Program, we proposed to remove 13 CQMs from the set of CQMs available for eligible hospitals and CAHs to report for the EHR Incentive Programs, beginning with the reporting periods in CY 2017. We proposed to remove such measures for both the Medicare and Medicaid EHR Incentive Programs.

We anticipate that this coordinated reduction in the overall number of CQMs reported electronically in both the Hospital IQR and the Medicare and Medicaid EHR Incentive Programs would reduce the challenges associated with electronic reporting for hospitals and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of electronic CQMs. For the list of measures we proposed to remove from the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs, as well as the rationale in support of our proposals to remove these measures, we refer readers to the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25175 through 25178). All of the remaining measures listed in Table 10 of the EHR Incentive Program Stage 2 final rule (77 FR 54083 through 54087) would be available for eligible hospitals and CAHs to report for the Medicare and Medicaid EHR Incentive Programs. From that available set of measures, we proposed the following reporting criteria for eligible hospitals and CAHs beginning with the reporting periods in CY 2017:

• For attestation: If only participating in the EHR Incentive Program, report on all 16 available CQMs.

• For electronic reporting—

++ If only participating in the EHR Incentive Program, report on 15 of the 16 available CQMs (among the 16 available CQMs, the Outpatient Quality Reporting (OQR) Program CQM (Emergency Department (ED)–3, NQF 0496) is not required to be reported on for electronic reporting, in which 15 of the 16 available CQMs can be selected to meet this reporting requirement); or

++ If participating in the EHR Incentive Program and the Hospital IQR Program, report on all 15 available CQMs (the electronic reporting of the Outpatient Quality Reporting (OQR) Program CQM (ED–3, NQF 0496) is not applicable when reporting on CQMs for both programs, which results in the reporting of 15 available CQMs).

We also considered an alternative proposal to require eligible hospitals and CAHs to select and report electronically on 8 CQMs for the reporting periods in CY 2017 and all available CQMs beginning with the reporting periods in CY 2018, which was further outlined in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25195). We noted our intent is to align, to the extent possible, the EHR Incentive Program reporting requirements with the Hospital IQR Program reporting requirements established in this final rule. We believe that the alignment of these programs will serve to reduce hospital reporting burden and encourage the adoption and meaningful use of CEHRT by eligible hospitals and CAHs. We invited public comment on these proposals.

Comment: Many commenters did not support the proposed requirement that hospitals report a full year of CQM data because of the burden it would impose on hospitals. One commenter indicated that the increase would be four times greater than previous years and would cause increased difficulties for hospitals transitioning to a new EHR system. Some commenters expressed concern that the increase in the volume of information being reported might increase susceptibility to inaccurate data. Commenters noted that EHR vendors are still struggling to overcome the barriers encountered during the first year of CQM reporting because designing, building, reviewing, and testing that takes place between hospitals and vendors is extremely expensive and extensive. Commenters also expressed concern that this effort will take resources away from true quality improvement efforts. One commenter acknowledged that once a CQM is in place, it can continue to gather data beyond implementation, but expressed concern regarding the ability of EHR vendors and health care providers to have all CQMs in place by January 1, 2017. The commenter suggested that CMS continue the current reporting period of one of the two final quarters of the reporting year.

Several commenters specifically expressed concern that the time period between when the final rule is published and the beginning of the CY 2017 reporting period is too short to make the appropriate health IT and workflow adjustments to accommodate transmission of a full year of CQM data. One commenter noted that requiring hospitals to submit a full year of CQM data for the CY 2017 reporting period would require hospitals to begin data collection on a full year of data prior to completion of the first deadline to report only one quarter of data which is February 28, 2017. Another commenter questioned whether CMS has considered its ability to receive data submissions for hundreds of thousands of cases from hospitals within a two-month period (January 1 through the February 28).

A few commenters expressed concern with the proposals to align the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program because there are differences in the available and required number of CQMs for reporting between the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs, particularly relating to the reporting of CQMs electronically (a full year) or by attestation (any continuous 90-day period) under the EHR Incentive Programs. One commenter encouraged CMS to change the CQM reporting period for both Hospital IQR Program and the Medicare

and Medicaid EHR Incentive Programs in CY 2017 to a 90-day period reflecting the proposed reporting period for attestation under the Medicare and Medicaid EHR Incentive Programs.

Response: We appreciate the commenters' concerns that reporting a full year of CQM data may impose a greater burden on hospitals than reporting one quarter of CQM data, but in response to the commenter's concern that the increase would be four times greater than previous years and would cause increased difficulties for hospitals transitioning to a new EHR system, we disagree. We believe that the burden associated with submitting a full year of CQM data will not be substantially greater than the burden associated with submitting a single quarter of data. Once CQMs are properly certified and mapped to successfully collect data for one quarter, collecting data for an additional 3 quarters should not require much additional burden. We believe that electronic reporting is an important step in the use of CEHRT, in which a full year reporting period that consists of data for four quarterly reporting periods is a critical component to making progress in electronic reporting.

In response to concerns that the reporting of a full year (consisting of four quarterly data reporting periods) of CQM data would cause the CMS receiving system to be susceptible to inaccurate data due to an increased volume of submitted CQM data, we believe that accuracy will be improved over time by assessing an increased volume of CQM data. Through the assessment of more data, we are able to identify and address issues surrounding CQM data more quickly. We continue to assess electronically submitted data for accuracy and reliability. If data are determined to be flawed, such data will be identified by CMS in order to preserve the integrity of data used for differentiating performance. We believe that, with the advancement of technology and the use of electronic measures, even more precise, accurate, and reliable data will be captured for analysis.

We appreciate commenters sharing their concerns about the challenges associated with electronic reporting, including the significant expenditure of resources required to make necessary changes to health IT systems, documentation or utilization of EHRs, and workflow process changes. We encourage eligible hospitals and CAHs to continue refining their electronic reporting implementation activities to successfully achieve electronic data capture and reporting despite mapping and integration issues or to work with their vendors to do so. We acknowledge commenters' concerns about the timing of the publication of the final rule in relation to the CY 2017 reporting period, and encourage early testing and the use of presubmission testing tools to reduce errors and inaccurate data submissions in CQM reporting. As time passes, we expect that hospitals will continue to build and refine their EHR systems and gain more familiarity with reporting CQM data, resulting in more accurate data submissions with fewer errors. We believe that the best way to encourage eligible hospitals and CAHs to invest in improving their EHR systems is by requiring reporting of additional CQMs.

In response to concerns regarding the ability of the our receiving systems to receive the significant volume of data submissions during the 2-month submission period, we have worked to continually develop and improve our CQM receiving system and are working to ensure that the infrastructure is in place to receive the full volume of CQM data submissions from eligible hospitals and CAHs by the February 28, 2018 deadline for the CY 2017 reporting period.

We disagree with commenters that a 90-day reporting period should apply for all eligible hospitals and CAHs, regardless of the reporting method (electronic reporting or attestation) or whether they have successfully demonstrated meaningful use in a prior year. While we are allowing a reporting period of any continuous 90-day period for eligible hospitals and CAHs reporting CQMs by attestation that demonstrate meaningful use for the first time in CY 2017, we believe a full-year reporting period (consisting of four quarterly data reporting periods) is appropriate for eligible hospitals and CAHs that have demonstrated meaningful use in a prior year, as well as for all eligible hospitals and CAHs that choose to report electronically regardless of whether they have previously demonstrated meaningful use.

Comment: As an alternative to the annual reporting of a full year of CQM data, a few commenters suggested that CMS require quarterly submission of the CQM data, with submission being required four-and-a-half months after the end of the reporting quarter to align the electronic submission requirements with the Hospital IQR Program chart-abstracted reporting requirements and with other quality reporting programs, such as the SNF Quality Reporting Program and meaningful use, to ensure sufficient time for providers to final-bill code all cases for a reporting quarter before being required to generate QRDA files for submission to CMS, and to alleviate pressure on providers, vendors, and the QualityNet team to put together and submit the required information for electronic CQM data submission. A few commenters noted that upgrading to a new edition of certified EHR technology during the same reporting period (CY 2017) that would require hospitals report a full year of CQM data could pose additional implementation difficulties. One commenter expressed the opinion that quarterly reporting would reduce the volume of data that vendors and CMS must process at one time, give providers more frequent benchmarking of their performance on these measures, and make the timing of electronic reporting consistent with reporting of chart-abstracted measures.

Response: We thank commenters for their suggestions and acknowledge their concerns regarding a two-month timeframe allotted for submitting a full year of CQM data. We agree with commenters that there may be advantages with an extended submission period, therefore, in this final rule, we are finalizing a modification to the proposed submission period regarding the electronic reporting of CQMs. We anticipate that following the close of the CMS data receiving system for the CY 2016 reporting period, we will re-open the system in late spring 2017 to be able to receive both QRDA I test files and QRDA I production files for the CY 2017 reporting period (consisting of four quarterly reporting periods). We believe that a longer submission period will provide eligible hospitals and CAHs with the flexibility to submit a full year of CQM data quarterly, bi-annually, or annually. This greater flexibility will allow eligible hospitals, CAHs, and vendors the flexibility to submit QRDA I files as soon as each calendar quarter ends, rather than waiting to submit all QRDA I files during the last two months of the submission period. We encourage all eligible hospitals, CAHs, and vendors to submit QRDA I files early, as well as to use one of the presubmission testing tools for electronic reporting, such as the CMS Pre-Submission Validation Application (PSVA), to allow additional time for testing and to make sure all required data files are successfully submitted by the deadline. The PSVA can be downloaded from the Secure File Transfer (SFT) section of the QualityNet Secure Portal at: *https://cportal.qualitynet.org/QNet/pgm_select.jsp.* We refer readers to section VIII.A.11.b.(4) of the preamble of this of this final rule for more information about the PSVA.

Comment: The majority of commenters supported the proposed removal of 13 CQMs from the EHR Incentive Programs beginning in CY 2017 in an effort to move quality measurement toward outcomes measures. Many commenters stated their belief that these measures were topped out, and that the measures' complexity could not be captured in an electronic form. A number of commenters also stated their belief that the CQM measure specifications were not feasible to implement. Others noted removing these measures would decrease administrative burden, minimize confusion among providers and provide alignment among the Hospital IQR Program the EHR Incentive Programs.

Response: We thank the commenters for their support of our proposal to remove 13 CQMs in an effort to move quality measurement toward outcomes measures. Therefore, for the reasons stated in section VIII.A.3.b.(3) of the preamble of this final rule, we are finalizing our proposal to remove the 13 CQMs beginning with the reporting periods in CY 2017.

Comment: Several commenters supported CMS' efforts to reduce reporting burden on hospitals, but expressed concern with the timeline of the proposal to remove 13 CQMs for CY 2017 because hospitals may need time to adjust workflows and work with health IT vendors to add support for measures not previously supported and ensure valid CQMs are submitted. Commenters encouraged CMS to consider the time, effort, and resources expended on reporting on these measures when deciding to remove them from the EHR Incentive Programs. One commenter noted that EHR vendors will phase out support for these measures and clinicians may become skeptical about benefits to workflow changes related to future measures if measures are continuously added and removed. Another commenter urged CMS to provide more lead time for the removal of measures that hospitals have dedicated so many resources to developing and implementing. Specifically, the commenter requested that for CY 2017, CMS maintain the current requirements of reporting four CQMs out of the current list of 28, in order to give hospitals more time to plan and prepare for implementation of additional CQMs in future years.

Response: We understand the commenters' concern with removing CQMs that have been previously reported and implemented in an existing EHR workflow, and we acknowledge the time, effort, and resources that hospitals expend on reporting on these measures. However, our decision to remove measures from the EHR Incentive Program and the Hospital IQR Program is an extension of our programmatic goal to continually refine the measure set and ensure that it consists of quality performance standards. We believe that a reduction in the overall number of CQMs reduces certification burden on eligible hospitals and CAHs and improves the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of CQMs.

We encourage eligible hospitals and CAHs that retain vendors to work closely together to ensure that a contract is in place which supports the hospital's quality reporting requirements and the annual update of quality measures. Also, we encourage eligible hospitals and CAHs to continue refining their electronic reporting implementation activities to successfully achieve electronic data capture and reporting despite mapping and integration issues or to work with their vendors to do so. We encourage early testing and the use of presubmission testing tools to reduce errors and inaccurate data submissions in CQM reporting. We will work to provide hospitals with the education, tools, and resources necessary to enhance their workflows to more seamlessly account for the removal or addition of CQMs.

Comment: A few commenters suggested that topped-out measures should not be removed from the Medicare and Medicaid EHR Incentive Programs measure set. One commenter opposed the proposal to remove the CQMs that are topped out, stating that the measures should not be retired until the CQM reporting process has matured. The commenter further stated that allowing hospitals the option to electronically report topped-out measures would provide them with an opportunity to test the accuracy of their EHR reporting systems. Another commenter requested that any topped-out CQM that is removed from the EHR Incentive Programs be kept on reserve so that performance can be monitored as necessary to ensure that performance and/or adherence to best practices do not decline. In addition, the commenter suggested that an alternative use of topped-out measures is inclusion as components of composite measures. A commenter recommended that CMS implement a periodic auditing system of measures designated as topped-out. The commenter expressed the opinion that such a system would ensure that performance remains satisfactorily high and also detect reductions in the quality of care.

Response: While we recognize the benefit of continuing the inclusion of topped-out measures until the CQM reporting process has further matured or for the assurance that performance remains satisfactorily high and the ability to detect reductions in the quality of care, retaining such measures in the Medicare and Medicaid EHR Incentive Programs measure set or as part of components of composite measures, or implementing a periodic auditing system of topped-out measures requires the maintenance of the topped-out measures. We must balance the costs of continued monitoring of a successful measure with high levels of performance with the adoption of other measures where there are opportunities for improvement in clinical quality.

Comment: A few commenters did not support the removal of measures because it may hinder on-going measurement and reduce performance improvements. One commenter requested that CMS maintain a library of measures that are not included in the program so that vendors and hospitals can still support monitoring and improving these removed measures.

Response: We disagree with commenters that the removal of these measures may hinder measurement and reduce performance improvement. Although eligible hospitals and CAHs are not reporting data for measures that have been removed from the Hospital IQR Program and EHR Incentive Programs, if the CQM specifications are maintained by the measure developer, eligible hospitals and CAHs are encouraged to continue to monitor data for their own efforts to improve quality. We appreciate the commenter's suggestion to maintain a library of CQMs that have been removed and will take it into consideration.

Comment: Several commenters did not support the proposed requirement that hospitals report on all CQMs in the Medicare and Medicaid EHR Incentive Programs because of concerns about general feasibility, accuracy, validity, and reliability of electronically-submitted measures. Several commenters suggested that CMS consider amending the proposal to require an addition of 2 to 4 CQMs to the CY 2016 required number of CQMs, which would require the reporting a total of 6 to 8 CQMs for the CY 2017 reporting period. A few commenters suggested an incremental approach requiring only 8 CQMs for two quarters for the first increase. Other commenters requested that CMS retain the current requirement of 4 CQMs until hospitals

have successfully operationalized reporting complete and accurate data on existing required CQMs before adding new measures. Commenters indicated that EHR vendors are not prepared for the functional and operational demands of an increase in CQM reporting. Further, commenters argued that requiring hospitals to collect electronic data for measures that still have flawed specifications and/or for services the hospitals do not provide is inefficient and burdensome. One commenter also noted that the CQM specifications have flaws that prove challenging with current clinical workflows, given how EHRs track orders and documentation and in some cases the measure specifications do not accurately measure the quality of care delivered, absent the development of manual workarounds that divert time and resources from patient care. These commenters recommended delaying any mandatory reporting of CQMs until these concerns are resolved.

Commenters also expressed concern that CQM data submission to CMS has not been fully tested at this point and recommended that expanding the required number of CQMs should be delayed until there has been successful transmission of data. Commenters noted that the infrastructure and reporting functionality for CQMs are not mature enough to facilitate mandatory electronic reporting for hospitals. Commenters recommended that CMS continue outreach to EHR vendors, hospital quality staff, and other affected stakeholders to identify and address structural problems prior to increasing the number of required CQMs.

Response: We believe that increasing the requirements for hospitals to report measures electronically is in line with our goals to make progress towards eventual electronic reporting on all CQMs in the Medicare and Medicaid EHR Incentive Programs. Retaining the reporting requirements from CY 2016 would not be in alignment with our goal to move toward the electronic reporting of all available CQMs. Eligible hospitals and CAHs have been engaged in the process of reporting CQM data electronically for the EHR Incentive Programs and Hospital IQR Program for several years (three years of pilot reporting and three years of voluntary reporting). However, we recognize the challenges associated with electronic reporting and encourage eligible hospitals and CAHs to continue refining their electronic reporting implementation activities and work with their vendors to achieve electronic capture and reporting despite mapping and integration issues. We encourage eligible hospitals and CAHs to work closely with their vendors to ensure that a contract is in place which supports the hospital's quality reporting requirements and the annual update of those measures. Reliable, accurate data and the engagement of electronic reporting are critical to advancing our goal of increasing the electronic reporting of CQMs. We recognize the importance of having feasible and accurate measure data and in order to readily identify issues, we need to assess more data. We believe that, with the advancement of technology and the use of electronic measures, even more precise, accurate, and reliable data will be captured for analysis.

In response to the commenters' concerns relating to vendors not being prepared for the functional and operational demands of an increase in CQM reporting, we note that CQM electronic specifications are posted at least 6 months prior to the start of the reporting period, and well in advance of the submission window. We believe this timeframe allows an adequate amount of time for vendors to make those updates while ensuring that the CQMs are still current and clinically valid once implemented.

We appreciate commenters sharing their concerns regarding flaws with measure specifications, the maturity of infrastructure and reporting functionality for CQMs, and CMS testing of CQM data submission. We note that measure specifications are updated routinely to account for changes, including, but not limited to, changes in billing and diagnosis codes and changes in medical practices. In order for CQMs to remain current and clinically valid, the specifications must be updated on a regular basis. We disagree with commenters that CQM reporting should be delayed until agreement is achieved regarding the maturity of CQM specifications. We believe that CQMs have matured since their inception, and any delay in the CQM reporting requirements would inhibit progress toward the eventual electronic reporting of all CQMs for the Medicare and Medicaid EHR Incentive Programs.

In this final rule, we are adopting a modification of our proposal and requiring the reporting of only 8 CQMs for eligible hospitals and CAHs that choose to report electronically, in response to commenters' suggestion of incrementally increasing the reporting requirements. We believe that this modification balances the concerns raised by commenters while simultaneously advancing our goal of increased CQM electronic reporting. While the number of CQMs required to report increases from 4 CQMs (as established for the CY 2016 reporting period) to 8 CQMs for the CY 2017 reporting period, we believe that a coordinated reduction in the overall number of CQMs in both the Hospital IQR Program (from 28 to 15 available CQMs) and Medicare and Medicaid EHR Incentive Programs (from 29 to 16 available CQMs) will reduce certification burden on hospitals and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of CQMs. It is one of our goals to expand electronic reporting in the Medicare and Medicaid EHR Incentive Programs. We intend to introduce additional CQMs into the Medicare and Medicaid EHR Incentive Programs as CQMs that support the programs goals become available.

After consideration of the public comments we received, we are finalizing the following policies. We are finalizing a modification to our proposal regarding the number of CQMs required for eligible hospitals and CAHs that report electronically for the Medicare and Medicaid EHR Incentive Programs and will require reporting on 8 CQMs beginning with the CY 2017 reporting period, which eligible hospitals and CAHs may select from the set of available CQMs listed in the table below. We are finalizing as proposed the removal of 13 CQMs from the set of CQMs available for eligible hospitals and CAHs to report for the Medicare and Medicaid EHR Incentive Programs, beginning with the reporting periods in CY 2017. For the list of CQMs we are removing, we refer readers to section VIII.A.3.b.(3) of the preamble of this final rule. All 16 of the remaining measures listed in Table 10 of the EHR Incentive Program Stage 2 final rule (77 FR 54083 through 54087) are available for eligible hospitals and CAHs to report for the Medicare and Medicaid EHR Incentive Programs. The following table lists the remaining 16 CQMs available for eligible hospitals and CAHs to report for the Medicare and Medicaid EHR Incentive Programs beginning in CY 2017.

CQMS FINALIZED FOR ELIGIBLE HOSPITALS AND CAHS BEGINNING WITH CY 2017

Short name	Measure name	NQF #
	Electronic Clinical Quality Measures (eCQMs)	
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163
ED–3	Median Time from ED Arrival to ED Departure for Discharged ED Patients	0496
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	+
ED–1*	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2*	Admit Decision Time to ED Departure Time for Admitted Patients	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
PC–01	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure)	0469
PC–05	Exclusive Breast Milk Feeding***	0480
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
STK–08	Stroke Education	+
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372

+ NQF endorsement has been removed.

The CQM reporting periods in CY 2017 for the Medicare and Medicaid EHR Incentive Programs are set out below. For the Medicare EHR Incentive Program, we are finalizing the proposed submission periods for eligible hospitals and CAHs reporting CQMs by attestation and are finalizing with modification the proposed submission periods for eligible hospitals and CAHs electronically reporting CQMs. We are providing States with the flexibility to determine the submission periods for reporting CQMs for their Medicaid EHR Incentive Program.

• Eligible hospitals and CAHs Reporting CQMs by Attestation:

++ For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2017, the reporting period is any continuous 90-day period within CY 2017. The submission period for attestation is the 2 months following the close of the calendar year, ending February 28, 2018.

++ For eligible hospitals and CAHs that demonstrated meaningful use in any year prior to 2017, the reporting period is the full CY 2017 (consisting of four quarterly data reporting periods). The submission period for attestation is the 2 months following the close of the calendar year, ending February 28, 2018.

• Eligible hospitals and CAHs Reporting CQMs Electronically: For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2017 or that have demonstrated meaningful use in any year prior to 2017, the reporting period is the full CY 2017 (consisting of four quarterly data reporting periods). The submission period for reporting CQMs electronically begins in late spring 2017 and continues through the 2 months following the close of the calendar year, ending February 28, 2018.

As we continue to align the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program, we are finalizing the same number of CQMs to be reported electronically for both programs. However, we are finalizing a policy under which eligible hospitals and CAHs reporting electronically will be required to report on 8 available CQMs. Thus, in this final rule, we are finalizing a modified version of our proposed reporting criteria regarding the number of CQMs eligible hospitals and CAHs are required to report electronically, starting with the reporting periods in CY 2017:

• For attestation: If only participating in the EHR Incentive Program, report on all 16 available CQMs.

• For electronic reporting: If only participating in the EHR Incentive Program, or participating in both the EHR Incentive Program and the Hospital IQR Program, report on 8 of the available CQMs.

For CY 2018 and future calendar years, we plan to continue to align the CQM reporting requirements for the Medicare and Medicaid EHR Incentive Programs with the Hospital IQR Program reporting requirements established in this final rule and future rules.

c. CQM Reporting Form and Method for the Medicare EHR Incentive Program in 2017

As finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759 through 49760), we removed the QRDA–III as an option for reporting under the Medicare EHR Incentive Program for eligible hospitals and CAHs. For the reporting periods in 2016 and future years, we are requiring QRDA–I for CQM electronic submissions for the Medicare EHR Incentive Program. As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49760), States would continue to have the option, subject to our prior approval, to allow or require QRDA–III for CQM reporting.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49578 through 49579), we established the following options for CQM submission for eligible hospitals and CAHs in the Medicare EHR Incentive Program for the reporting periods in 2017:

• Eligible hospital and CAH options for Medicare EHR Incentive Program participation *(single program participation)*—

++ Option 1: Attest to CQMs through the EHR Registration & Attestation System; or

++ Option 2: Electronically report CQMs through QualityNet Portal.

• Eligible hospital and CAH options for electronic reporting for multiple programs *(for example, EHR Incentive Program plus Hospital IQR Program participation)*—electronically report through QualityNet Portal.

As stated in the 2015 EHR Incentive Programs Final Rule (80 FR 62894), in 2017, eligible hospitals and CAHs have two options to report CQM data, either through attestation or use of established methods for electronic reporting where feasible. However, starting in 2018, eligible hospitals, and CAHs participating in the Medicare EHR Incentive Program must electronically report CQMs using CEHRT where feasible; and attestation to CQMs will no longer be an option except in certain

circumstances where electronic reporting is not feasible. Therefore, we encourage eligible hospitals and CAHs to begin electronically reporting CQMs as soon as feasible.

For the Medicaid EHR Incentive Program, States will continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or if they wish to allow reporting through attestation. Any changes that States make to their CQM reporting methods must be submitted through the State Medicaid Health IT Plan (SMHP) process for CMS review and approval prior to being implemented.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25246 through 25247), we proposed to continue our policy that electronic submission of CQMs will require the use of the most recent version of the CQM electronic specification for each CQM to which the EHR is certified. In the event that an eligible hospital or CAH has certified EHR technology that is certified to the 2014 Edition and not certified to all 16 CQMs that would be available for reporting in 2017 under our proposals, we proposed to require that an eligible hospital or CAH would need to have its EHR technology certified to all such CQMs in order to meet the reporting requirements for 2017. For electronic reporting in 2017, this means eligible hospitals and CAHs would be required to use the Spring 2016 version of the CQM electronic specifications available on the eCQI Resource Center Web page (*https://ecqi.healthit.gov/*). We solicited public comment on this proposal.

Comment: One commenter expressed concern that the vendor community will not have adequate time to deliver the updated products to the market in time for all providers to meet the reporting requirements for CY 2107, which would require use of EHR technology certified to the 2015 Edition. The commenter explained that the proposed changes in CQM reporting necessitates sufficient time for vendors and providers to test and deploy CEHRT. The commenter acknowledged that measures need to evolve, but stated that a balance needs to be reached such that the churn around development and deployment is not endless. Therefore, the commenter urged CMS to make greater strides to enact a ''predictable'' cycle from measure development to provider data submission.

Response: We believe requiring use of the most recent version of the CQM electronic specification for each CQM is important in allowing us to collect relevant clinical and electronic data. We note that the commenter's statement regarding the use of EHR technology certified to the 2015 Edition is not accurate and clarify that CMS proposed to accept the use of EHR technology certified to the 2014 or 2015 Edition for CQM reporting in 2017. We further note that, consistent with prior policy, a provider may continue to use their current certified health IT module for CQMs as an EHR certified for CQMs under the 2014 Edition certification criteria and it does not need to be recertified each time it is updated to a more recent version of the CQMs (80 FR 62889). With the continuing evolution of technology and clinical standards, as well as the need for a predictable cycle from measure development to provider data submission, on December 31, 2015, we published in the **Federal Register** (80 FR 81824 through 81828) a Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs. We requested comments on the establishment of an ongoing cycle for the introduction and certification of new measures, the testing of updated measures, and the testing and certification of submission capabilities in future rulemaking. We intend to address such policies in future rulemaking.

Comment: One commenter expressed concern that requiring electronic submission of CQM data using the most recent version of the CQM electronic specification for each CQM may create a disconnect in the timing cycle of the regulatory adoption of standards and the rapid evolution of electronic standards for CQM reporting. The commenter recommended that CMS and ONC collaborate to establish a regulatory framework that is more responsive to the speed at which standards are developed, maintained, upgraded and improved.

Response: We appreciate the commenter's concerns about the rapidly evolving electronic standards and the timing cycle for the regulatory adoption of standards; we will continue to collaborate with colleagues at ONC to ensure that our policies are responsive to evolving electronic standards to the greatest extent feasible.

Comment: Several commenters supported the proposals to align the CERHT requirements, measure set, and deadlines between the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program because these proposals would decrease the burden on organizations who currently report for both programs.

Response: We thank the commenters for this support.

Comment: A few commenters supported the alignment of the reporting requirements for the EHR Incentive Programs and the Hospital IQR Program, which would reduce provider burden and minimize confusion about reporting criteria across various quality reporting programs. However, these commenters expressed concern about the expansion of CQMs with the current state of EHR technology. One commenter urged CMS, as part of its certification process, to seek stakeholder input and to define standards and structure for EHR vendors that allows documentation to fit into the clinical workflow and interact with providers at the point-of-contact to guide them to provide timely and appropriate care. One commenter urged CMS to utilize chart abstraction for quality reporting until the EHR transformation is made to allow clinicians to focus on delivering high quality patient focused care without the distraction of CQM reporting using an EHR structure that has yet to evolve to support true meaningful use.

Response: We thank the commenters for this support. We will continue to seek stakeholder input to define standards and structure for EHR vendors that allows documentation to fit into the clinical workflow and interact with providers at the point-of-contact to guide them to provide timely and appropriate care. We appreciate the commenter's recommendation to utilize chart abstraction for quality reporting until EHR systems are more mature. However, when eligible hospitals and CAHs work with their vendors to ensure that EHRs are appropriately structured in a way that fits in with the clinical work flow to yield reliable data through electronic CQMs, we believe that electronic CQMs promote high quality outcomes, lower costs, and ultimately decrease reporting burden on hospitals as compared with chart-abstracted CQMs.

After consideration of the public comments we received, we are finalizing our proposal to continue the policy that electronic submission of CQMs will require the use of the most recent version of the CQM electronic specification for each CQM to which the EHR is certified. In the event that an eligible hospital or CAH has certified EHR technology that is certified to the 2014 Edition and not certified to the 16 available CQMs (as established in this final rule) that would be available for reporting in 2017 under our finalized polices, we are finalizing our proposal that requires an eligible hospital or CAH to have its EHR technology certified to such CQMs in order to meet the reporting requirements for 2017.

As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759), an EHR certified for CQMs under the 2014 Edition certification criteria does not need to be recertified each time it is updated to a more recent version of the CQMs. We proposed to accept the use of EHR technology certified to the 2014 or 2015 Edition for CQM reporting in 2017. Certification to the 2015 Edition is expected to be available beginning in 2016. (For further information on CQM reporting, we refer readers to the EHR Incentive Program Web site where guides and tip sheets are available for each reporting option (*http://www.cms.gov/ehrincentiveprograms*).) As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759), we encourage health IT developers to test any updates, including any updates to the CQMs and CMS reporting requirements based on the CMS Implementation Guide for Quality Reporting Document Architecture (QRDA) Category I and Category III (CMS Implementation Guide for QRDA) for Eligible Professional Programs and Hospital Quality Reporting (HQR), on an annual basis.

The form and method of electronic submission are further explained in subregulatory guidance and the certification process. For example, the following documents are updated annually to reflect the most recent CQM electronic specifications: The CMS Implementation Guide for QRDA; program specific performance calculation guidance; and CQM electronic specifications and guidance documents. These documents are located on the eCQI Resource Center Web page: (*https://ecqi.healthit.gov/*).

We invited public comments on these proposals.

We did not receive comments on our proposed policy. Therefore, we are finalizing our proposal to accept the use of EHR technology certified to the 2014 or 2015 Edition for CQM reporting in 2017.

IX. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2016 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this final rule. MedPAC recommendations for the IPPS for FY 2017 are addressed in Appendix B to this final rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's Web site at: *http://www.medpac.gov.*

X. Other Required Information

A. Requests for Data From the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are now available on compact disc (CD) format. However, many of the files are available on the Internet at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* We listed the data files and the cost for each file, if applicable, in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25247 through 25249).

Commenters interested in discussing any data files used in construction of this final rule should contact Michael Treitel at (410) 786–4552.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25249 through 25257), we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs) (except for the ICRs addressed under section X.B.5. of the preamble of this final rule).

2. ICRs for Add-On Payments for New Services and Technologies

Section II.H.1. of the preambles of the proposed rule (81 FR 25031 through 25033) and this final rule discusses add-on payments for new services and technologies. Specifically, this section states that applicants for add-on payments for new medical services or technologies for FY 2018 must submit a formal request. A formal request includes a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement. In addition, the request must contain a significant sample of the data to demonstrate that the medical service or technology meets the high-cost threshold.

We believe the burden associated with this requirement is exempt from the PRA under 5 CFR 1320.3(c), which defines the agency collection of information subject to the requirements of the PRA as information collection imposed on 10 or more persons within any 12-month period. This information collection does not impact 10 or more entities in a 12-month period. For FYs 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, and 2017, we received 1, 4, 5, 3, 3, 5, 5, 7, 9, and 9 applications, respectively. (We note that 2 applications received for FY 2017 that were discussed in the proposed rule are not addressed in this final rule because the technology did not receive FDA approval by July 2016.)

We did not receive any public comments regarding this information collection.

3. ICRs for the Occupational Mix Adjustment to the FY 2017 Wage Index (Hospital Wage Index Occupational Mix Survey)

Section III.E. of the preambles of the proposed rule (81 FR 25064 through 25065) and this final rule discuss the occupational mix adjustment to the proposed and final FY 2017 wage index. While the preamble does not contain any new ICRs, we note that there is an OMB approved information collection request associated with the hospital wage index.

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require us to collect data at least once every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program in order to construct

an occupational mix adjustment to the wage index. We collect the data via the occupational mix survey.

The burden associated with this information collection requirement is the time and effort required to collect and submit the data in the Hospital Wage Index Occupational Mix Survey to CMS. The aforementioned burden is subject to the PRA; it is currently approved under OMB control number 0938–0907.

We did not receive any public comments regarding this information collection.

4. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.J.3. of the preambles of the proposed rule (81 FR 25069) and this final rule discuss changes to the proposed and final wage index based on hospital reclassifications. As stated in that section, under section 1886(d)(10) of the Act, the MGCRB has the authority to accept short-term IPPS hospital applications requesting geographic reclassification for wage index and to issue decisions on these requests by hospitals for geographic reclassification for purposes of payment under the IPPS.

The burden associated with this application process is the time and effort necessary for an IPPS hospital to complete and submit an application for reclassification to the MGCRB. The burden associated with this requirement is subject to the PRA. It is currently approved under OMB control number 0938–0573.

We did not receive any public comments regarding this information collection.

5. ICRs for Application for GME Resident Slots

The information collection requirements associated with the preservation of resident cap positions from closed hospitals, addressed under section IV.J.3. of the preamble of this final rule, are not subject to the Paperwork Reduction Act, as stated in section 5506 of the Affordable Care Act.

6. ICRs for the Notice of Observation Treatment by Hospitals and CAHs

In section IV.L. of the preambles of the proposed rule (81 FR 25131 through 25134) and this final rule, we discuss our implementation of the NOTICE Act (Pub. L. 114–42), which amended section 1866(a)(1) of the Act to require hospitals and CAHs to provide written and oral notification to Medicare beneficiaries receiving observation services as outpatients for more than 24 hours. We have developed a standardized format for the notice (the MOON), which will be disseminated during the normal course of related business activities. The standardized notice discussed in this final rule is simultaneously being subject to public review and comment through the Office of Management and Budget (OMB) Paperwork Reduction Act process before implementation under OMB control number 0938–new.

In the proposed rule, we estimated that it would take hospitals and CAHs 5 minutes (0.0833 hour) to complete and deliver each notice. We estimated an annual cost burden of $5,461,430 or approximately $889.19 per hospital or CAH.

Comment: A number of commenters suggested that CMS had underestimated the burden. Some commenters believed that the estimates did not account fully for the costs that hospitals and CAHs will incur for business functions such as system programming, creating internal operating procedures, scanning, and translation. One commenter suggested that CMS break out the burden separately for CAHs and non-CAHs. One commenter was concerned that the burden on smaller, rural hospitals would be particularly large. One commenter recommended that the estimated delivery time should be increased.

Response: We believe the burden estimate in the proposed rule appropriately took into account the time to gather and enter the necessary data and information (including the information to be inserted into the free-text fields), review the instructions, complete and review necessary responses, and deliver the notice to the beneficiary. The burden estimates were not intended to include time spent on customary and usual business practices. We did not break out the impact on CAHs and non-CAHs separately, as we anticipate a general, comparable burden on CAHs and hospitals.

As discussed below, we have reassessed our proposed burden estimate and for this final rule and we have increased the estimated time for hospitals to prepare and deliver the MOON from 5 minutes to 15 minutes. This increase addresses the public comments received on the proposed rule related to the burden specific to the requirements for delivery of the MOON; for example, the population of a free text field on the MOON to indicate why a beneficiary is receiving outpatient observation services. We believe the increase from 5 minutes to 15 minutes adequately accounts for additional time spent complying with the MOON delivery requirements.

For this final rule, we estimate that it will take hospitals and CAHs 15 minutes (0.25 hour) to complete and deliver each notice. In 2014, there were approximately 1,399,999 claims for Medicare outpatient observation services lasting greater than 24 hours furnished by 6,142 hospitals and CAHs.[393] The annual hour burden is estimated to be 350,000 (1,399,999 responses × 0.25 hour). To derive average cost, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, we used the mean hourly wage of $33.55 and the cost of fringe benefits, $33.55 (calculated at 100 percent of salary), to determine an adjusted hourly wage of $67.10. This is necessarily a rough adjustment because fringe benefits and overhead costs vary significantly from employer to employer, methods of estimating these costs vary widely from study to study, and hospitals vary widely both in terms of size and geographic location. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonable accurate estimation method. The cost per response is approximately $16.78 based on an hourly salary rate of $67.10 and the 15-minute response estimate. By multiplying the annual responses by $16.78, the annual cost burden estimate is $23,491,983 (1,399,999 responses × $16.78) or approximately $3,824.81 per hospital or CAH ($23,491,983/6,142).

7. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. This program expanded our voluntary Hospital Quality Initiative. The Hospital IQR Program originally consisted of a ''starter set'' of 10 quality measures. The collection of information associated with the original starter set of quality measures was previously approved under OMB control number 0938–0918. All of the information collection requirements previously approved under OMB control number 0938–0918 have been combined with the information collection request currently approved under OMB control number 0938–1022. We no longer use OMB control number 0938–0918.

[393] Source: CMS Office of Enterprise and Data Analytics.

We added additional quality measures to the Hospital IQR Program and submitted the information collection request to OMB for approval. This expansion of the Hospital IQR Program measures was part of our implementation of section 5001(a) of the Deficit Reduction Act of 2005 (DRA). Section 1886(b)(3)(B)(viii)(III) of the Act, added by section 5001(a) of the DRA, requires that the Secretary expand the ''starter set'' of 10 quality measures that were established by the Secretary as of November 1, 2003, to include measures ''that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings.'' The burden associated with these reporting requirements is currently approved under OMB control number 0938–1022.

In section VIII.A.3.b. of the preamble of this final rule, we are finalizing our proposal to remove 13 eCQM versions of measures, 2 ''topped-out'' chart-abstracted measures, and 2 structural measures, beginning with the FY 2019 payment determination. However, we note that the total number of measures removed is 15 because the STK–4 and VTE–5 measures were removed twice—once in the chart-abstracted form and again in electronic form.

The 13 eCQM versions of measures we are removing are: (1) AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142); (2) AMI–7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival; (3) AMI–10: Statin Prescribed at Discharge; (4) HTN: Healthy Term Newborn (NQF #0716); (5) PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147); (6) SCIP–Inf–1a: Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision (NQF #0527); (7) SCIP–Inf–2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528); (8) SCIP–Inf–9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero; (9) STK–4: Thrombolytic Therapy (NQF #0437); (10) VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373); (11) VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram); (12) VTE–5: Venous Thromboembolism Discharge Instructions; and (13) VTE–6: Incidence of Potentially Preventable Venous Thromboembolism. The two chart-abstracted measures we are removing are: (1) STK–4: Thrombolytic Therapy (NQF #0437); and (2) VTE–5: Venous Thromboembolism Discharge Instructions. The two structural measures we are removing are: (1) Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and (2) Participation in a Systematic Clinical Database Registry for General Surgery.

We believe that removing 13 eCQMs will reduce burden for hospitals, as they will have a smaller number of eCQMs from which to select. As finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698), hospitals are required to select 4 out of 28 available eCQMs on which to report data beginning with the FY 2018 payment determination. As discussed below, in this rule, we are not finalizing our proposal that hospitals must report on all of the available eCQMs in the Hospital IQR Program. Instead, we are finalizing a modified version of our proposal and requesting that, for the CY 2017 reporting period/FY 2019 payment determination and CY 2018 reporting period/FY 2020 payment determination, hospitals must report on 8 of the available eCQMs in the Hospital IQR Program. Because 13 eCQMs are being removed from a pool of 28 eCQMs, hospitals will then have a total pool of only 15 eCQMs to choose from, which will decrease the burden associated with selecting and reporting data. However, because we are now requiring hospitals to submit data on 8 of the available eCQMs included in the Hospital IQR Program measure set, the modest reduction in burden associated with the decreased number of eCQMs from which hospitals may choose, will be offset by the increased burden associated with submitting data on 8 eCQMs instead of 4 eCQMs. We discuss the burden associated with our finalized proposal to require the submission of 8 of the available eCQMs included in the Hospital IQR Program measure set below.

We also believe that there will be a reduction in burden for hospitals as a result of the removal of the two chart-abstracted measures listed above (STK–4 and VTE–5). Due to the burden associated with the collection of chart-abstracted data (based on updated measure record abstraction time estimates from the third quarter in 2014 through the second quarter in 2015, the number of reporting periods in a calendar year, and the number of IPPS hospitals reporting), we estimate that the removal of STK–4 will result in a burden reduction of approximately 303,534 hours and approximately $9.9 million across all 3,300 IPPS hospitals participating in the Hospital IQR Program for the FY 2019 payment determination.

In addition, we estimate that the removal of VTE–5 will result in a burden reduction of approximately 1,437,843 hours and approximately $47.2 million across all 3,300 IPPS hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. More specifically, for both the STK and VTE measure sets, we calculated the hours of burden by taking the difference in the burden estimates from this FY 2017 IPPS/LTCH PPS final rule and the burden estimates from the FY 2016 IPPS/LTCH PPS final rule. With regard to STK–4, because it is the only STK measure left in the Hospital IQR Program, and in this FY 2017 IPPS/LTCH PPS final rule, we are finalizing our proposal to remove it, we calculated the total burden hours as follows: 0 hours (time required to report in CY 2017) − 303,534 hours (time required to report in CY 2016) = − 303,534 hours for the STK measure set. With regard to the VTE measure set, we used an updated estimate (based on data from the third quarter of 2014 through second quarter of 2015), that the time per record (that is, to report all 4 of the VTE measures in the Hospital IQR Program during the noted time period) is 28 minutes; thus, we estimate a burden reduction of 7 minutes for removing 1 VTE measure. Based on this estimate, we deducted 21 minutes from the 28-minute estimate to account for the removal of VTE–1, VTE–2, and VTE–3 in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49645) and subsequent removal of VTE–5 in this final rule, for a total of 7 minutes to report on the one remaining VTE chart-abstracted measure in the Hospital IQR Program. We then calculated the estimated total hours of burden per hospital for reporting the remaining VTE measure as follows: 7 minutes per record/60 minutes per hour × 4 reporting quarters per year × 198.05 records per hospital per quarter = 92 burden hours per hospital. Because there are 3,300 IPPS hospitals, we then multiplied 92 hours per hospital × 3,300 hospitals to get a total annual burden estimate of 304,997 hours to report the 1 remaining measure in the VTE measure set. The reduction in the total burden hours for VTE from this FY 2017 IPPS/LTCH PPS final rule and the FY 2016 IPPS/LTCH PPS final rule, is calculated as follows: 304,997 (FY 2017 total annual estimate) − 1,742,840 (FY 2016 total annual estimate) = − 1,437,843 hours for the VTE measure set. We note that this burden estimate is revised based on the updated estimates mentioned above, and as such, is different from what we stated in the proposed rule (81 FR 25251). In the FY

2017 IPPS/LTCH PPS proposed rule, we used the incorrect time estimate (3 minutes) associated with the removal of one VTE measure.

We believe that there will be a negligible burden reduction due to the removal of two structural measures. Consistent with previous years (80 FR 49762), we estimate a burden of 15 minutes per hospital to report all four previously finalized structural measures and to complete other forms (such as the Extraordinary Circumstances Extension/Exemption Request Form). Therefore, our burden estimate of 15 minutes per hospital remains unchanged because we believe the reduction in burden associated with removing these two structural measures will be sufficiently minimal that it will not substantially impact this estimate.

In addition, in section VIII.A.6. of the preamble of this final rule, we discuss refinements to two previously adopted measures beginning with the FY 2018 payment determination: (1) Expanding the cohort for the Hospital-Level, Risk-standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (NQF #2579); and (2) adopting the modified Patient Safety and Adverse Events Composite (NQF #0531). Because these claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional burden on hospitals will result from the refinements to these two claims-based measures.

Also, in section VIII.A.7. of the preamble of this final rule, we discuss our adoption of four claims-based measures to the Hospital IQR Program measure set beginning with the FY 2019 payment determination: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure; (3) Spinal Fusion Clinical Episode-Based Payment Measure; and (4) Excess Days in Acute Care after Hospitalization for Pneumonia. Because these claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional burden on hospitals will result from the addition of these four claims-based measures.

For the FY 2019 payment determination and the FY 2020 payment determination, in section VIII.A.8. of the preamble of this final rule, we are requiring hospitals to submit data for 8 of the available eCQMs included in the Hospital IQR Program measure set in a manner that will permit eligible hospitals to align Hospital IQR Program requirements with some requirements under the Medicare and Medicaid EHR Incentive Programs. This is a modification from our proposal, which was to require all available eCQMs in the Hospital IQR Program measure set. Specifically, hospitals will be required to submit a full calendar year of data on 8 of the 15 eCQMs in the Hospital IQR Program measure set, on an annual basis, for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination. We believe that the burden associated with submitting a full year of eCQM data will not be substantially greater than the burden associated with transmission of a single quarter of data. As described in section VII.A.10.d of the preamble of this final rule, the CMS data receiving system requires that each QRDA I file include data for one patient, per quarter, per reporting CCN. Once hospitals establish their protocols to ensure this is maintained, hospitals and vendors should not experience much added burden reporting an additional 3 quarters of data. However, in our conservative estimates here, we calculate as if burden is four times as much in an abundance of caution.

We believe that the total burden associated with the eCQM reporting policy will be similar to that previously outlined in the Medicare EHR Incentive Program Stage 2 final rule (77 FR 54126 through 54133). In that final rule, the burden estimate for a hospital to report all 16 eCQMs is 2 hours and 40 minutes (160 total minutes or 10 minutes per measure) per submission for a 3-month period (77 FR 54127). We believe that this estimate is accurate and appropriate to apply to the Hospital IQR Program because we are aligning the eCQM reporting requirements between both programs. Therefore, using the estimate of 10 minutes per measure, we anticipate that our finalized policies to require: (1) Reporting on 8 of the available eCQMs (8 eCQMs for the CY 2017 reporting period/FY 2019 payment determination); and (2) submission of one year of eCQM data (covering Q1, Q2, Q3, and Q4), will result in a burden of 80 minutes per quarter per hospital to report one medical record containing information on all the required eCQMs. In total, for the FY 2019 payment determination, we expect our policy to require hospitals to report data on 8 eCQMs for 4 quarters (as compared to our previously finalized requirement to report data on 4 eCQMs for 1 quarter) to represent a burden increase of 15,400 hours across all 3,300 IPPS hospitals participating in the Hospital IQR Program. This figure was derived by calculating the difference between the FY 2017 burden estimate of 17,600 hours (80 minutes per record/60 minutes per hour × 4 reporting quarters per year × 1 record per hospital per quarter × 3,300 hospitals) and the FY 2016 burden estimate of 2,200 hours (20 minutes per record/60 minutes per hour × 1 reporting quarter per year × 1 record per hospital per quarter × 3,300 hospitals) (80 FR 49763), for an incremental increase of 15,400 hours.

Furthermore, we estimate that reporting these eCQMs can be accomplished by staff with a mean hourly wage of $16.42 per hour.[394] However, obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and firm sizes. In addition, the precise cost elements assigned as ''indirect'' or ''overhead'' costs, as opposed to direct costs or employee wages, are subject to some interpretation at the firm level. Therefore, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. This is a change from how we have accounted for the cost of overhead in our previous rules regarding the Hospital IQR Program. In calculating labor cost, we estimate an hourly labor cost of $32.84 ($16.42 base salary + $16.42 fringe) and a cost increase of $505,736 (15,400 additional burden hours × $32.84 per hour) across approximately 3,300 hospitals participating in the Hospital IQR Program to report a full calendar year of data for 8 eCQMs, on an annual basis.

We did not propose any changes to our validation requirements related to chart-abstracted measures, but provided some background information as basis for our eCQM validation proposals. As noted in the FY 2016 IPPS/LTCH IPPS final rule (80 FR 49762 and 49763), for validation of chart-abstracted data for the FY 2018 payment determination and subsequent years, we require hospitals to provide 72 charts per hospital per year (with an average page length of 1,500), including 40 charts for HAI validation and 32 charts for clinical process of care validation, for a total of

[394] Occupational Outlook Handbook. Available at: *http://www.bls.gov/oes/2012/may/oes292071.htm.*

108,000 pages per hospital per year. We reimburse hospitals at 12 cents per photocopied page (79 FR 50346) for a total per hospital cost of $12,960. For hospitals providing charts digitally via a re-writable disc, such as encrypted CD–ROMs, DVDs, or flash drives, we will reimburse hospitals at a rate of 40 cents per digital media (80 FR 49837), and additionally hospitals will be reimbursed $3.00 per record (78 FR 50956). For hospitals providing charts via secure file transfer, we will reimburse hospitals at a rate of $3.00 per record (78 FR 50835).

In section VIII.A.11. of the preamble of this final rule, beginning in spring 2018 for the FY 2020 payment determination, we discuss our expansion the existing validation process for the Hospital IQR Program data to include a random sample of up to 200 hospitals for validation of eCQMs in the Hospital IQR Program. In previous years (79 FR 50347), we estimated a total burden of 16 hours (960 minutes) for the submission of 12 records, which will equal 1 hour and 20 minutes per record (960 minutes/12 records). Applying the time per individual submission of 1 hour and 20 minutes (or 80 minutes) for the 32 records that hospitals submit beginning with the FY 2020 payment determination, we estimate a total burden of approximately 43 hours (1 hour and 20 minutes × 32 records) for each hospital selected for participation in eCQM validation. We estimate that approximately 43 hours of work for up to 200 hospitals will increase the eCQM validation burden hours from 0 hours (as this is the first instance where eCQM validation is being added as a requirement) to 8,533 labor hours.

As previously stated, with respect to eCQMs, the labor performed can be accomplished by staff, with a mean hourly wage of $16.42.[395] Further, in calculating labor costs, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. Therefore, we estimate a fully burdened labor rate of $32.84 ($16.42 base salary + $16.42 fringe) per hour. Therefore, using these assumptions, we estimate an hourly labor cost of $32.84 and a cost increase of $280,224 (8,533 additional burden hours × $32.84 per hour) across the (up to) 200 hospitals selected for eCQM validation, on an annual basis. Consistent with the chart-abstraction validation process, we will reimburse hospitals providing records via secure file transfer, at a rate of $3.00 per record.

Lastly, in section VIII.A.15. of the preamble of this final rule, we discuss our adoption of updates to our Extraordinary Circumstances Extensions or Exemptions (ECE) policy by: (1) Extending the general ECE request deadline for non-eCQM circumstances from 30 to 90 calendar days following an extraordinary circumstance; and (2) establishing a separate submission deadline for ECE requests with respect to eCQM reporting circumstances of April 1 following the end of the reporting calendar year. Consistent with previous years, we estimate a burden of 15 minutes per hospital to report all forms (including the ECE request form) and structural measures. We believe that the updates to the ECE deadlines will have no effect on burden for hospitals, because we are not making any changes that will increase the amount of time necessary to complete the form. In addition, the burden associated with the completion of this form is included in the 15 minutes allocated for all forms and structural measures.

In summary, under OMB number 0938–1022, we estimate a total burden decrease of approximately 1,717,444 hours, for a total cost decrease of approximately $56.4 million across approximately 3,300 hospitals participating in the Hospital IQR Program as a result of the policies in this final rule.

ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS UNDER OMB CONTROL NUMBER 0938–1022

Activity	Estimated time per record (minutes) FY 2017	Number reporting quarters per year FY 2017	Number of hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Annual burden (hours) across hospitals FY 2017	Net difference in annual burden hours (FY 2017–FY 2016)
Removal of Stroke (STK–4) measure	0	4	3,300	39	0	0	−303,534
Removal of Venous thromboembolism (VTE–5)	25	4	3,300	198	92	304,997	−1,437,843
Reporting on 8 electronic Clinical Quality Measures	80	4	3,300	1	5.33	17,600	15,400
eCQM Validation	80	4	200	8	43	8,533	8,533

Total Change in Burden Hours: −1,717,444.
Total Cost Estimate: Hourly Wage ($32.84) × Change in Burden Hours (−1,717,444) = −$56,400,861.

This estimate excludes the burden associated with the NHSN and HCAHPS measures, both of which are submitted under separate information collection requests and are approved under OMB control numbers 0920–0666 and 0938–0981, respectively. The burden estimates in this final rule are the estimates for which we are requesting OMB approval.

We received the following public comments regarding our burden estimates.

Comment: Some commenters expressed concern about the amount of change required for documenting new measures, which creates challenges in accurately reflecting patient severity of illness. As an example, one commenter noted that last year's severe sepsis and septic shock measure (SEP–1) introduced requirements for documentation that have not been easily implemented. Therefore, this commenter indicated that the value of very specific documentation has to be weighed against the value for patient care that it brings. Likewise, other commenters expressed concern regarding the number of measures required by Medicare hospital performance and reporting programs

[395] Occupational Outlook Handbook. Available at: *http://www.bls.gov/oes/2012/may/oes292071.htm.*

and the burden associated with reporting, monitoring, and transmitting data for these quality measures. These commenters cited the Institute of Medicine (IOM)'s April 2015 Vital Signs report on Core Metrics for Health and Health Care Progress and recommended that CMS adopt the IOM 15 core measure areas, along with 39 additional priority measures, in which to provide benchmarks and improve overall health system performance, which, they argue, would reduce overall measure burden across all programs by creating a streamlined measure set that provides the most value for patients and providers.

Response: We understand that many of the requirements of the Hospital IQR Program increase the reporting burden on hospitals, and, before proposing any measure, we critically weigh this burden against the benefit we believe will be achieved in the improvement of quality of care. We also note that, this year, every new measure we proposed is claims-based; claims-based measures do not require additional documentation from providers. Thus, there should be no increase in burden based on new measures in this final rule. As we move forward, we will continue to consider the number of measures in this and other programs and consider the aggregate effect of reporting.

8. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in sections VIII.B. of the preambles of the proposed rule (81 FR 25205 through 25213) and this final rule, section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year.

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 28124), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50957 through 50959), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50347 through 50348), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49764) for a detailed discussion of the burden for the program requirements that we have previously adopted. Below we discuss only any changes in burden that will result from the proposals we are finalizing in this final rule.

In section VIII.B.3.b. of the preamble of this final rule, we are finalizing our proposal that PCHs submit data on the Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) measure for an expanded cohort of patients. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50285) we finalized a sampling methodology for Clinical Process/Oncology Care Measures, which includes the Oncology: Radiation Dose Limits to Normal Tissues measure. Because our previous burden estimates were based on the maximum sample of 25 patients for this measure, the expansion of the patient cohort will increase the pool of patients from which the sample can be drawn but will not raise the burden for this measure beyond that which we described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50347 through 50348).

In section VIII.B.4.b. of the preamble of this final rule, we are finalizing our proposal to adopt the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure beginning with the FY 2019 program year. This is a claims-based measure, and therefore, does not require PCHs to submit any new data. Thus, this measure will not pose any new burden on PCHs.

In summary, as a result of our finalized policies, we do not anticipate any changes to previously finalized burden estimates.

9. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section IV.H. of the preambles of the proposed rule (81 FR 25099 through 25177) and this final rule, we discuss requirements for the Hospital VBP Program. Specifically, in this final rule, with respect to quality measures, we are finalizing our proposals to: include selected ward non-Intensive Care Unit (ICU) locations in certain NHSN measures beginning with the FY 2019 program year; adopt the Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) and the Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF) measures beginning with the FY 2021 program year; update the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia (PN) Hospitalization (Updated Cohort) measure beginning with the FY 2021 program year; and adopt the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery measure beginning with the FY 2022 program year.

As required under section 1886(o)(2)(A) of the Act, the additional and updated measures are required for the Hospital IQR Program. Therefore, their inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program. Therefore, the burden associated with these reporting requirements is currently approved under OMB control number 0938–1022.

10. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

As discussed in section VIII.C.5 of the preambles of the proposed rule (81 FR 25214 through 25215) and this final rule, we are retaining the following 13 previously finalized quality measures for use in the LTCH QRP:

LTCH QRP Quality Measures Previously Adopted for the FY 2014 Payment Determinations and Subsequent Years

Measure title	IPPS/LTCH PPS Final rule	Annual payment determination: Initial and subsequent APU years
National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51745 through 51747); Adopted the NQF endorsed version and expanded measure (with standardized infection ratio [SIR]) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53619).	FY 2014 payment determination and subsequent years.

LTCH QRP QUALITY MEASURES PREVIOUSLY ADOPTED FOR THE FY 2014 PAYMENT DETERMINATIONS AND SUBSEQUENT YEARS—Continued

Measure title	IPPS/LTCH PPS Final rule	Annual payment determination: Initial and subsequent APU years
National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51747 through 51748); Adopted the NQF endorsed and expanded measure (with SIR) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53619).	FY 2014 payment determination and subsequent years.
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750); Adopted the NQF endorsed version in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863); Adopted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49731 through 49736) to fulfill IMPACT Act requirements.	FY 2014 payment determination and subsequent years.
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).	Adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627); Revised data collection timeframe in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50858 through 50861); Revised data collection timeframe in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50289 through 50290).	FY 2016 payment determination and subsequent years.
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).	Adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631); Revised data collection timeframe in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50857 through 50858).	FY 2016 payment determination and subsequent years.
National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50863 through 50865).	FY 2017 payment determination and subsequent years.
National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50865 through 50868).	FY 2017 payment determination and subsequent years.
All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals (NQF #2512).	Adopted in FY 2014 IPPS/LTCH PPS final rule (78 FR 50868 through 50874); Adopted the NQF endorsed version in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49730 through 49731).	FY 2017 payment determination and subsequent years.
National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50301 through 50305).	FY 2018 payment determination and subsequent years.
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877); Revised data collection timeframe in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290 through 50291); Adopted an application of the measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49736 through 49739) to fulfill IMPACT Act requirements.	FY 2018 payment determination and subsequent years.
Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50291 through 50298).	FY 2018 payment determination and subsequent years.
Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50298 through 50301).	FY 2018 payment determination and subsequent years.
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted an application of the measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747) to fulfill IMPACT Act requirements.	FY 2018 payment determination and subsequent years.

As discussed in section VIII.C.6 and VIII.C.7 of the preamble of this final rule, we are finalizing the addition of the following four measures for use in the LTCH QRP:

LTCH QRP QUALITY MEASURES NEWLY FINALIZED FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Measure title	Annual payment determination: Initial and subsequent APU years
Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP *	FY 2018 payment determination and subsequent years.

LTCH QRP QUALITY MEASURES NEWLY FINALIZED FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Measure title	Annual payment determination: Initial and subsequent APU years
Discharge to Community-PAC LTCH QRP *	FY 2018 payment determination and subsequent years.
MSPB–PAC LTCH QRP *	FY 2018 payment determination and subsequent years.
Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC LTCH QRP **	FY 2020 payment determination and subsequent years.

* Finalized in this FY 2017 IPPS/LTCH PPS final rule for the FY 2018 payment determination and subsequent years.
** Finalized in this FY 2017 IPPS/LTCH PPS final rule for the FY 2020 payment determination and subsequent years.

Currently, LTCHs use two separate data collection mechanisms to report quality data to CMS. Six of the 13 measures being retained in this FY 2017 IPPS/LTCH PPS final rule are currently collected via the CDC's NHSN. The NHSN is a secure, Internet-based HAI tracking system maintained and managed by the CDC. The NHSN enables health care facilities to collect and use data about HAIs, adherence to clinical practices known to prevent HAIs, and other adverse events within their organizations. NHSN data collection occurs via a Web-based tool hosted by the CDC and is provided free of charge to facilities. In the proposed rule, we did not propose any new quality measures that would be collected via the CDC's NHSN. Therefore, at this time, there will be no additional burden related to this submission method. Any burden related to NHSN-based quality measures we have retained in this final rule has been previously discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445) and FY 2016 IPPS/LTCH PPS final rule (80 FR 49766) and has been previously approved under OMB control number 0920–0666, with an expiration date of November, 31, 2016.

In addition to the previously finalized All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From LTCHs (NQF #2512), we are finalizing our proposals to add three Medicare FFS claims-based measures in this final rule: Potentially Preventable 30 Day Post-Discharge Readmission Measure for LTCH QRP; Discharge to Community-PAC LTCH QRP; and MSBP–PAC LTCH QRP. Because these claims-based measures will be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional information collection will be required from the LTCHs. We did not propose new assessment-based quality measures in the LTCH QRP in the proposed rule for the FY 2018 payment determination and subsequent years.

The remaining assessment-based quality measure data are reported to CMS by LTCHs using the LTCH CARE Data Set. In section VIII.C.9.d. of the preamble of this of this final rule, we discuss our proposal to expand the data collection timeframe for the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) (77 FR 53624 through 53627), beginning with the FY 2019 payment determination. The data collection time frame and associated data submission deadlines are currently aligned with the Influenza Vaccination Season (IVS) (October 1 of a given year through March 31 of the subsequent year), and only require data collection during the 2 calendar year quarters that align with the IVS. We are finalizing our proposal to expand the data collection timeframe from just 2 quarters (covering the IVS) to a full four quarters or 12 months. We refer readers to section VIII.C.9.d. of the preamble of this final rule for further details on the expansion of data collection for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), including data collection timeframes and associated submission deadlines. We originally finalized this measure for use in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627). Although we finalized data collection for this measure to coincide with the IVS, we originally proposed year-round data collection. The associated PRA package, which was approved under OMB control number 0938–1163, included burden calculations that aligned with our original proposal for year-round data collection. All subsequent PRA packages, and the PRA package that is currently under review, included burden calculations reflecting year-round (12 month) data collection for this measure. Because of this, the change in the data collection timeframe for this measure, and any associated burden related to increased data collection, has already been accounted for in the total burden figures included in this section of the preamble of this final rule.

For the FY 2020 payment determination and subsequent years, we are finalizing our proposal to use one new assessment based quality measure in the LTCH QRP: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP. This is a cross-setting measure that satisfies the required addition of a quality measure under the domain of medication reconciliation, as mandated by section 1899B of the Act, as added by the IMPACT Act. In addition to the newly finalized Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP quality measure, the remaining six measures, outlined below, will continue to be collected utilizing the LTCH CARE Data Set.

The LTCH CARE Data Set Version 2.01 has been approved under OMB control number 0938–1163. The LTCH CARE Data Set Version 2.01 contains data elements related to patient demographic data, various voluntary questions, as well as data elements related to the following quality measures:

- Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678);
- Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).

We have submitted a revision to the PRA package that addressed the changes from LTCH CARE Data Set Version 2.01 to Version 3.00. The LTCH CARE Data Set Version 3.00, which was implemented April 1, 2016, contains those data elements included in Version 2.01, as well as additional data elements in order to allow for the collection of data associated with the following quality measures:

- Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) (previously finalized in the FY 2016 IPPS/LTCH PPS final rule);

• Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) (previously finalized in the FY 2015 IPPS/LTCH PPS final rule);

• Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632) (previously finalized in the FY 2015 IPPS/LTCH PPS final rule); and

• Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF # 2631) (previously finalized in the FY 2016 IPPS/LTCH PPS final rule).

The LTCH CARE Data Set Version 4.00, effective April 1, 2018, will contain those data elements included in Version 3.00, as well as additional data elements in order to allow for the collection of data associated with the newly finalized quality measure: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP.

Each time we add new data elements to the LTCH CARE Data Set related to newly proposed or finalized LTCH QRP quality measures, we are required by the PRA to submit the expanded data collection instrument to OMB for review and approval. Section 1899B(m) of the Act, as added by IMPACT Act, provides that the PRA requirements do not apply to section 1899B of the Act and the sections referenced in section 1899B(a)(2)(B) of the Act that require modifications in order to achieve the standardization of patient assessment data. We believe that the LTCH CARE Data Set Version 3.00 falls under the PRA provisions in section 1899B(m) of the Act. We believe that all additional data elements added to the LTCH CARE Data Set Version 3.00 are for the purpose of standardizing patient assessment data, as required under section 1899B(a)(2)(B) of the Act. As noted above, the LTCH CARE Data Set Version 3.00 will be updated to Version 4.00, effective April 1, 2018, to include data elements for the newly finalized Drug Regimen Review Conducted with Follow-Up for Identified Issues- PAC LTCH QRP quality measure. For the reasons discussed above, we believe that the LTCH CARE Data Set Version 4.00 also falls under the PRA provisions in section 1899B(m) of the Act.

A comprehensive list of all data elements included in the LTCH CARE Data Set Version 3.00 is available in the LTCH QRP Manual which is accessible on the LTCH QRP Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*. For a discussion of burden related to LTCH CARE Data Set Version 3.00, we refer readers to section I.M. of Appendix A of this final rule.

We discuss and respond to public comments we received on these information collection requirements in the section I.M. of Appendix A of this final rule.

11. ICRs for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. We refer to this program as the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program.

In section VIII.D. of the preambles of the proposed rule (81 FR 25238 through 25244) and this final rule, we are finalizing the following measure-related changes: To update a previously finalized measure (Screening for Metabolic Disorders); and to adopt two new measures beginning with the FY 2019 payment determination (SUB–3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and subset measure SUB–3a Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664), and Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF). In addition, we are finalizing our proposal to include SUB–3: Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and subset measure SUB–3a: Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664) in the list of measures covered by the global sample for the FY 2019 payment determination and subsequent years as proposed. We also are finalizing that we will make the data for the IPFQR Program available as soon as possible and to no longer specify in rulemaking when measure data will be publicly available, when the approximately 30-day preview period will occur, or that the preview period will begin approximately 12 weeks before the public display date, but rather to announce these using subregulatory guidance. Lastly, for the FY 2017 payment determination only, we are also finalizing our proposal that, if it is technically feasible to display the data in December 2016, we will provide data to IPFs for a 2-week preview period that will start on October 1, 2016 as proposed. Moreover, we are finalizing as proposed that as a courtesy, for the FY 2017 payment determination only, if we are able to display the data in December 2016, we will ensure that IPFs have approximately 30 days for review if they so choose by providing IPFs with their data as early as mid-September.

We refer readers to the FY 2015 IPF PPS final rule (79 FR 45978 through 45980) and the FY 2016 IPF PPS final rule (80 FR 46720 through 46721) for a detailed discussion of the burden for the IPFQR Program requirements that we have previously adopted. Below we discuss only the changes in burden resulting from the newly finalized policies in this final rule. Although we are finalizing provisions that impact policies beginning in both the FY 2017 and FY 2019 payment determinations, IPFs must take steps to comply with all of these policies beginning in FY 2017. For example, data collection for the measures that affect FY 2019 payment determination begins in FY 2017, and the changes to the public display dates take effect beginning with the posting of data that informs the FY 2017 payment determination on *Hospital Compare* during FY 2017. For purposes of calculating burden, we will attribute the costs to the year in which these costs begin; for the purposes of all of the newly finalized policies in this final rule, that year is FY 2017.

We believe that approximately 1,684 [396] IPFs will participate in the IPFQR Program for requirements occurring in FY 2017 and subsequent years. Based on program data, we believe that each IPF will submit measure data on approximately 848 [397] cases per year. In prior rulemaking, we estimated that the time required to chart-abstract data for chart-abstracted measures is 12 minutes per case per measure.[398] Based on the experience of other quality reporting programs, such as the Hospital IQR Program, we are updating this estimate to 15 minutes (that is, 0.25 hour) per case per measure. We are only finalizing one new chart-abstracted measure this year: SUB–3/subset SUB–3a. The other measure that we are finalizing, Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF, is claims-based and, therefore, does not require IPFs to report any additional data.

We estimate that reporting data for the IPFQR Program measures can be

[396] In the FY 2016 IPF PPS final rule, we estimated 1,617 IPFs and are adjusting that estimate by +67 to account for more recent data.

[397] In the FY 2016 IPF PPS final rule, we estimated 431 cases per year and are adjusting that estimate by +417 to account for more recent data.

[398] 80 FR 46720.

accomplished by staff with a mean hourly wage of $16.42.[399] However, obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and firm sizes. In addition, the precise cost elements assigned as ''indirect'' or ''overhead'' costs, as opposed to direct costs or employee wages, are subject to some interpretation at the firm level. Therefore, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. In calculating the labor cost, we estimate an hourly labor cost of $32.84 ($16.42 base salary + $16.42 fringe). The following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit (at 36.25% in $/hr)	Adjusted hourly wage ($/hr)
Medical Records and Health Information Technician	29–2071	16.42	16.42	32.84

We do not believe that our update to a previously finalized measure will affect our previous burden estimate for that measure. As noted above, one of our newly finalized measures is claims-based and will not result in increased burden. Therefore, increased burden will occur primarily as a result of our newly finalized chart-abstracted measure. We estimate that this measure will result in an increase in burden of 212 hours per IPF (1 measure × (848 cases/measure × 0.25 hour/case)) or 357,008 hours across all IPFs (212 hours/IPF × 1,684 IPFs). The increase in costs will be approximately $6,962 per IPF (212 hours × $32.84/hour) or $11,724,143 across all IPFs (357,008 hours × 32.84/hour).

Consistent with our estimates in the FY 2015 IPF PPS final rule (79 FR 45979), we believe the estimated burden for training personnel on the revised data collection and submission requirements will be 2 hours per IPF or 3,368 hours (2 hours/IPF × 1,684 IPFs) across all IPFs. Therefore, we estimate the cost for this training will be $65.68 ($32.84/hour × 2 hours) for each IPF or $110,605 ($32.84/hour × 3,368 hours) for all IPFs.

Finally, IPFs must submit to CMS aggregate population counts for Medicare and non-Medicare discharges by age group and diagnostic group, and sample size counts for measures for which sampling is performed (that is, measures eligible for the global sample). Because the population for the SUB–3 and SUB–3a measure is nearly identical to the population for both the SUB–1 measure and the SUB–2 and SUB–2a measure, we believe that the addition of 1 chart-abstracted measure will lead to a negligible change in burden associated with nonmeasure data collection.

In section VIII.D.7. of the preamble of this final rule, we are finalizing our proposal to specify in subregulatory guidance, when measure data will be publicly available and when the preview period will occur, instead of in rulemaking as we have previously done. We are no longer specifying how far in advance of the public display date the preview period will occur. We do not believe this policy will result in any change in burden because it does not require IPFs to report any more or less data. Rather, the timeline for public display of that data is simply shifting.

In the table below, we set out a summary of annual burden estimates.

ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS UNDER OMB CONTROL NUMBER 0938–1171 (CMS–10432)

Finalized action [preamble section]	Respondents	Responses per respondent	Burden per response (hours)*	Total annual burden (hours)	Labor cost ($/hr)	Total cost ($)
Add NQF #1664 [VIII.D.4.a.]	1,684	848	0.25	357,008	32.84	11,724,143
Add Readmissions Measure [VIII.D.4.b.]	1,684	0	0	0	32.84	0
Training	1,684	1	2	3,368	32.84	110,605
Shift Public Display Timeline [VIII.D.7.]	1,684	0	0	0	32.84	0
	1,684			360,376	32.84	11,834,748

12. ICRs for the Electronic Health Record (EHR) Incentive Programs and Meaningful Use

In section VIII.E. of the preambles of the proposed rule (81 FR 25244 through 25247) and this final rule, we discuss our proposals to align the Medicare and Medicaid EHR Incentive Programs reporting and submission timelines for electronically submitted clinical quality measures for eligible hospitals and CAHs with the Hospital IQR Program's reporting and submission timelines for the FY 2019 payment determination. Because these newly finalized policies for data collection in this final rule will align with the reporting requirements in place for the Hospital IQR Program, and eligible hospitals and CAHs still have the option to submit their clinical quality measures via attestation for the Medicare and Medicaid EHR Incentive Programs for CY 2017 reporting, we do not believe there is any additional burden for this collection of information. However, starting with CY 2018 reporting, eligible hospitals and CAHs participating in the Medicare EHR Incentive Programs must electronically report CQMs using CEHRT where feasible; and attestation to CQMs will no longer be an option except in certain

[399] *http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html.*

circumstances where electronic reporting is not feasible (80 FR 62894).

We did not receive any public comments regarding this information collection. We refer readers to the table in section X.B.7. of the preamble of this final rule for burden estimates relating to the reporting of 8 CQMs.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble of this final rule, the Centers for Medicare and Medicaid Services confirms, as final, the interim final rules that appeared in the August 17, 2015 (80 FR 49594) and April 21, 2016 (81 FR 23428) **Federal Register**s and further amends 42 CFR Chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.926 is amended by adding paragraph (u) to read as follows:

§ 405.926 Actions that are not initial determinations.

* * * * *

(u) Issuance of notice to an individual entitled to Medicare benefits under Title XVIII of the Act when such individual received observation services as an outpatient for more than 24 hours, as specified under § 489.20(y) of this chapter.

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 3. The authority citation for Part 412 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Pub. L. 113–67, sec. 112 of Pub. L. 113–93, and sec. 231 of Pub. L. 114–113.

■ 4. Section 412.64 is amended by adding paragraph (d)(1)(vii) and revising paragraphs (h)(4) introductory text and (h)(4)(vi) introductory text to read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(vii) For fiscal year 2017, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraphs (d)(2) and (3) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.75 percentage point.

* * * * *

(h) * * *

(4) For discharges on or after October 1, 2004 and before October 1, 2017, CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology:

* * * * *

(vi) For discharges on or after October 1, 2012 and before October 1, 2017, the minimum wage index value for the State is the higher of the value determined under paragraph (h)(4)(iv) of this section or the value computed using the following alternative methodology:

* * * * *

■ 5. Section 412.103 is amended by adding a new paragraph (b)(6) to read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

* * * * *

(b) * * *

(6) *Lock-in date for the wage index calculation and budget neutrality.* In order for a hospital to be treated as rural in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (2), and (4) and (h) for the payment rates for the next Federal fiscal year, the hospital's filing date must be no later than 70 days prior to the second Monday in June of the current Federal fiscal year and the application must be approved by the CMS Regional Office in accordance with the requirements of this section.

* * * * *

■ 6. Section 412.106 is amended by revising paragraph (g)(1)(iii)(C) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C)(*1*) For fiscal years 2014 and 2015, CMS will base its estimates of the amount of hospital uncompensated care on the most recent available data on utilization for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (4) of this section.

(*2*) For fiscal year 2016, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (4) of this section, using data on Medicaid utilization from 2012 or 2011 cost reports from the most recent HCRIS database extract, the 2012 cost report data submitted to CMS by IHS hospitals, and the most recent available data on Medicare SSI utilization.

(*3*) For fiscal year 2017, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (4) of this section, using data on Medicaid utilization from 2011, 2012, and 2013 cost reports from the most recent HCRIS database extract, the 2011 and 2012 cost report data submitted to CMS by IHS hospitals, and the most recent available 3 years of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data).

* * * * *

■ 7. Section 412.140 is amended by revising paragraph (d)(2) to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.

* * * * *

(d) * * *

(2) A hospital meets the chart-abstracted validation requirement with respect to a fiscal year if it achieves a

75-percent score, as determined by CMS.

* * * * *

■ 8. Section 412.160 is amended by revising the definitions of ''Achievement threshold (or achievement performance standard)'', ''Benchmark'', and ''Cited for deficiencies that pose immediate jeopardy'' to read as follows:

§ 412.160 Definitions for the Hospital Value-Based Purchasing (VBP) Program.

* * * * *

Achievement threshold (or achievement performance standard) means the median (50th percentile) of hospital performance on a measure during a baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the measures in the Efficiency and Cost Reduction domain, and the median (50th percentile) of hospital performance on a measure during the performance period with respect to a fiscal year, for the measures in the Efficiency and Cost Reduction domain.

* * * * *

Benchmark means the arithmetic mean of the top decile of hospital performance on a measure during the baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the measures in the Efficiency and Cost Reduction domain, and the arithmetic mean of the top decile of hospital performance on a measure during the performance period with respect to a fiscal year, for the measures in the Efficiency and Cost Reduction domain.

Cited for deficiencies that pose immediate jeopardy means that, during the applicable performance period, the Secretary cited the hospital for immediate jeopardy on at least three surveys using the Form CMS–2567, Statement of Deficiencies and Plan of Correction. CMS assigns an immediate jeopardy citation to a performance period as follows: (1) If the Form CMS–2567 only contains one or more EMTALA-related immediate jeopardy citations, CMS uses the date that the Form CMS–2567 is issued to the hospital; (2) If the Form CMS–2567 only contains one or more Medicare conditions of participation immediate jeopardy citations, CMS uses the survey end date generated in ASPEN; and (3) If the Form CMS–2567 contains both one or more EMTALA-related immediate jeopardy citations and one or more Medicare conditions of participation immediate jeopardy citations, CMS uses the survey end date generated in ASPEN.

* * * * *

■ 9. Section 412.170 is amended by revising the definition of ''Applicable period'' to read as follows:

§ 412.170 Definitions for the Hospital-Acquired Condition Reduction Program.

* * * * *

Applicable period is, unless otherwise specified by the Secretary, with respect to a fiscal year, the 2-year period (specified by the Secretary) from which data are collected in order to calculate the total hospital-acquired condition score under the Hospital-Acquired Condition Reduction Program.

* * * * *

■ 10. Section 412.204 is amended by revising paragraph (d) introductory text and adding paragraph (e) to read as follows:

§ 412.204 Payment to hospitals located in Puerto Rico.

* * * * *

(d) *FY 2005 through December 31, 2015.* For discharges occurring on or after October 1, 2004 and before January 1, 2016, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

* * * * *

(e) *January 1, 2016 and thereafter.* For discharges occurring on or after January 1, 2016, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to 100 percent of a national prospective payment rate for inpatient operating costs, as determined under § 412.212.

■ 11. Section 412.256 is amended by revising paragraph (a)(1) to read as follows:

§ 412.256 Application requirements.

(a) * * *

(1) An application must be submitted to the MGCRB according to the method prescribed by the MGCRB, with an electronic copy of the application sent to CMS.

* * * * *

■ 12. Section 412.374 is amended by revising paragraph (b) introductory text and adding paragraph (e) to read as follows:

§ 412.374 Payments to hospitals located in Puerto Rico.

* * * * *

(b) *FY 2005 through FY 2016.* For discharges occurring on or after October 1, 2004 and on or before September 30, 2016, payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of the following:

* * * * *

(e) *FY 2017 and subsequent fiscal years.* For discharges occurring on or after October 1, 2016, payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are based on 100 percent of the Federal rate, as determined under § 412.308.

■ 13. Section 412.503 is amended by adding definitions of ''MSA'', ''MSA-dominant area'', and ''MSA-dominant hospital'' and revising the definitions of ''Outlier payment'' and ''Subsection (d) hospital'', to read as follows:

§ 412.503 Definitions.

* * * * *

MSA means a Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget.

MSA-dominant area means an MSA in which an MSA-dominant hospital is located.

MSA-dominant hospital means a hospital that has discharged more than 25 percent of the total subsection (d) hospital Medicare discharges in the MSA (not including discharges paid by a Medicare Advantage plan) in which the hospital is located.

* * * * *

Outlier payment means an additional payment beyond the long-term care hospital standard Federal payment rate or the site neutral payment rate (including, when applicable, the blended payment rate), as applicable, for cases with unusually high costs.

* * * * *

Subsection (d) hospital means, for purposes of § 412.522, a hospital defined in section 1886(d)(1)(B) of the Social Security Act and includes any hospital that is located in Puerto Rico and that would be a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Social Security Act if it were located in one of the 50 States.

* * * * *

■ 14. Section 412.507 is amended by revising paragraph (a) and adding paragraph (b)(3) to read as follows:

§ 412.507 Limitation on charges to beneficiaries.

(a) *Prohibited charges.* Except as provided in paragraph (b) of this section, a long-term care hospital may not charge a beneficiary for any covered services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary

are greater than the amount the hospital is paid under the prospective payment system.

(1) If Medicare has paid at the full LTCH prospective payment system standard Federal payment rate, that payment applies to the hospital's costs for services furnished until the high-cost outlier threshold is met.

(2) If Medicare pays less than the full LTCH prospective payment system standard Federal payment rate and payment was not made at the site neutral payment rate (including, when applicable, the blended payment rate), that payment only applies to the hospital's costs for those costs or days used to calculate the Medicare payment.

(3) For cost reporting periods beginning on or after October 1, 2016, for Medicare payments to a long-term care hospital described in § 412.23(e)(2)(ii), that payment only applies to the hospital's costs for those costs or days used to calculate the Medicare payment.

(4) If Medicare has paid at the full site neutral payment rate, that payment applies to the hospital's costs for services furnished until the high-cost outlier is met.

(b) * * *

(3) For cost reporting periods beginning on or after October 1, 2016, a long-term care hospital described in § 412.23(e)(2)(ii) may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter, for items and services as specified under § 489.20(a) of this chapter, and for services provided during the stay for which benefit days were not available and that were not the basis for adjusted LTCH prospective payment system payment amount under § 412.526.

■ 15. Section 412.522 is amended by adding paragraph (c)(2)(v) to read as follows:

§ 412.522 Application of site neutral payment rate.

* * * * *

(c) * * *

(2) * * *

(v) The limitation on long-term care hospital admissions from referring hospitals specified in § 412.538.

* * * * *

■ 16. Section 412.523 is amended by adding paragraph (c)(3)(xiii) to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(xiii) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2016, and ending September 30, 2017.* The LTCH PPS standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2016, and ending September 30, 2017, is the standard Federal payment rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.75 percent and further adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

■ 17. Section 412.525 is amended by adding paragraph (d)(6), to read as follows:

§ 412.525 Adjustments to the Federal prospective payment.

* * * * *

(d) * * *

(6) The limitation on long-term care hospital admissions from referring hospitals specified in § 412.538.

■ 18. The section heading of § 412.534 is revised to read as follows:

§ 412.534 Special payment provisions for long-term care hospitals-within-hospitals and satellites of long-term care hospitals, effective for discharges occurring in cost reporting periods beginning on or before September 30, 2016.

* * * * *

■ 19. The section heading of § 412.536 is revised to read as follows:

§ 412.536 Special payment provisions for long-term care hospitals and satellites of long-term care hospitals that discharge Medicare patients admitted from a hospital not located in the same building or on the same campus as the long-term care hospital or satellite of the long-term care hospital, effective for discharges occurring on or before September 30, 2016 or in cost reporting periods beginning on or before June 30, 2016.

* * * * *

■ 20. Section 412.538 is added to read as follows:

§ 412.538 Limitation on long-term care hospital admissions from referring hospitals.

(a) *Scope.* (1) The provisions of this section apply to all long-term care hospitals excluded from the hospital inpatient prospective payment system under § 412.23(e), except as specified in paragraph (a)(2) of this section, effective for—

(i) Discharges occurring in cost reporting periods beginning on or after October 1, 2016 (for long-term care hospitals that formerly would have been subject to § 412.534); or

(ii) Discharges occurring on or after October 1, 2016 in cost reporting periods beginning on or after July 1, 2016 (for long-term care hospitals that would not have been formerly subject to § 412.534).

(2) Notwithstanding the preceding paragraphs of this section, the provisions of this section do not apply to—

(i) A long-term care hospital described in § 412.23(e)(2)(ii); or

(ii) A long-term care hospital described in § 412.23(e)(2)(i) that meets the criteria in § 412.22(f).

(3) For purposes of this section, all long-term care hospitals described in paragraph (a)(1) of this section and all referring hospitals are as identified by CCN.

(b) *Discharges at or below the applicable percent threshold.* For any long-term care hospital that is not exempted by paragraph (a)(2) of this section with discharges occurring as described in paragraph (a)(1) of this section, of which no more than the applicable percent threshold (as defined in paragraph (e) of this section) was admitted to the long-term care hospital from a single referring hospital, payments are the amount otherwise payable under this subpart without adjustment under this section.

(c) *Discharges in excess of the applicable percent threshold.* For any long-term care hospital that is not exempted by paragraph (a)(2) of this section with discharges occurring as described in paragraph (a)(1) of this section, of whom more than the applicable percentage threshold (as defined in paragraph (e) of this section) was admitted to the long-term care hospital from a single referring hospital, payments for the Medicare discharges that caused the long-term care hospital to exceed or remain in excess of such threshold are paid at the lesser of the amount otherwise payable under this subpart without adjustment under this section or the amount equivalent to the hospital inpatient prospective payment system amount as defined in paragraph (f) of this section. Payments for discharges not in excess of the applicable percentage threshold (as defined in paragraph (e) of this section) are the amount otherwise payable under this subpart without adjustment under this section.

(d) *Determination of exceeding the applicable percentage threshold.*

(1) *General.* The determination of whether a long-term care hospital (as described in paragraph (a)(1)) of this section has exceeded its applicable percentage threshold (as defined in paragraph (e) of this section) in regard to discharges described in paragraph (a)(1) of this section that were admitted

from a single referring hospital is made by comparing the long-term care hospital's percentage of Medicare discharges occurring as described in paragraph (a)(1) of this section (as calculated under paragraph (d)(2) of this section) to the long-term care hospital's applicable percentage threshold in paragraph (e) of this section.

(2) *Percentage of Medicare discharges.* For each referring hospital, the percentage of Medicare discharges admitted to the long-term care hospital is calculated by dividing the amount in paragraph (d)(2)(i) of this section by the amount in paragraph (d)(2)(ii) of this paragraph.

(i) The number of the long-term care hospital's Medicare discharges in the cost reporting period that were admitted from a single referring hospital on whose behalf an outlier payment was not made to that referring hospital, and for whom payment was not made by a Medicare Advantage plan.

(ii) The long-term care hospital's total number of Medicare discharges in its cost reporting period for whom payment was not made by a Medicare Advantage plan.

(e) *Applicable percentage threshold.* (1) *General.* For the purposes of this section, except as provided for in paragraphs (e)(2) and (3) of this section, ''applicable percentage threshold'' means 25 percent.

(2) *Special treatment of exclusively rural long-term care hospitals.* In the case of a long-term care hospital that is located in a rural area as defined in § 412.503, the applicable percentage threshold means 50 percent. If a long-term care hospital has multiple locations, all locations of the long-term care hospital must be in a rural area (as defined in § 412.503) in order to be treated as rural under this section.

(3) *Special treatment for long-term care hospitals located in an MSA with an MSA-dominant hospital.* In the case of a long-term care hospital that admits Medicare patients from a referring MSA-dominant hospital (as defined in § 412.503), the applicable percentage threshold means the MSA-dominant hospital's percentage of total subsection (d) hospital Medicare discharges in the MSA in which the long-term care hospital is located during the cost reporting period for which the adjustment under this section is made, but in no case is less than 25 percent or more than 50 percent. The determination of the applicable percentage threshold in this paragraph does not include discharges paid by a Medicare Advantage plan. If a long-term care hospital has multiple locations payable under this subpart, all locations of the long-term care hospital must be in an MSA with an MSA-dominant hospital in order to be treated as such under this section.

(f) *Determining the amount equivalent to the hospital inpatient prospective payment system amount.*—(1) As specified in paragraphs (b) and (c) of this section, CMS calculates an amount payable under subpart O that is equivalent to an amount that would be paid for the services provided if such services had been provided in an inpatient prospective payment system hospital (that is, the amount that would be determined under the rules at § 412.1(a)). This amount is based on the sum of the applicable hospital inpatient prospective payment system operating standardized amount and capital Federal rate in effect (as set forth in section § 412.529(d)(4)) at the time of the long-term care hospital discharge.

(2) In addition to the payment amount under paragraph (f)(1) of this section, an additional payment for high-cost outlier cases is based on the applicable fixed-loss amount established for the hospital inpatient prospective payment system in effect at the time of the long-term care hospital discharge.

■ 21. Section 412.560 is amended by revising paragraph (c)(1) to read as follows:

§ 412.560 Participation, data submission, and other requirements under the Long-Term Care Hospital Quality Reporting (LTCHQR) Program.

* * * * *

(c) * * *

(1) A long-term care hospital that wishes to request an exception or extension with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 22. The authority for Part 413 is revised to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 3201 of Pub. L. 112–96 (126 Stat. 156), sec. 632 of Pub. L. 112–240 (126 Stat. 2354), sec. 217 of Pub. L. 113–93 (129 Stat. 1040), and sec., 204 of Pub. L. 113–295 (128 Stat. 4010).

■ 23. Section 413.17 is amended by revising paragraph (d)(1) introductory text to read as follows:

§ 413.17 Cost to related organizations.

* * * * *

(d) * * *

(1) An exception is provided to this general principle if the provider demonstrates by convincing evidence to the satisfaction of the contractor, that—

* * * * *

■ 24. Section 413.24 is amended by revising paragraphs (f)(4)(i), (ii), and (iv) to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(f) * * *

(4) * * *

(i) As used in this paragraph, ''provider'' means a hospital, skilled nursing facility, home health agency, hospice, organ procurement organization, histocompatibility laboratory, rural health clinic, federally qualified health center, community mental health center, or end-stage renal disease facility.

(ii) Effective for cost reporting periods beginning on or after October 1, 1989 for hospitals, cost reporting periods ending on or after February 1, 1997 for skilled nursing facilities and home health agencies, cost reporting periods ending on or after December 31, 2004 for hospices, and end-stage renal disease facilities, and cost reporting periods ending on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers, a provider is required to submit cost reports in a standardized electronic format. The provider's electronic program must be capable of producing the CMS standardized output file in a form that can be read by the contractor's automated system. This electronic file, which must contain the input data required to complete the cost report and to pass specified edits, must be forwarded to the contractor for processing through its system.

* * * * *

(iv) Effective for cost reporting periods ending on or after September 30, 1994 for hospitals, cost reporting periods ending on or after February 1, 1997 for skilled nursing facilities and home health agencies, cost reporting periods ending on or after December 31, 2004 for hospices and end-stage renal disease facilities, and cost reporting

periods ending on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers, a provider must submit a hard copy of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a statement signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report. During a transition period (first two cost-reporting periods on or after December 31, 2004 for hospices and end-stage renal disease facilities, and the first two cost-reporting periods on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, community mental health centers), providers must submit a hard copy of the completed cost report forms in addition to the electronic file. The following statement must immediately precede the dated signature of the provider's administrator or chief financial officer:

I hereby certify that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by _____(Provider Name(s) and Number(s)) for the cost reporting period beginning ___and ending ___and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

* * * * *

■ 25. Section 413.79 is amended by revising paragraphs (k)(1)(i) and (ii) and (k)(2), (3), (4), and (7)(ii) and (iii) to read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(k) * * *

(1) * * *

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For rural track programs started on or after October 1, 2012, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital.

(ii) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the third year of the rural track's existence are training in the rural track at the urban hospital and are designated at the beginning of their training to be rotated to the rural hospital(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2002, or for more than one-half of the duration of the program effective for cost reporting periods beginning on or after October 1, 2003, and the number of years those residents are training at the urban hospital. For rural track programs started on or after October 1, 2012, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section.

(2) If an urban hospital rotates residents to a separately accredited rural track program at a rural nonprovider site(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d) through (g). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track FTE limitation, determined as follows:

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s). For rural track programs started on or after October 1, 2012, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s).

(ii)(A) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(*1*) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at—

(*i*) The urban hospital and are designated at the beginning of their training to be rotated to a rural nonprovider site(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000 and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(*ii*) The rural nonprovider site(s); and

(*2*) The number of years in which the residents are expected to complete each program based on the minimum accredited length for the type of program.

(B) For rural track programs started on or after October 1, 2012, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section.

(3) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the rural hospital may not include those residents in its FTE count (if the rural track is not a new program under paragraph (e)(3) of this section, or if the rural hospital's FTE count exceeds that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For rural track programs started on or after October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s)

for one-half or less than one-half of the duration of the program, the rural hospital may not include those residents in its FTE count (if the rural track is not a new program under paragraph (e)(3) of this section, or if the rural hospital's FTE count exceeds that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation.

(4)(i) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural nonprovider site(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000 and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d) through (g), as applicable. The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

(A) For the first 3 years of the rural track's existence, the rural track FTE limitation for the urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the rural nonprovider site(s).

(B) Beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(*1*) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at the rural nonprovider site(s) or are designated at the beginning of their training to be rotated to the rural nonprovider site(s) for a period that is less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2002, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(*2*) The length of time in which the residents are training at the rural nonprovider site(s) only.

(ii) For rural track programs started on or after October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural nonprovider site(s) for one-half or less than one-half of the duration of the program, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(g). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

(A) Prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for the urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the rural nonprovider site(s).

(B) Beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(*1*) The highest number of residents in any program year who, during the fifth year of the rural track's existence, are training in the rural track at the rural nonprovider site(s) or are designated at the beginning of their training to be rotated to the rural nonprovider site(s) for a period that is for one-half or less than one-half of the duration of the program; and

(*2*) The ratio of the length of time in which the residents are training at the rural nonprovider site(s) only to the total duration of the program.

* * * * *

(7) * * *

(ii)(A) For rural track programs started prior to October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and, during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) and subject to paragraph (k)(7)(iii) of this section for the rural track programs started prior to the adoption of such new OMB standards for delineating statistical areas.

(B) For rural track programs started on or after October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and, during the 5-year period that is used to calculate the urban hospital's rural track FTE limit, that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) and subject to paragraph (k)(7)(iii) of this section for the rural track programs started prior to the adoption of such new OMB standards for delineating statistical areas.

(iii)(A) For rural track programs started prior to October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, regardless of whether the redesignation of the rural hospital occurs during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, or after the 3-year period used to calculate the urban hospital's rural track FTE limit, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) based on the rural track programs started prior to the change in the hospital's geographic designation. In order for the urban hospital to receive or use the adjustment to its FTE resident cap for training FTE residents in the rural track residency program that was started prior to the most recent OMB standards for delineating statistical areas adopted by CMS, one of the following two conditions must be met by the end of a period that begins when the most recent OMB standards for delineating statistical areas are adopted by CMS and continues through the end of the second residency training year following the date the most recent OMB delineations are adopted by CMS: The hospital that has been redesignated from rural to urban must reclassify as rural under § 412.103 of this chapter, for purposes of IME only; or the urban hospital must find a new site that is geographically rural consistent with the most recent geographical location delineations adopted by CMS. In order to receive an adjustment to its FTE resident cap for an additional new rural track residency program, the urban hospital must participate in a rural track program with sites that are geographically rural based on the most recent geographical location delineations adopted by CMS.

(B) For rural track programs started on or after October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program

under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, regardless of whether the redesignation of the rural hospital occurs during the 5-year period that is used to calculate the urban hospital's rural track FTE limit, or after the 5-year period used to calculate the urban hospital's rural track FTE limit, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) based on the rural track programs started prior to the change in the hospital's geographic designation. In order for the urban hospital to receive or use the adjustment to its FTE resident cap for training FTE residents in the rural track residency program that was started prior to the most recent OMB standards for delineating statistical areas adopted by CMS, one of the following two conditions must be met by the end of a period that begins when the most recent OMB standards for delineating statistical areas are adopted by CMS and continues through the end of the second residency training year following the date the most recent OMB delineations are adopted by CMS: The hospital that has been redesignated from rural to urban must reclassify as rural under § 412.103 of this chapter, for purposes of IME only; or the urban hospital must find a new site that is geographically rural consistent with the most recent geographical location delineations adopted by CMS. In order to receive an adjustment to its FTE resident cap for an additional new rural track residency program, the urban hospital must participate in a rural track program with sites that are geographically rural based on the most recent geographical location delineations adopted by CMS.

* * * * *

§ 413.200 [Amended]

■ 26. In § 413.200, amend paragraph (c)(1)(i) by removing the phrase ''three months'' and adding in its place the phrase ''5 months''.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 27. The authority citation for Part 489 is revised to read as follows:

Authority: Secs. 1102 1819, 1820(E), 1861, 1864(M), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh)).

■ 28. Section 489.20 is amended by adding paragraph (y) to read as follows:

§ 489.20 Basic commitments.

* * * * *

(y) In the case of a hospital or critical access hospital, to provide notice, as specified in paragraphs (y)(1) and (2) of this section, to each individual entitled to Medicare benefits under Title XVIII of the Act when such individual receives observation services as an outpatient for more than 24 hours. Notice must be provided to the individual not later than 36 hours after observation services are initiated or sooner if the individual is transferred, discharged, or admitted. Notice may be provided before such individual receives 24 hours of observation services as an outpatient.

(1) *Written notice.* Hospitals and critical access hospitals must use a standardized written notice, as specified by the Secretary, which includes the following information:

(i) An explanation of the status of the individual as an outpatient receiving observation services and not as an inpatient of the hospital or critical access hospital and the reason for status as an outpatient receiving observation services; and

(ii) An explanation of the implications of such status as an outpatient on services furnished by the hospital or critical access hospital (including services furnished on an inpatient basis), such as Medicare cost-sharing requirements, and subsequent eligibility for Medicare coverage for skilled nursing facility services.

(2) *Oral notice.* The hospital must give an oral explanation of the written notification described in paragraph (y)(1) of this section.

(3) *Signature requirements.* The written notice specified in paragraph (y)(1) of this section must either—

(i) Be signed by the individual who receives observation services as an outpatient or a person acting on the individual's behalf to acknowledge receipt of such notification; or

(ii) If the individual who receives observation services as an outpatient or the person acting on behalf of the individual refuses to provide the signature described in paragraph (y)(1) of this section, is signed by the staff member of the hospital or critical access hospital who presented the written notification and includes the name and title of the staff member, a certification that the notification was presented, and the date and time the notification was presented.

Dated: July 25, 2016.

Andrew M. Slavitt,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 27, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning On or After October 1, 2016, and Payment Rates for LTCHs Effective for Discharges Occurring On or After October 1, 2016

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2017 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2017. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this final rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that will be effective for cost reporting periods beginning on or after October 1, 2016.

In addition, we are setting forth a description of the methods and data we used to determine the LTCH PPS standard Federal payment rate that will be applicable to Medicare LTCHs for FY 2017.

In general, except for SCHs and MDHs, for FY 2017, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (including, as discussed in section IV.F. of the preamble of this final rule, uncompensated care payments under section 1886(r)(2) of the Act); the

updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

We note that section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017).

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Pub. L. 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Pub. L. 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital-specific rates based on its FY 2002 cost report. Section 5003(c) of Pub. L. 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate. Further, based on the provisions of section 5003(d) of Pub. L. 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor.

As discussed in section IV.A. of the preamble of this final rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, CMS calculated the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to calculate a Puerto Rico-specific standardized amount. For operating costs for inpatient hospital discharges occurring in FY 2017 and subsequent fiscal years, consistent with the provisions of section 1886(d)(9)(E) of the Act as amended by section 601 of Pub. L. 114–113, subsection (d) Puerto Rico hospitals will continue to be paid based on 100 percent of the national standardized amount. Because Puerto Rico hospitals are now paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update, our discussion below does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are making changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2017. In section III. of this Addendum, we discuss our policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2017. In section IV. of this Addendum, we set forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2017. In section V. of this Addendum, we discuss policy changes for determining the LTCH PPS standard Federal payment rate for LTCHs paid under the LTCH PPS for FY 2017. The tables to which we refer to in the preamble of this final rule are listed in section VI. of this Addendum and are available via the Internet on the CMS Web site.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2017

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. Below we discuss the factors we used for determining the prospective payment rates for FY 2017.

In summary, the standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2017, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section IV.B. of the preamble of this final rule for a complete discussion on the FY 2017 inpatient hospital update. Below is a table with these four options:

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.025	0.0	−2.025
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.3	−0.3	−0.3	−0.3
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Applicable Percentage Increase Applied to Standardized Amount	1.65	−0.375	0.975	−1.05

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2017.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index changes are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act. We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2016 budget neutrality factor and applying a revised factor.
- As discussed below and in section III.G. of the preamble of this final rule, an adjustment to offset the cost of the 3-year hold harmless transitional wage index provisions provided by CMS as a result of the implementation of the new OMB labor market area delineations (beginning with FY 2015).
- An adjustment to remove the FY 2016 outlier offset and apply an offset for FY 2017, as provided for under section 1886(d)(3)(B) of the Act.
- As discussed below and in section II.D. of the preamble of this final rule, a recoupment to meet the requirements of section 631 of ATRA to adjust the standardized amount to offset the estimated amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.
- As discussed below and in section IV.P. of the preamble of this final rule, we are applying a (1/0.998) adjustment to the FY 2017 payment rates using our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to permanently prospectively remove the 0.2 percent reduction to the rate put in place in FY 2014 to offset the estimated increase in IPPS expenditures associated with the projected increase in inpatient encounters that was expected to result from the new inpatient admission guidelines under the 2-midnight policy.
- As discussed below and in section IV.P. of the preamble of this final rule, we are applying a temporary one-time prospective increase to the FY 2017 payment rates of 0.6 percent or a factor of 1.006 using our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to address the effects of the 0.2 percent reduction to the payment rate for the 2-midnight policy in effect for FY 2014, FY 2015, and FY 2016.

For FY 2017, consistent with current law, we applied the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we applied a uniform, national budget neutrality adjustment to the FY 2017 wage index for the rural floor. We note that, in section III.H.2.b. of the preamble to this final rule, we are extending the imputed floor policy (both the original methodology and alternative methodology) for FY 2017. Therefore, for FY 2017, in this final rule, we are continuing to include the imputed floor (calculated under the original and alternative methodologies) in calculating the uniform, national rural floor budget neutrality adjustment, which will be reflected in the FY 2017 wage index.

In prior fiscal years, CMS made an adjustment to ensure the effects of the rural community hospital demonstration program required under section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration program for an additional 5 years, were budget neutral as required under section 410A(c)(2) of Public Law 108–173. As discussed in section IV.K.3. of the preamble to this final rule, given the small number of participating hospitals and the limited time of participation during FY 2017, as we proposed, we are foregoing the process of estimating the costs attributable to the demonstration for FY 2017 and instead analyzing the set of finalized cost reports for reporting periods beginning in FY 2016 when they become available. In addition, we discuss how we will reconcile the budget neutrality offset amounts identified in the IPPS final rules for FYs 2011 through 2016 with the actual costs of the demonstration for those years, considering the fact that the demonstration will end December 31, 2016. We stated that we believe it would be appropriate to conduct this analysis for FYs 2011 through 2016 at one time, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available. Such an aggregate analysis encompassing the cost experience through the end of the period of performance of the demonstration represents an administratively streamlined method, allowing for the determination of any appropriate final adjustment to the IPPS rates and obviating the need for

multiple fiscal-year-specific calculations and regulatory actions. Given the general lag of 3 years in finalizing cost reports, we expect any such analysis to be conducted in FY 2020. Therefore, for FY 2017, we are not making any adjustment to the standardized amounts for the rural community hospital demonstration program. We refer the reader to section IV.K. of the preamble of this final rule for a complete discussion on the rural community hospital demonstration program.

A. Calculation of the Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2017, we are continuing to use the national labor-related and nonlabor-related shares (which are based on the FY 2010-based hospital market basket) that were used in FY 2016. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2017, as discussed in section III. of the preamble of this final rule, we are continuing to use a labor-related share of 69.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we applied the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this final rule and are available via the Internet on the CMS Web site.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Accordingly, we calculated the FY 2017 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, in this final rule, we are using the revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2017 (which replaced the FY 2006-based IPPS operating and capital market baskets in FY 2014). As discussed in section IV.B. of the preamble of this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we reduced the FY 2017 applicable percentage increase (which is based on IHS Global Insight, Inc.'s (IGI's) second quarter 2016 forecast of the FY 2010-based IPPS market basket) by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2017) of 0.3 percentage point, which is calculated based on IGI's second quarter 2016 forecast.

In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are further updating the standardized amount for FY 2017 by the estimated market basket percentage increase less 0.75 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of the Act, as added and amended by sections 3401(a) and 10319(a) of the Affordable Care Act, further state that these adjustments may result in the applicable percentage increase being less than zero. The percentage increase in the market basket reflects the average change in the price of goods and services comprising routine, ancillary, and special care unit hospital inpatient services.

Based on IGI's 2016 second quarter forecast of the hospital market basket increase (as discussed in Appendix B of this final rule), the most recent forecast of the hospital market basket increase for FY 2017 is 2.7 percent. As discussed earlier, for FY 2017, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that could be applied to the standardized amount. We refer readers to section IV.B. of the preamble of this final rule for a complete discussion on the FY 2017 inpatient hospital update to the standardized amount. We also refer readers to the table above for the four possible applicable percentage increases that will be applied to update the national standardized amount. The standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the Internet on the CMS Web site reflect these differential amounts.

Although the update factors for FY 2017 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2017 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this final rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the FY 2017 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the

CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude critical access hospitals at the time of this final rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS-excluded cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.

• As in the past, we adjusted the FY 2017 standardized amount to remove the effects of the FY 2016 geographic reclassifications and outlier payments before applying the FY 2017 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on FY 2017 payment policies.

• We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

• Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

• In order to further ensure that we capture only FFS claims, as we proposed, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We also remove organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.

• The Bundled Payments for Care Improvement (BPCI) initiative, developed under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Under the BPCI initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. On January 31, 2013, CMS announced the first set of health care organizations selected to participate in the BPCI initiative. Additional organizations were selected in 2014. For additional information on the BPCI initiative, we refer readers to the CMS Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html.*

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343), for FY 2013 and subsequent fiscal years, we finalized a methodology to treat hospitals that participate in the BPCI initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process (which includes recalibration of the MS–DRG relative weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis) without regard to a hospital's participation within these bundled payment models (that is, as if they are not participating in those models under the BPCI initiative). For FY 2017, as we proposed, we are continuing to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations.

• Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, as we have done for the last 3 fiscal years, for FY 2017 and subsequent years, we are continuing to apply the hospital readmissions payment adjustment and the hospital VBP payment adjustment on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we applied the readmissions payment adjustment factor and the hospital VBP payment adjustment factor on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

For the purpose of calculating the FY 2017 readmissions payment adjustment factors, we used excess readmission ratios and aggregate payments for excess readmissions based on admissions from the prior fiscal year's applicable period because hospitals have had the opportunity to review and correct these data before the data were made public under the policy we adopted regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act. For FY 2017, in this final rule, we calculated the readmissions payment adjustment factors using excess readmission ratios and aggregate payments for excess readmissions based on admissions from the finalized applicable period for FY 2017 as hospitals have had the

opportunity to review and correct these data under our policy regarding the reporting of hospital-specific readmission rates consistent with section 1886(q)(6) of the Act. We discuss our policy regarding the reporting of hospital-specific readmission rates for FY 2017 in section IV.G.3.f. of the preamble of this final rule. (For additional information on our general policy for the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53400).)

In addition, for FY 2017, in this final rule, for the purpose of modeling aggregate payments when determining all budget neutrality factors, we used proxy hospital VBP payment adjustment factors for FY 2017 that are based on data from a historical period because hospitals have not yet had an opportunity to review and submit corrections for their data from the FY 2017 performance period. (For additional information on our policy regarding the review and correction of hospital-specific measure rates under the Hospital VBP Program, consistent with section 1886(o)(10)(A)(ii) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53578 through 53581), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74544 through 74547), and the Hospital Inpatient VBP final rule (76 FR 26534 through 26536).)

- The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments will receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured and an additional statutory adjustment, will be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2017 (as we did for the last 3 fiscal years), we included estimated empirically justified Medicare DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we considered estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

- When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.F. of the preamble to this final rule and below, we are continuing the FY 2014 finalized methodology under which we will take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we included estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section IV. of the preamble to this final rule, when computing payments under the Federal national rate plus 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate, we are continuing to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs.

- We include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2017. Similar to FY 2016, we are including this adjustment based on data on the prior year's performance. Payments for hospitals will be estimated based on the applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2017.

a. Recalibration of MS-DRG Relative Weights

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.G. of the preamble of this final rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For FY 2017, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2015 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2016 labor-related share percentages, the FY 2016 relative weights, and the FY 2016 pre-reclassified wage data, and applied the FY 2017 hospital readmissions payment adjustments and estimated FY 2017 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2016 labor-related share percentages, the FY 2017 relative weights, and the FY 2016 pre-reclassified wage data, and applied the same FY 2017 hospital readmissions payment adjustments and estimated FY 2017 hospital VBP payment adjustments applied above.

Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.999079 and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we also applied the MS–DRG reclassification and recalibration budget neutrality factor of 0.999079 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2016.

b. Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage

index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2017, we are adjusting 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this final rule.

To compute a budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2015 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2017 relative weights and the FY 2016 pre-reclassified wage indexes, applied the FY 2016 labor-related share of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the FY 2017 hospital readmissions payment adjustment and the estimated FY 2017 hospital VBP payment adjustment; and
- Aggregate payments using the FY 2017 relative weights and the FY 2017 pre-reclassified wage indexes, applied the labor-related share for FY 2017 of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same FY 2017 hospital readmissions payment adjustments and estimated FY 2017 hospital VBP payment adjustments applied above.

In addition, we applied the MS–DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2016 to FY 2017. By applying this methodology, we determined a budget neutrality adjustment factor of 1.000209 for changes to the wage index.

We note that, in prior fiscal years, we used a three-step process and combined the recalibration and wage index budget neutrality factors into one factor by multiplying the recalibration adjustment factor by the wage index adjustment factor. Because these two adjustments are required under two different sections of the Act (sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E)(i) of the Act) and the law requires that the wage index budget neutrality adjustment not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent for FY 2017, we separated these two adjustments and applied them individually to the standardized amount. Applying these factors individually rather than as a combined factor has no effect mathematically on adjusting the standardized amount.

c. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the budget neutrality adjustment factor for FY 2017, we used FY 2015 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2017 labor-related share percentages, FY 2017 relative weights and FY 2017 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the FY 2017 hospital readmissions payment adjustments and the estimated FY 2017 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2017 labor-related share percentages, FY 2017 relative weights, and FY 2017 wage data after such reclassifications, and applied the same FY 2017 hospital readmissions payment adjustments and the estimated FY 2017 hospital VBP payment adjustments applied above.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this final rule, which is available via the Internet on the CMS Web site. This table reflects reclassification crosswalks for FY 2017, and applies the policies explained in section III. of the preamble to this final rule. Based on these simulations, we calculated a budget neutrality adjustment factor of 0.988224 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The FY 2017 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2016 budget neutrality adjustment factor. We note that the FY 2017 budget neutrality adjustment reflects FY 2017 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this final rule.

d. Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) and the imputed floor under § 412.64(h)(4) are equal to the aggregate prospective payments that would have been made in the absence of such provisions. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.H. of the preamble of this final rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor and the imputed floor is a national adjustment to the wage index.

As noted above and as discussed in section III.H.2. of the preamble of this final rule, we are extending the imputed floor policy (both the original methodology and alternative

methodology) for FY 2017. Therefore, in order to ensure that aggregate payments to hospitals are not affected, similar to prior years, for FY 2017, we follow our policy of including the imputed floor (calculated under the original and alternative methodologies) in the national rural floor budget neutrality adjustment to the wage index.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2017, we calculated a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2017 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we used the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the new OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the FY 2017 rural Puerto Rico wage index was calculated based on the average of the FY 2017 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660), San German, PR (CBSA 41900) and San Juan-Carolina-Caguas, PR (CBSA 41980).

To calculate the national rural floor and imputed floor budget neutrality adjustment factor, we used FY 2015 discharge data to simulate payments and the post-reclassified national wage indexes and compared the following:

- National simulated payments without the national rural floor and imputed floor; and
- National simulated payments with the national rural floor and imputed floor.

Based on this comparison, we determined a national rural floor and imputed floor budget neutrality adjustment factor of 0.993200. The national adjustment was applied to the national wage indexes to produce a national rural floor and imputed floor budget neutral wage index.

e. Wage Index Transition Budget Neutrality

As discussed in section III.G. of the preamble of this final rule, in the past, we have provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts.

Similar to FY 2005, for FY 2015, we determined that the transition to using the new OMB labor market area delineations would have the largest impact on hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations. To alleviate the decreased payments associated with having a rural wage index, in calculating the area wage index, similar to the transition provided in the FY 2005 IPPS final rule, we finalized a policy to generally assign the hospitals in these counties the urban wage index value of the CBSA where they are physically located in FY 2014 for FYs 2015, 2016, and 2017. FY 2017 will be the final year of this 3-year transition policy. We note that the 1-year blended wage index transitional policy for all hospitals that experienced any decrease in their wage index value expired in FY 2015.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50372 through 50373), in the past, CMS has budget neutralized transitional wage indexes. We stated that because we established a policy that allows for the application of a transitional wage index only when it benefits the hospital, we believe that it would be appropriate to ensure that such a transitional policy does not increase aggregate Medicare payments beyond the payments that would be made had we simply adopted the OMB delineations without any transitional provisions. Therefore, as we did for FYs 2015 and 2016, for FY 2017, we used our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to make an adjustment to the national standardized amounts to ensure that total payments for the effect of the 3-year transitional wage index provisions will equal what payments would have been if we had fully adopted the new OMB delineations without providing these transitional provisions. To calculate the transitional wage index budget neutrality factor for FY 2017, we used FY 2015 discharge data to simulate payments and compared the following:

- Aggregate payments using the OMB delineations for FY 2017, the FY 2017 relative weights, FY 2017 wage data after such reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, application of the rural floor budget neutrality adjustment factor to the wage index, and application of the FY 2017 hospital readmissions payment adjustments and the estimated FY 2017 hospital VBP payment adjustments; and
- Aggregate payments using the OMB delineations for FY 2017, the FY 2017 relative weights, FY 2017 wage data after such reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, application of the rural floor budget neutrality adjustment factor to the wage index, application of the 3-year transitional wage indexes, and application of the same FY 2017 hospital readmissions payment adjustments and the estimated FY 2017 hospital VBP payment adjustments applied above.

Based on these simulations, we calculated a budget neutrality adjustment factor of 0.999994. Therefore, for FY 2017, we applied a transitional wage index budget neutrality adjustment factor of 0.999994 to the national average standardized amounts to ensure that the effects of these transitional wage indexes are budget neutral.

We note that the budget neutrality adjustment factor calculated above is based on the increase in payments in FY 2017 that will result from the final year of the 3-year transitional wage index policies. Therefore, we are applying this budget neutrality adjustment factor as a one-time adjustment to the FY 2017 national standardized amounts in order to offset the increase in payments in FY 2017 as a result of this final year of the 3-year transitional wage index. For FY 2017, we did not take into consideration the adjustment factor applied to the national standardized amounts in the previous fiscal year's update when calculating the current fiscal year transitional wage index budget neutrality adjustment factor (that is, this adjustment is not applied cumulatively).

f. Case-Mix Budget Neutrality Adjustment

(1) Background

Below we summarize the recoupment adjustment to the FY 2017 payment rates, as required by section 631 of the ATRA, to account for the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. We refer readers to section II.D. of the preamble of this final rule for a complete discussion regarding our policies for FY 2017 in this final rule and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix.

(2) Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA) to the National Standardized Amount

Section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment totaling $11 billion by FY 2017. Our actuaries estimated that if CMS were to fully account for the $11 billion recoupment required by section 631 of the ATRA in FY 2014, a one-time −9.3 percent adjustment to the standardized amount would be necessary. It is often our practice to delay or phase-in payment rate adjustments over more than 1 year, in order to moderate the effect on payment rates in any 1 year. Therefore, consistent with the policies that we have adopted in many similar cases, for FY 2014, FY 2015 and FY 2016, we applied a −0.8 percent adjustment to the standardized amount. For FY 2017, as we proposed, we are applying a −1.5 percent adjustment to the standardized amount. We refer the reader to section II. D. 6. of the preamble to this final rule for a complete discussion on this adjustment. We note that, as section 631 of the ATRA instructs the Secretary to make a recoupment adjustment only to the standardized amount, this adjustment does not apply to the hospital-specific payment rates.

g. Adjustment to IPPS Rates Resulting From 2-Midnight Policy

As discussed in section IV. P. of the preamble to this final rule, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50906 through 50954), we adopted the 2-midnight policy effective for dates of admission on or after October 1, 2013. We used our authority under section 1886(d)(5)(I)(i) of the Act to make a reduction of 0.2 percent to the standardized amount, the Puerto Rico standardized amount, and the hospital-specific payment rate, and we used our authority under section 1886(g) of the Act to make a reduction of 0.2 percent to the national capital Federal rate and the Puerto Rico-specific capital rate, in order to offset the estimated increase of $220 million in IPPS expenditures in FY 2014 as a result of the 2-midnight policy.

In *Shands Jacksonville Medical Center, Inc.* v. *Burwell,* No. 14–263 (D.D.C.) and related cases, hospitals challenged the 0.2 percent reduction in IPPS rates to account for the estimated $220 million in additional FY 2014 expenditures resulting from the 2-midnight policy. In its Memorandum Opinion, issued September 21, 2015, the Court found that the ''Secretary's interpretation of the exceptions and adjustments provision is a reasonable one'' for this purpose. However, the Court also ordered the 0.2 percent reduction remanded back to the Secretary, without vacating the rule, to correct certain procedural deficiencies in the promulgation of the 0.2 percent reduction and reconsider the adjustment. In accordance with the Court's order, we published a notice with comment period that appeared in the December 1, 2015 **Federal Register** (80 FR 75107), which discussed the basis for the 0.2 percent reduction and its underlying assumptions and invited comments on the same in order to facilitate our further consideration of the FY 2014 reduction.

We still believe that the assumptions underlying the 0.2 percent reduction to the rates put in place beginning in FY 2014 were reasonable at the time we made them in 2013. Nevertheless, taking all the factors discussed in section IV. P of the preamble to this final rule into account, we believe it is appropriate to use our authority under section 1886(d)(5)(I)(i) to prospectively remove, beginning in FY 2017, the 0.2 percent reduction to the standardized amount and hospital-specific rates put in place beginning in FY 2014. The 0.2 percent reduction was implemented by including a factor of 0.998 in the calculation of the FY 2014 standardized amount and hospital-specific rates, permanently reducing the standardized amount and hospital-specific rates for FY 2014 and future years until the 0.998 is removed. As we proposed, we are permanently removing the 0.998 reduction beginning in FY 2017 by including a factor of (1/0.998) in the calculation of the FY 2017 standardized amount and hospital specific rate.

In addition, for the reasons discussed in section IV.P of the preamble of this final rule, we believe that it is appropriate to use our authority under section 1886(d)(5)(I)(i) to temporarily increase the standardized amount and hospital-specific rates, only for FY 2017, to address the effect of the 0.2 percent reduction to the standardized amount and hospital-specific rates in effect for FY 2014, the 0.2 percent reduction to the standardized amount and hospital-specific rates in effect for FY 2015 (recall the 0.998 factor included in the calculation of the FY 2014 payment rates permanently reduced the payment rates for FY 2014 and future years until it is removed), and the 0.2 percent reduction to the standardized amount and hospital-specific payment rates in effect for FY 2016. We believe that the most transparent, expedient, and administratively feasible method to accomplish this is a temporary one-time prospective increase to the FY 2017 standardized amount and hospital-specific rates of 0.6 percent (= 0.2 percent + 0.2 percent + 0.2 percent). Specifically, we are including a factor of 1.006 in the calculation of the standardized amount and the hospital-specific rates in FY 2017 and then removing this temporary one-time prospective increase by including a factor of (1/1.006) in the calculation of the standardized amount and hospital-specific rates for FY 2018.

We refer the reader to section IV.P. of the preamble to this final rule for a complete discussion.

h. Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2017 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934, and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the 5.1 percent target by dividing the total operating

outlier payments by the total operating DRG payments plus outlier payments. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html*.

(1) FY 2017 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for detailed discussion of the changes.

As we have done in the past, to calculate the FY 2017 outlier threshold, we simulated payments by applying FY 2017 payment rates and policies using cases from the FY 2015 MedPAR file. Therefore, in order to determine the FY 2017 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2015 to FY 2017. As discussed in the FY 2015 IPPS/LTCH PPS final rule, we believe that a methodology that is based on 1-year of charge data will provide a more stable measure to project the average charge per case because our prior methodology used a 6-month measure, which inherently uses fewer claims than a 1-year measure and makes it more susceptible to fluctuations in the average charge per case as a result of any significant charge increases or decreases by hospitals. The methodology we proposed, and are finalizing, to calculate the charge inflation factor for FY 2017 and subsequent fiscal years is as follows:

- To produce the most stable measure of charge inflation, we applied the following inclusion and exclusion criteria of hospitals claims in our measure of charge inflation: include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); included CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; included hospitals in Maryland; and removed PPS excluded cancer hospitals who have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we captured only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we captured only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS.

In the FY 2016 IPPS/LTCH final rule (80 FR 49779–49780), we stated that commenters were concerned that they were unable to replicate the calculation of the charge inflation factor that CMS used in the proposed rule. In response to those comments, we stated that we continue to believe that it is optimal to use the most recent period of charge data available to measure charge inflation. In addition, similar to FY 2016, for FY 2017 we grouped claims data by quarter in the table below to allow the public access to these data and the ability to replicate the claims summary for the claims with discharge dates through September 30, 2015, that are available under the current LDS structure. In order to provide even more information in response to the commenters' request, similar to FY 2016, for FY 2017 we have made available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (click on the link on the left titled ''FY 2017 IPPS Proposed Rule Home Page'' and then click the link ''FY 2017 Proposed Rule Data Files'') a more detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor. In the proposed rule we stated that we would continue to work with our systems teams and privacy office to explore expanding the information available in the current LDS, perhaps through the provision of a supplemental data file for future rulemaking.

Quarter	Covered charges (January 1, 2014, through December 31, 2014)	Cases (January 1, 2014, through December 31, 2014)	Covered charges (January 1, 2015, through December 31, 2015)	Cases (January 1, 2015, through December 31, 2015)
1	$126,156,195,005	2,479,295	$134,250,323,661	2,546,078
2	122,171,248,575	2,445,370	126,880,227,174	2,416,569
3	119,364,629,662	2,364,553	122,165,668,615	2,308,537
4	124,733,843,923	2,436,787	90,677,073,204	1,696,180
Total	492,425,917,165	9,726,005	473,973,292,654	8,967,364

Under this methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2017, as we proposed, we compared the average covered charge per case of $50,360 ($492,425,917,165/9,726,005) from the second quarter of FY 2014 through the first quarter of FY 2015 (January 1, 2014, through December 31, 2014) to the average covered charge per case of $52,855 ($473,973,292,654/8,967,364) from the second quarter of FY 2015 through the first quarter of FY 2016 (January 1, 2015, through December 31, 2015). This rate-of-change

was 4.4 percent (1.043957) or 9.8 percent (1.089846) over 2 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified above.

Comment: Many commenters were concerned with what they stated was a lack of transparency with respect to the charge inflation component of the fixed-loss threshold calculation. One commenter stated that it is unable to match the figures in the table from the proposed rule with publicly available data sources and that CMS did not disclose the source of the data. The commenter further stated that CMS has not made the necessary data available, or any guidance that describes whether and how CMS edited such data to arrive at the total of quarterly charges and charges per case used to measure charge inflation. Consequently, the commenter stated that the table provided in the proposed rule is not useful in assessing the accuracy of the charge inflation figure that CMS used in the proposed rule to calculate the outlier threshold. The commenter noted that CMS provided a detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor. The commenters appreciated the additional data, but still believed that CMS has not provided enough specific information and data to allow the underlying numbers used in CMS' calculation of the charge inflation factor to be replicated and/or tested for accuracy. The commenter concluded that in the absence of more specific data and information about how the data were edited by CMS to arrive at the totals used in the charge inflation calculation, CMS has not provided adequate notice to allow for meaningful comment.

Response: We responded to a similar comment in the FY 2015 IPPS/LTCH final rule (79 FR 50375) and FY 2016 IPPS/LTCH final rule (80 FR 49779 through 49780) and refer readers to those final rules for our complete response. While the charge data may not be immediately available after the issuance of this final rule, we believe the data and supporting files we have provided will provide the commenters with additional information that can be verified once the charge data are available. We have produced the actual figures we used and disclosed our formula. We intend to post the actual charge data as soon as possible so that the public can verify the raw data with the figures we used in the calculation. As stated above and in the proposed rule, the charge data used to calculate the charge inflation factor are sourced from our MedPAR database.

In addition, as stated in last year's final rule, we continue to believe that it is optimal to use the most recent period of charge data available to measure charge inflation. Similar to last year, the commenters did not propose to use charge data from a different period to compute the charge inflation factor. If we computed the charge inflation factor using the latest data available to the public at the time of issuance of this final rule, we would need to compare charge data from FY 2014 (October 2013–September 2014) to FY 2015 (October 2014–September 2015), data which would be at least 10 months old compared to the charge data we currently use that are 4 months old.

Comment: One commenter requested that CMS add the claims data used to compute the charge inflation factor to the list of limited data set (LDS) files that can be ordered through the usual LDS data request process.

Response: There are limitations on how expeditiously we can add the charge data to the LDS. After consulting with our systems teams and privacy office, we do not anticipate being able to provide the charge data we currently use to calculate the charge inflation factor within the commenter's requested timeframe. We prefer using the latest data available at the time of the proposed and final rules to compute the charge inflation factor because we believe it leads to greater accuracy in the calculation of the fixed-loss cost outlier threshold. If the charge data are still not available for replication after the FY 2018 IPPS/LTCH PPS proposed rule, we would invite commenters to suggest alternative data sources that we could use to calculate the charge inflation factor (such as older data). As noted, we believe that using older data may not provide the same accuracy as the current data we use, and therefore the commenters should inform us which is more important to them, the need to have complete access to the data we use in our methodology or the greater accuracy provided by the use of more up-to-date data. As noted above, the data we currently use will eventually be publicly available for replication but not in the timeframe the commenter has requested. To summarize, we are confronted with a dilemma—either we use older data that commenters can access earlier, or we use the most up-to-date data which will be more accurate, but will not be available to the public until after publication of the proposed and final rules. We continue to believe the latter approach, using the best available data to produce a more accurate charge inflation factor, is preferable.

As we have done in the past, in the FY 2017 IPPS/LTCH proposed rule, we proposed to establish the FY 2017 outlier threshold using hospital CCRs from the December 2015 update to the Provider-Specific File (PSF)—the most recent available data at the time of the development of the proposed rule. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we apply the following edits to providers' CCRs in the PSF. We believe that these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF. We do not apply the adjustment factors described below to hospitals assigned the statewide average CCR.

For FY 2017, we proposed to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). We proposed that, if more recent data become available, we would use those data to calculate the final FY 2017 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we did for the last 3 fiscal years, we proposed to adjust the CCRs from the December 2015 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2014 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2015 update of the PSF. We note that, in the proposed rule, we used total transfer-adjusted cases from FY 2015 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from 1 year

to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology above, for the proposed rule, we calculated a December 2014 operating national average case-weighted CCR of 0.280907 and a December 2015 operating national average case-weighted CCR of 0.272363. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2014 operating national average case-weighted CCR from the December 2015 operating national average case-weighted CCR and then dividing the result by the December 2014 national operating average case-weighted CCR. This resulted in a proposed national operating CCR adjustment factor of 0.969585.

We used the same methodology proposed above to adjust the capital CCRs. Specifically, for the proposed rule, we calculated a December 2014 capital national average case-weighted CCR of 0.024615 and a December 2015 capital national average case-weighted CCR of 0.024008. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2014 capital national average case-weighted CCR from the December 2015 capital national average case-weighted CCR and then dividing the result by the December 2014 capital national average case-weighted CCR. This resulted in a proposed national capital CCR adjustment factor of 0.975335.

As discussed above, for FY 2017, we applied the final year of the 3-year transitional wage index because of the adoption of the new OMB labor market area delineations. Also, as discussed in section III.B.3. of the preamble to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.H.3. of the preamble of this final rule, in accordance with section 10324(a) of the Affordable Care Act, we created a wage index floor of 1.0000 for all hospitals located in States determined to be frontier States. We note that the frontier State floor adjustments were calculated and applied after rural and imputed floor budget neutrality adjustments were calculated for all labor market areas, in order to ensure that no hospital in a frontier State will receive a wage index less than 1.0000 due to the rural and imputed floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the outlier threshold for FY 2017, it was necessary to apply the 3-year transitional wage indexes and adjust the wage index of those eligible hospitals in a frontier State when calculating the outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2017. If we did not take the above into account, our estimate of total FY 2017 payments would be too low, and, as a result, our outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2017 outlier payments, we proposed not to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We stated that we continue to believe that, due to the policy implemented in the June 9, 2003 Outlier Final Rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We note that we have instructed MACs to identify to CMS for potential reconciliation any instances where: (1) A hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that period. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we proposed not to make any assumptions regarding the effects of reconciliation on the outlier threshold calculation.

Comment: Commenters were concerned with CMS' decision not to consider outlier reconciliation in developing the outlier threshold and stated that CMS did not provide objective data concerning the number of hospitals that have been subjected to reconciliation and the amounts recovered during this process.

Response: The commenters' views were similar to comments received and responded to in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50376 through 50377), and we refer readers to that rule for our response.

As described in sections IV.G. and IV.H., respectively, of the preamble of this final rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the hospital VBP payment adjustments and the hospital readmissions payment adjustments in the outlier threshold calculation or the outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments will continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we proposed to exclude the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the new uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2017 we proposed allocating an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold will best approximate the amount we will pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we will be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim

uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2017, we proposed to include estimated FY 2017 uncompensated care payments in the computation of the outlier fixed-loss cost threshold. Specifically, we proposed to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1 of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. We proposed a threshold of $23,681 and calculated total operating Federal payments of $82,727,323,366 and total outlier payments of $4,445,892,903. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this proposed threshold met the 5.1 percent target. As a result, we proposed an outlier fixed-loss cost threshold for FY 2017 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $23,681.

Comment: One commenter believed that it is important that CMS accurately calculate prior year actual payment comparisons to the 5.1 percent target. The commenter asserted that it is not possible for CMS to appropriately modify the methodology to achieve an accurate result if CMS is not aware of, or misinformed about, inaccuracies resulting from the prior year's methodology. The commenter cited the FY 2016 IPPS/LTCH PPS proposed rule as an example where CMS indicated that actual outlier payments for FY 2015 would equal about 4.88 percent of overall payments, while in the FY 2017 IPPS/LTCH PPS proposed rule, CMS indicated that, for FY 2015, actual outlier payments would equal about 4.68 percent of MS–DRG payments.

The commenter stated that it was concerned that CMS believed the agency would reach the 5.1 percent target for FY 2015 (based on the estimate in the FY 2016 proposed rule) only to learn that the original estimate in the FY 2016 proposed rule was overestimated compared to the FY 2017 proposed rule. The commenter concluded it is critical that CMS not allow the use of incomplete data from prior years to affect its calculation of current period thresholds.

Another commenter noted that the final outlier threshold established by CMS is always significantly lower than the threshold set forth in the proposed rule. The commenter believed the decline is most likely due to the use of updated CCRs or other data in calculating the final threshold. The commenter stated this emphasizes that CMS must use the most recent data available when the agency calculates the outlier threshold. The commenter cited as an example that, in the proposed rule, CMS used data from the December 2015 PSF file, but at the time the proposed rule was issued, the March 2016 PSF file was available.

Response: We responded to similar comments in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50378 through 50379) and refer the reader to that rule for our response.

Comment: Some commenters believed that the outlier threshold should be further reduced because outlier payments this year are on target to fall below the 5.1 percent target. The commenter suggested that CMS consider calculating the threshold at the midpoint of the target (approximately 5.5 percent) in order to ensure that the final total of outlier payments is between the statutory requirements of 5 to 6 percent of total payments.

Another commenter recommended that that threshold be maintained at the FY 2016 outlier threshold because CMS has underpaid outlier payments in prior fiscal years. One commenter noted that CMS' estimate of FY 2015 outlier payments in the proposed rule was 4.68 percent, which is below the 5.1 percent target. The commenter believed that by applying a 2-year charge inflation factor and a 1-year CCR factor that CMS is inadvertently compounding its charge increase with lower costs and overstating the outlier threshold. The commenter suggested that CMS apply the following formula to compute the FY 2017 outlier threshold: Step 1—FY 2015 Difference = (5.1 percent Target − 4.68 percent estimate from FY 2015 = 0.42 percent)/4.68 percent estimate from FY 2015 = 8.97 percent; Step 2—Suggested FY 2017 Threshold = Threshold from FY 2015 of $24,626 * (100 − 8.97 from Step 1 = 91.03 percent) = $22,417.

Response: We responded to similar comments in the FY 2015 IPPS/LTCH final rule (78 FR 50379) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49783) and refer readers to those final rules for our complete responses.

Comment: One commenter was concerned that CMS constantly misestimates the 5.1 percent target. The commenter recommended that CMS conduct additional analysis to evaluate the methodology for incorporating uncompensated care and DSH payments into the outlier threshold calculation.

Response: As discussed above, we include updates to the uncompensated care payment calculation as part of the fixed-loss outlier threshold calculation. Without additional information or data analysis, we are unsure what exactly the commenter is referencing when the commenter stated that CMS should further evaluate the methodology for incorporating uncompensated care and DSH payments into the outlier threshold calculation. It would have been beneficial to us if the commenter had specifically identified the areas that CMS should review and suggested alternative approaches. We already conduct analysis of uncompensated care and DSH payments, but are open to other approaches. However, without more specificity, we cannot meaningfully respond to or adopt the commenter's suggestion.

After consideration of the public comments we received, we are not making any changes to our methodology in this final rule for FY 2017. Therefore, we are using the same methodology we proposed to calculate the final outlier threshold.

Similar to the table provided in the proposed rule, for this final rule, we are providing the following table that displays covered charges and cases by quarter in the periods used to calculate the charge inflation factor based on the latest claims data from the MedPAR file.

Quarter	Covered charges (April 1, 2014, through March 31, 2015)	Cases (April 1, 2014, through March 31, 2015)	Covered charges (April 1, 2015, through March 31, 2016)	Cases (April 1, 2015, through March 31, 2016)
1	$135,268,674,848	2,559,124	$100,321,539,956	1,825,635
2	122,486,434,387	2,450,512	127,944,664,075	2,432,402
3	119,706,545,046	2,370,067	124,301,570,497	2,340,555

Quarter	Covered charges (April 1, 2014, through March 31, 2015)	Cases (April 1, 2014, through March 31, 2015)	Covered charges (April 1, 2015, through March 31, 2016)	Cases (April 1, 2015, through March 31, 2016)
4	125,106,133,072	2,441,645	126,979,101,227	2,343,069
Total	502,567,787,353	9,821,348	479,546,875,755	8,941,661

Under our current methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2017, we compared the average covered charge per case of $51,171 ($502,567,787,353/9,821,348) from the third quarter of FY 2014 through the second quarter of FY 2015 (April 1, 2014, through March 31, 2015) to the average covered charge per case of $56,361 ($479,546,875,755/8,941,661) from the third quarter of FY 2015 through the second quarter of FY 2016 (April 1, 2015, through March 31, 2016). This rate-of-change is 4.8 percent (1.048067) or 9.8 percent (1.098446) over 2 years.

As we have done in the past, we are establishing the FY 2017 outlier threshold using hospital CCRs from the March 2016 update to the Provider-Specific File (PSF)—the most recent available data at the time of development of this final rule. For FY 2017, we also are continuing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below).

Therefore, as we did for the last 3 fiscal years, we are adjusting the CCRs from the March 2016 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2015 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2016 update of the PSF. We note that we used total transfer-adjusted cases from FY 2015 to determine the national average case-weighted CCRs for both sides of the comparison.

Using the methodology above, we calculated a March 2015 operating national average case-weighted CCR of 0.278734 and a March 2016 operating national average case-weighted CCR of 0.270034. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2015 operating national average case-weighted CCR from the March 2016 operating national average case-weighted CCR and then dividing the result by the March 2015 national operating average case-weighted CCR. This resulted in a national operating CCR adjustment factor of 0.96879.

We also used the same methodology above to adjust the capital CCRs. Specifically, we calculated a March 2015 capital national average case-weighted CCR of 0.024375 and a March 2016 capital national average case-weighted CCR of 0.023688. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the March 2015 capital national average case-weighted CCR from the March 2016 capital national average case-weighted CCR and then dividing the result by the March 2015 capital national average case-weighted CCR. This resulted in a national capital CCR adjustment factor of 0.971819.

As discussed above, similar to the proposed rule, for FY 2017 we applied the following policies (see discussion above for more details):

- The final year of the 3-year transitional wage index because of the adoption of the new OMB labor market area delineations.
- In accordance with section 10324(a) of the Affordable Care Act, we created a wage index floor of 1.0000 for all hospitals located in States determined to be frontier States.
- As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2017 outlier payments, we did not make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement.
- We excluded the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.
- We used the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. We calculated a threshold of $23,570 and calculated total operating Federal payments of $83,347,416,971 and total outlier payments of $4,479,256,519. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold met the 5.1 percent target. As a result, we are finalizing an outlier fixed-loss cost threshold for FY 2017 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $23,570.

(2) Other Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2017 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 6.14 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we reduced the FY 2017 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that were applied to the standardized amount based on the FY 2017 outlier threshold are as follows:

	Operating standardized amounts	Capital federal rate
National	0.948999	0.938575

We applied the outlier adjustment factors to the FY 2017 payment rates after removing the effects of the FY 2016 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.183 or capital CCRs greater than 0.17, or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available only via the Internet on the CMS Web site) contains the statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the above range. Effective for discharges occurring on or after October 1, 2016, these statewide average ratios will replace the ratios posted on our Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Tables.html*. Table 8B listed in section VI. of this Addendum (and available via the Internet on the CMS Web site) contains the comparable statewide average capital CCRs. As previously stated, the CCRs in Tables 8A and 8B will be used during FY 2017 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the Internet on the CMS Web site) contains the statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in Change Request 3966. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR ratio at any time as long as the guidelines of Change Request 3966 are followed. In addition, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010, which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS Web site: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf*.

(3) FY 2015 Outlier Payments

Our current estimate, using available FY 2015 claims data, is that actual outlier payments for FY 2015 were approximately 4.68 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2015, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 2015. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2015 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier Final Rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe that it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the intent of the language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section calls for the Secretary to ensure that outlier payments are equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe this language reflects the intent of Congress regarding the prospectivity of the IPPS. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that because the MedPAR claims data for the entire FY 2016 will not be available until after September 30, 2016, we are unable to provide an estimate of actual outlier payments for FY 2016 based on FY 2016 claims data in this final rule. We will provide an estimate of actual FY 2016 outlier payments in the FY 2018 IPPS/LTCH PPS proposed rule.

5. FY 2017 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site) contain the national standardized amounts that we are applying to all hospitals, except hospitals located in Puerto Rico, for FY 2017. The standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site). The amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 69.6 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are applying a labor-related share of 62 percent, unless application of that percentage will result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the standardized amounts reflecting the applicable percentage increases for FY 2017.

The labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2017 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site). Similar to above, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the

application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2016 national standardized amount to the FY 2017 national standardized amount. The second through fifth columns display the changes from the FY 2016 standardized amounts for each applicable FY 2017 standardized amount. The first row of the table shows the updated (through FY 2016) average standardized amount after restoring the FY 2016 offsets for outlier payments, demonstration budget neutrality, geographic reclassification budget neutrality, new labor market delineation wage index transition budget neutrality, retrospective documentation and coding adjustment under section 7(b)(1)(B) of Public Law 110–90 and an adjustment to the standardized amount using our authority under section 1886(d)(5)(I)(i) of the Act to permanently prospectively remove the 0.2 percent reduction to the payment rate established in FY 2014 to offset the estimated increase in IPPS expenditures as a result of the 2-midnight policy. The MS–DRG reclassification and recalibration and wage index budget neutrality adjustment factors are cumulative. Therefore, those FY 2016 adjustment factors were not removed from this table.

CHANGE OF FY 2016 STANDARDIZED AMOUNTS TO THE FY 2017 STANDARDIZED AMOUNTS

	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
FY 2016 Base Rate after removing: 1. FY 2016 Geographic Reclassification Budget Neutrality (0.988169) 2. FY 2016 Rural Community Hospital Demonstration Program Budget Neutrality (0.999837) 3. Cumulative FY 2008, FY 2009, FY 2012, FY 2013, FY 2014, FY 2015 and FY 2016 Documentation and Coding Adjustments as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110–90 and Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012 (0.9255) 4. FY 2016 Operating Outlier Offset (0.948998).. 5. FY 2016 New Labor Market Delineation Wage Index Transition Budget Neutrality Factor (0.999998).. 6. FY 2017 2-Midnight Rule Permanent Adjustment (1/0.998)..	If Wage Index is Greater Than 1.0000: Labor (69.6 percent): $4,394.09; Nonlabor (30.4 percent): $1,919.26. If Wage Index is less Than or Equal to 1.0000: Labor (62 percent): $3,914.28; Nonlabor (38 percent): $2,399.07.	If Wage Index is Greater Than 1.0000: Labor (69.6 percent): $4,394.09; Nonlabor (30.4 percent): $1,919.26. If Wage Index is less Than or Equal to 1.0000: Labor (62 percent): $3,914.28; Nonlabor (38 percent): $2,399.07.	If Wage Index is Greater Than 1.0000: Labor (69.6 percent): $4,394.09; Nonlabor (30.4 percent): $1,919.26. If Wage Index is less Than or Equal to 1.0000: Labor (62 percent): $3,914.28; Nonlabor (38 percent): $2,399.07.	If Wage Index is Greater Than 1.0000: Labor (69.6 percent): $4,394.09; Nonlabor (30.4 percent): $1,919.26. If Wage Index is less Than or Equal to 1.0000: Labor (62 percent): $3,914.28; Nonlabor (38 percent): $2,399.07.
FY 2017 Update Factor	1.0165	0.99625	1.00975	0.9895
FY 2017 MS–DRG Recalibration Budget Neutrality Factor.	0.999079	0.999079	0.999079	0.999079
FY 2017 Wage Index Budget Neutrality Factor.	1.000209	1.000209	1.000209	1.000209
FY 2017 Reclassification Budget Neutrality Factor.	0.988224	0.988224	0.988224	0.988224
FY 2017 Operating Outlier Factor	0.948999	0.948999	0.948999	0.98999
Cumulative Factor: FY 2008, FY 2009, FY 2012, FY 2013, FY 2014, FY 2015, FY 2016 and FY 2017 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110–90 and Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012.	0.9118	0.9118	0.9118	0.9118
FY 2017 New Labor Market Delineation Wage Index 3-Year Hold Harmless Transition Budget Neutrality Factor.	0.999994	0.999994	0.999994	0.999994
FY 2017 2–Midnight Rule One-Time Prospective Increase.	1.006	1.006	1.006	1.006
National Standardized Amount for FY 2017 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (69.6/30.4).	Labor: $3,839.57; Nonlabor: $1,677.06.	Labor: $3,763.08; Nonlabor: $1,643.65.	Labor: $3,814.07; Nonlabor: $1,665.92.	Labor: $3,737.58; Nonlabor: $1,632.51.
National Standardized Amount for FY 2017 if Wage Index is less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38).	Labor: $3,420.31; Nonlabor: $2,096.32.	Labor: $3,352.17; Nonlabor: $2,054.56.	Labor: $3,397.59; Nonlabor: $2,082.40.	Labor: $3,329.46; Nonlabor: $2,040.63.

B. Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the Internet on the CMS Web site), contain the labor-related and nonlabor-related shares that we used to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2017. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. In section III. of the preamble of this final rule, we discuss the data and methodology for the FY 2017 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make such adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively).

For FY 2014, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50985 through 50987), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule.

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we are continuing to use the same COLA factors in FY 2017 that were used in FY 2016 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. Below is a table listing the COLA factors for FY 2017.

FY 2017 COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Area	Cost of living adjustment factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.19
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, the next update to the COLA factors for Alaska and Hawaii will occur in FY 2018.

C. Calculation of the Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2017

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2017 equals the Federal rate (which includes uncompensated care payments).

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (which, as discussed in section IV.F. of the preamble of this final rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2017 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for MDHs for FY 2017 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described below. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987 or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

1. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula below is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming FY. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described above) to project the threshold for the upcoming FY. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described above).

Step 1—Determine the MS–DRG and MS–DRG relative weight for each claim based on the ICD–10–CM procedure and diagnosis codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described above.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost of Living Adjustment)] × (1 + IME + (DSH * 0.25))

—Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (l + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating cost-to-charge ratio)

—Capital Costs = (Billed Charges × Capital cost-to-charge ratio).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

—Operating Cost-to-Charge Ratio to Total Cost-to-Charge Ratio = (Operating Cost-to-Charge Ratio)/(Operating Cost-to-Charge Ratio + Capital Cost-to-Charge Ratio)

—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating Cost-to-Charge Ratio to Total Cost-to-Charge Ratio + Federal Payment with IME, DSH + Uncompensated Care Payment + New Technology Add-On Payment Amount

—Capital Cost-to-Charge Ratio to Total Cost-to-Charge Ratio = (Capital Cost-to-Charge Ratio)/(Operating Cost-to-Charge Ratio + Capital Cost-to-Charge Ratio)

—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6: Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)

—Operating Outlier Payment = (Operating Costs—Operating Outlier Threshold) × Marginal Cost Factor

—Capital Outlier Payment = (Capital Costs—Capital Outlier Threshold) × Marginal Cost Factor

The payment rate is further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount is further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also are reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we added the uncompensated care payment to the total claim payment amount. As noted in the formula above, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments.

2. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As noted above, section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) extended the MDH program through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Currently MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the greater of the updated hospital-specific rates based on either FY 1982, FY 1987 or FY 2002 costs per discharge.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2017

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data Under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Adjustment for Failure to be a Meaningful EHR User Under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.025	0.0	−2.025
MFP Adjustment Under Section 1886(b)(3)(B)(xi) of the Act	−0.3	−0.3	−0.3	−0.3
Statutory Adjustment Under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Applicable Percentage Increase Applied to Hospital-Specific Rate	1.65	−0.375	0.975	−1.05

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section IV.B. of the preamble of this final rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital-specific rate for an SCH or an MDH is adjusted by the MS–DRG reclassification and recalibration budget neutrality factor of 0.999079, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate that an SCH or MDH will receive for its discharges beginning on or after October 1, 2016. We note that, in this final rule, for FY 2017, we are not making a documentation and coding adjustment to the hospital-specific rate. We refer readers to section II.D. of the preamble of this final rule for a complete discussion regarding our policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix.

Also, as discussed above and in section IV.P. of the preamble of this final rule, we are making an adjustment to the hospital-specific rates using our authority under section 1886(d)(5)(I)(i) of the Act to permanently prospectively remove the 0.2 percent reduction to the payment rates established in FY 2014 to offset the estimated increase in IPPS expenditures as a result of the 2-midnight policy. In addition, as discussed above and in section IV.P. of the preamble of this final rule, we are applying a temporary one-time prospective increase to the FY 2017 hospital-specific rates of 0.6 percent by including a temporary one-time factor of 1.006 in the calculation of the hospital-specific rates, using our authority under section 1886(d)(5)(I)(i) of the Act, to address the effects of the 0.2 percent reduction to the rates for the 2-midnight policy in effect for FY 2014, FY 2015, and FY 2016.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2017

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. Effective with that cost reporting period, over a 10-year transition period (which extended through FY 2001) the payment methodology for Medicare acute care hospital inpatient capital-related costs changed from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

The basic methodology for determining Federal capital prospective rates is set forth in the regulations at §§ 412.308 through 412.352. Below we discuss the factors that we used to determine the capital Federal rate for FY 2017, which is effective for discharges occurring on or after October 1, 2016.

The 10-year transition period ended with hospital cost reporting periods beginning on or after October 1, 2001 (FY 2002). Therefore, for cost reporting periods beginning in FY 2002, all hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. For FY 1992, we computed the standard Federal payment rate for capital-related costs under the IPPS by updating the FY 1989 Medicare inpatient capital cost per case by an actuarial estimate of the increase in Medicare inpatient capital costs per case. Each year after FY 1992, we update the capital standard Federal rate, as provided at § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for blended payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs. Accordingly, historically, under the capital PPS, we have computed a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. Effective with discharges occurring on or after October 1, 2004, in conjunction with the change to the operating payment methodology, we adopted a methodology for computing capital payments made to hospitals located in Puerto Rico based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the national capital Federal rate (69 FR 49185). Effective with discharges on or after January 1, 2016, operating IPPS payments to hospitals located in Puerto Rico are now based on 100 percent of the Federal rate—the operating payment methodology is no longer a blend of 75 percent of the Federal rate and 25 percent of the Puerto Rico rate. Consistent with historical practice and under the authority of section 1886(g) of the Act, as discussed in section V.B.3. of the preamble of this final rule, we are making the capital IPPS payments to hospitals located in Puerto Rico based on 100 percent of the capital Federal rate, effective with discharges on or after October 1, 2016, and will no longer be based on the current 75/25 blended rate.

A. Determination of the Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

In the discussion that follows, we explain the factors that we used to determine the capital Federal rate for FY 2017. In particular, we explain why the FY 2017 capital Federal rate increases approximately 1.84 percent, compared to the FY 2016 capital Federal rate. As discussed in the impact analysis in Appendix A to this final rule, we estimate that capital payments per discharge will increase approximately 0.8 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors.

Specifically, we adjust the projected CIPI rate-of-increase as appropriate each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The update factor for FY 2017 under that framework is 0.9 percent based on the best data available at this time. The update factor under that framework is based on a projected 1.2 percent increase in the FY 2010-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a forecast error correction of −0.3 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2017 CIPI projection in that same section of this Addendum. Below we describe the policy adjustments that we are applying in the update framework for FY 2017.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); and
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2017, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase will equal 0.5 percent for FY 2017. The net adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected total increase in case-mix. Therefore, the net adjustment for case-mix change in FY 2017 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2015 DRG reclassification and recalibration as part of our update for FY 2017. We estimate that FY 2015 DRG reclassification and recalibration resulted in no change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are making a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2017.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of −0.3 percentage point was calculated for the FY 2015 update, for which there are historical data. That is, current historical data indicate that the forecasted FY 2015 CIPI (1.5 percent) used in calculating the FY 2015 update factor was 0.3 percentage points higher than actual realized price increases (1.2 percent). This over-prediction was primarily due to prices from municipal bond yields declining in 2015 whereas the forecast projected an increase. Therefore, we are making a −0.3 percentage point adjustment for forecast error in the update for FY 2017.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculated this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflected how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity increases that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual increase is due to each of these factors. The capital update framework thus provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this final rule, we are continuing to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2017 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2017, we are using an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 2010 and extending through FY 2014. Based on these data, we estimated that case-mix constant intensity declined during FYs 2010 through 2014. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this

approach, because we estimate that intensity declined during that 5-year period, we believe it is appropriate to continue to apply a zero intensity adjustment for FY 2017. Therefore, we are making a 0.0 percentage point adjustment for intensity in the update for FY 2017.

Above, we described the basis of the components used to develop the 0.9 percent capital update factor under the capital update framework for FY 2017 as shown in the following table.

CMS FY 2017 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.2
Intensity	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	0.5
Projected Case-Mix Change	0.5
Subtotal	1.2
Effect of FY 2015 Reclassification and Recalibration	0.0
Forecast Error Correction	−0.3
Total Update	0.9

*The capital input price index represents the FY 2010-based CIPI.

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2016 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2017. (We refer readers to MedPAC's Report to the Congress: Medicare Payment Policy, March 2016, Chapter 3, available on the Web site at: *http://www.medpac.gov*.)

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments.

For FY 2016, we estimated that outlier payments for capital would equal 6.35 percent of inpatient capital-related payments based on the capital Federal rate in FY 2016. Based on the thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs will equal 6.14 percent for inpatient capital-related payments based on the capital Federal rate in FY 2017. Therefore, we are applying an outlier adjustment factor of 0.9386 in determining the capital Federal rate for FY 2017. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2017 will be lower than the percentage for FY 2016.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The FY 2017 outlier adjustment of 0.9386 is a 0.22 percent change from the FY 2016 outlier adjustment of 0.9365. Therefore, the net change in the outlier adjustment to the capital Federal rate for FY 2017 is 1.0022 (0.9386/0.9365). Thus, the outlier adjustment will increase the FY 2017 capital Federal rate by 0.22 percent compared to the FY 2016 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. Because we are determining capital IPPS payments to hospitals located in Puerto Rico based on 100 percent of the capital Federal rate beginning in FY 2017, we have not calculated a separate GAF for Puerto Rico, and therefore, we are not applying a separate budget neutrality adjustment for the Puerto Rico GAF. Similarly, the budget neutrality factor for DRG reclassifications and recalibration nationally is applied in determining the capital IPPS Federal rate, and is applicable for all hospitals, including those hospitals located in Puerto Rico.

To determine the national capital rate factors for FY 2017, we compared estimated aggregate capital Federal rate payments based on the FY 2016 MS–DRG classifications and relative weights and the FY 2016 GAF to estimated aggregate capital Federal rate payments based on the FY 2016 MS–DRG classifications and relative weights and the FY 2017 GAFs. To achieve budget neutrality for the changes in the national GAFs, based on calculations using updated data, we are applying an incremental budget neutrality adjustment factor of 0.9995 for FY 2017 to the previous cumulative FY 2016 adjustment factor of 0.9860, yielding an adjustment factor of 0.9855 through FY 2017.

We then compared estimated aggregate capital Federal rate payments based on the FY 2016 MS–DRG relative weights and the FY 2017 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the FY 2017 MS–DRG classifications and relative weights and the FY 2017 GAFs. The incremental adjustment factor for DRG classifications and changes in relative weights is 0.9996. The cumulative adjustment factor for MS–DRG classifications and changes in relative weights and for changes in the GAFs through FY 2017 is 0.9851. (We note that all the values are calculated with unrounded numbers.)

The GAF/DRG budget neutrality adjustment factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the MS–DRG relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor for changes in the GAF (including geographic reclassification) and the MS–DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification has on the other payment parameters, such as the payments for DSH or IME.

The cumulative adjustment factor of 0.9991 (the product of the incremental national GAF budget neutrality adjustment factor of 0.9995 and the incremental DRG budget neutrality adjustment factor of 0.9996) accounts for the MS–DRG reclassifications and recalibration and for changes in the GAFs. It also incorporates the effects on the GAFs of FY 2017 geographic reclassification decisions made by the MGCRB compared to FY 2016 decisions. However, it does not account for

changes in payments due to changes in the DSH and IME adjustment factors.

As discussed in section V.C. of the preamble of this final rule, we are making an adjustment of (1/0.998) to the national capital Federal rate to remove the 0.2 percent reduction (an adjustment factor of 0.998) to the national capital Federal rate to offset the estimated increase in capital IPPS expenditures associated with the 2-midnight policy. This is consistent with the adjustment to the operating IPPS standardized amount and the hospital-specific payment rates. In addition, consistent with the approach for the operating IPPS standardized amount and hospital-specific payment rates and for the reasons discussed in sections IV.P. and V.C. of the preamble of this final rule, we are making a one-time prospective adjustment of 1.006 in FY 2017 to the national capital Federal rate to address the effect of the 0.2 percent reduction to the national capital Federal rates in effect for FY 2014, FY 2015, and FY 2016. We also are removing this one-time prospective adjustment through an adjustment of (1/1.006) to the national capital Federal rate in FY 2018, consistent with the approach for the operating IPPS standardized amount and hospital-specific payment rates (as discussed in section IV.P. of the preamble of this final rule). We refer readers to sections IV.P. and V.C. of the preamble of this final rule for a complete discussion of these issues.

4. Capital Federal Rate for FY 2017

For FY 2016, we established a capital Federal rate of $438.75 (as revised, in the FY 2016 IPPS/LTCH PPS correction notice CMS–1632–CN2 (80 FR 60060 and 60061)). We are establishing an update of 0.9 percent in determining the FY 2017 capital Federal rate for all hospitals. As a result of this update, the budget neutrality factors discussed earlier, and the adjustments to remove the 0.2 percent reductions (both the (1/0.998) adjustment to permanently remove the 0.2 percent reduction and the one-time 0.6 percent adjustment) resulting from the 2-midnight policy, we are establishing a national capital Federal rate of $446.81 for FY 2017. The national capital Federal rate for FY 2017 was calculated as follows:

- The FY 2017 update factor is 1.009, that is, the update is 0.9 percent.
- The FY 2017 budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS–DRG classifications and relative weights and changes in the GAFs is 0.9991.
- The FY 2017 outlier adjustment factor is 0.9386.
- The 2-midnight policy adjustment to permanently remove the 0.2 percent reduction is (1/0.998).
- The 2-midnight one-time policy adjustment is 1.006.

(We note that, as discussed in section V.C. of the preamble of this final rule, we are not making an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rate for FY 2017.)

Because the FY 2017 capital Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, indirect medical education costs, and payments to hospitals serving a disproportionate share of low-income patients, we are not making additional adjustments in the capital Federal rate for these factors, other than the budget neutrality factor for changes in the MS–DRG classifications and relative weights and for changes in the GAFs.

We are providing the following chart that shows how each of the factors and adjustments for FY 2017 affects the computation of the FY 2017 national capital Federal rate in comparison to the FY 2016 national capital Federal rate. The FY 2017 update factor has the effect of increasing the capital Federal rate by 0.9 percent compared to the FY 2016 capital Federal rate. The GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.09 percent. The FY 2017 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.22 percent compared to the FY 2016 capital Federal rate. The permanent 2-midnight policy adjustment has the effect of increasing the capital Federal rate by 0.2 percent and the temporary 2-midnight policy adjustment has the effect of increasing the capital Federal rate by 0.6 percent. The combined effect of all the changes would increase the national capital Federal rate by approximately 1.84 percent compared to the FY 2016 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2016 CAPITAL FEDERAL RATE AND FY 2017 CAPITAL FEDERAL RATE

	FY 2016	FY 2017	Change	Percent change
Update Factor [1]	$1.0130	$1.009	1.009	0.9
GAF/DRG Adjustment Factor [1]	0.9976	0.9991	0.9991	−0.09
Outlier Adjustment Factor [2]	0.9365	0.9386	1.0022	0.22
Permanent 2-midnight Policy Adjustment Factor	N/A	1.002	1.002	0.2
One-Time 2-midnight Policy Adjustment Factor	N/A	1.006	1.006	0.6
Capital Federal Rate	438.75	446.81	1.0184	1.84

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2016 to FY 2017 resulting from the application of the 0.9991 GAF/DRG budget neutrality adjustment factor for FY 2017 is a net change of 0.9991 (or −0.09 percent).

[2] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2017 outlier adjustment factor is 0.9386/0.9365, or 1.0022 (or 0.22 percent).

In this final rule, we also are providing the following chart that shows how the final FY 2017 capital Federal rate differs from the proposed FY 2017 capital Federal rate as presented in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25280).

COMPARISON OF FACTORS AND ADJUSTMENTS: PROPOSED FY 2017 CAPITAL FEDERAL RATE AND FINAL FY 2017 CAPITAL FEDERAL RATE

	Proposed FY 2017	Final FY 2017	Change	Percent change
Update Factor [1]	$1.0090	$1.0090	1.0000	0.00
GAF/DRG Adjustment Factor [1]	0.9993	0.9991	0.9998	−0.02
Outlier Adjustment Factor [2]	0.9374	0.9386	1.0013	0.13
Permanent 2-midnight Policy Adjustment Factor	1.002	1.002	1.000	0.00
One-Time 2-midnight Policy Adjustment Factor	1.006	1.006	1.000	0.00
Capital Federal Rate	446.35	446.81	1.0010	0.10

B. Calculation of the Inpatient Capital-Related Prospective Payments for FY 2017

For purposes of calculating payments for each discharge during FY 2017, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The outlier thresholds for FY 2017 are in section II.A. of this Addendum. For FY 2017, a case would qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments (including both the empirically justified Medicare DSH payment and the estimated uncompensated care payment, as discussed in section II.A.4.g.(1) of this Addendum) is greater than the prospective payment rate for the MS–DRG plus the fixed-loss amount of $23,570.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50603 through 50607), we rebased and revised the CIPI to a FY 2010 base year to reflect the more current structure of capital costs in hospitals. For a complete discussion of this rebasing, we refer readers to the FY 2014 IPPS/LTCH PPS final rule.

2. Forecast of the CIPI for FY 2017

Based on the latest forecast by IHS Global Insight, Inc. (second quarter of 2016), we are forecasting the FY 2010-based CIPI to increase 1.2 percent in FY 2017. This reflects a projected 1.6 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 2.7 percent increase in other capital expense prices in FY 2017, partially offset by a projected 1.6 percent decline in vintage-weighted interest expense prices in FY 2017. The weighted average of these three factors produces the forecasted 1.2 percent increase for the FY 2010-based CIPI as a whole in FY 2017.

IV. Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2017

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. (We note that, in accordance with § 403.752(a), RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25281), the FY 2017 rate-of-increase percentage for updating the target amounts for the 11 cancer hospitals, children's hospitals, the short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs is the estimated percentage increase in the IPPS operating market basket for FY 2017, in accordance with applicable regulations at § 413.40. Based on IHS Global Insight, Inc.'s 2016 first quarter forecast, we estimated that the FY 2010-based IPPS operating market basket update for FY 2017 would be 2.8 percent (that is, the estimate of the market basket rate-of-increase). However, we proposed that if more recent data became available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2017. Therefore, based on IHS Global Insight, Inc.'s 2016 second quarter forecast, with historical data through 2016 first quarter, we estimate that the FY 2010-based IPPS operating market basket update for FY 2017 is 2.7 percent (that is, the estimate of the market basket rate-of-increase). For children's hospitals, the 11 cancer hospitals, hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute

care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs, the FY 2017 rate-of-increase percentage that will be applied to the FY 2016 target amounts in order to determine the final FY 2017 target amounts is 2.7 percent.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble of this final rule and section V. of the Addendum to this final rule for the update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2017. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Changes to the Payment Rates for the LTCH PPS for FY 2017

A. LTCH PPS Standard Federal Payment Rate for FY 2017

1. Background

In section VII. of the preamble of this final rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2017.

Under § 412.523(c)(3)(ii) of the regulations, for LTCH PPS rate years beginning RY 2004 through RY 2006, we updated the standard Federal rate annually by a factor to adjust for the most recent estimate of the increases in prices of an appropriate market basket of goods and services for LTCHs. We established this policy of annually updating the standard Federal rate because, at that time, we believed that was the most appropriate method for updating the LTCH PPS standard Federal rate for years after the initial implementation of the LTCH PPS in FY 2003. Therefore, under § 412.523(c)(3)(ii), for RYs 2004 through 2006, the annual update to the LTCH PPS standard Federal rate was equal to the previous rate year's Federal rate updated by the most recent estimate of increases in the appropriate market basket of goods and services included in covered inpatient LTCH services.

In determining the annual update to the standard Federal rate for RY 2007, based on our ongoing monitoring activity, we believed that, rather than solely using the most recent estimate of the LTCH PPS market basket update as the basis of the annual update factor, it was appropriate to adjust the standard Federal rate to account for the effect of documentation and coding in a prior period that was unrelated to patients' severity of illness (71 FR 27818). Accordingly, we established under § 412.523(c)(3)(iii) that the annual update to the standard Federal rate for RY 2007 was zero percent based on the most recent estimate of the LTCH PPS market basket at that time, offset by an adjustment to account for changes in case-mix in prior periods due to the effect of documentation and coding that were unrelated to patients' severity of illness. For RY 2008 through FY 2011, we also made an adjustment to account for the effect of documentation and coding that was unrelated to patients' severity of illness in establishing the annual update to the standard Federal rate as set forth in the regulations at §§ 412.523(c)(3)(iv) through (c)(3)(vii). For FYs 2012 through 2016, we updated the standard Federal rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3)(A)(i) (citing sections 1886(b)(3)(B)(xi)(II), 1886(m)(3)(A)(ii), and 1886(m)(4) of the Act as set forth in the regulations at §§ 412.523(c)(3)(viii) through (c)(3)(xii).

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the other adjustment specified in section 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as ''the multifactor productivity (MFP) adjustment'') as discussed in section VII.E.2. of the preamble of this final rule.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.E.2.a. of the preamble of this final rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For FY 2016, consistent with our historical practice, we established an update to the LTCH PPS standard Federal payment rate based on the full estimated LTCH PPS market basket increase of 2.4 percent and the 0.7 percentage point reductions required by sections 1886(m)(3)(A)(i) and 1886(m)(3)(A)(ii) with 1886(m)(4)(E) of the Act. Accordingly, at § 412.523(c)(3)(xii) of the regulations, we established an annual update of 1.7 percent to the standard Federal payment rate for FY 2016 (80 FR 49636 through 49637). In addition, as discussed in that same final rule, the annual update for FY 2016 was further reduced by 2.0 percentage points for LTCHs that failed to submit quality reporting data in accordance with the requirements of the LTCH QRP under section 1886(m)(5) of the Act.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25281), based on the best available data at that time, we proposed an annual update to the LTCH PPS standard Federal payment rate of 1.45 percent for FY 2017, which was based on the full estimated increase in the LTCH PPS market basket of 2.7 percent (based on the proposed rebased and revised 2013-based LTCH market basket present in that same proposed rule), less the proposed MFP adjustment of 0.5 percentage point consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.75 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(F) of the Act. For LTCHs that fail to submit the required quality reporting data for FY 2017 in accordance with the LTCH QRP, the annual update is further reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act. Accordingly, we proposed an annual update to the LTCH PPS standard Federal payment rate of −0.55 percent for LTCHs that fail to submit the required quality reporting data for FY 2017 (that is, the proposed full update of 1.45 percent and less 2.0 percentage points for failure to submit quality reporting data as required by section 1886(m)(5) of the Act). Consistent with our historical practice, we also proposed to use the best data available to determine the update for FY 2017 in the final rule.

For FY 2017, in this final rule, based on the best available data, as we proposed, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 1.75 percent, which is based on the full estimated increase in the LTCH PPS market basket of 2.8 percent, less the MFP adjustment of 0.3 percentage point consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.75 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(F) of the Act. (As discussed in section VII.E. of the preamble of this final rule, as we proposed, we are rebasing and revising the 2009-based

LTCH-specific market basket to reflect a 2013 base year.) For LTCHs that fail to submit the required quality reporting data for FY 2017 in accordance with the LTCH QRP, the annual update is further reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act (as discussed in greater detail in section VII.E.2.c. of the preamble of this final rule). Accordingly, as we proposed, we are establishing an annual update to the LTCH PPS standard Federal payment rate of −0.25 percent for LTCHs that fail to submit the required quality reporting data for FY 2017. This −0.25 percent update was calculated based on the full estimated increase in the LTCH PPS market basket of 2.8 percent, less a MFP adjustment of 0.3 percentage point, less an additional adjustment of 0.75 percentage point required by the statute, and less 2.0 percentage points for failure to submit quality reporting data as required by section 1886(m)(5) of the Act.

2. Development of the FY 2017 LTCH PPS Standard Federal Payment Rate

We continue to believe that the annual update to the LTCH PPS standard Federal payment rate should be based on the most recent estimate of the increase in the LTCH PPS market basket, including any statutory adjustments. Consistent with our historical practice, for FY 2017, as we proposed, we applied the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the LTCH PPS standard Federal payment rate for FY 2017, we also made certain regulatory adjustments, consistent with past practices. Specifically, in determining the FY 2017 LTCH PPS standard Federal payment rate, as we proposed, we applied a budget neutrality adjustment factor for the changes related to the area wage adjustment (that is, changes to the wage data and labor-related share) in accordance with § 412.523(d)(4). We also used more recent data to determine the update to the LTCH PPS standard Federal payment rate for FY 2017 in this final rule.

For FY 2016, we established an annual update to the LTCH PPS standard Federal payment rate of 1.7 percent based on the full estimated LTCH PPS market basket increase of 2.4 percent, less the MFP adjustment of 0.5 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.2 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. Accordingly, at § 412.523(c)(3)(xii), we established an annual update to the LTCH PPS standard Federal payment rate for FY 2015 of 1.7 percent. That is, we applied an update factor of 1.017 to the FY 2015 Federal rate of $41,043.71 to determine the FY 2016 LTCH PPS standard Federal payment rate. We also applied an area wage level budget neutrality factor for FY 2016 of 1.000513 to the LTCH PPS standard Federal payment rate to ensure that any changes to the area wage level adjustment would not result in any change in estimated aggregate LTCH PPS payments. Consequently, we established a LTCH PPS standard Federal payment rate for FY 2016 of $41,762.85 (calculated as $41,043.71 × 1.017 × 1.000513) (80 FR 49797).

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25281, based on the best available data at that time, we proposed an annual update to the LTCH PPS standard Federal payment rate of 1.45 percent (as described above). Accordingly, under § 412.523(c)(3)(xiii), we proposed to apply a factor of 1.0145 to the FY 2017 LTCH PPS standard Federal payment rate of $41,762.85 to determine the proposed FY 2017 LTCH PPS standard Federal payment rate. Also, under proposed § 412.523(c)(3)(xiii), in conjunction with the provisions of § 412.523(c)(4), we proposed to apply an annual update to the LTCH PPS standard Federal payment rate of −0.55 percent (that is, a proposed update factor of 0.9945) for FY 2017 for LTCHs that fail to submit the required quality reporting data for FY 2017 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we also proposed to apply an area wage level budget neutrality factor to the FY 2017 LTCH PPS standard Federal payment rate of 0.998723, based on the best available data at that time, to ensure that any proposed changes to the area wage level adjustment (that is, the proposed annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we proposed an LTCH PPS standard Federal payment rate of $42,314.31 (calculated as $41,762.85 × 1.0145 × 0.998723) for FY 2017. For LTCHs that fail to submit quality reporting data for FY 2017, in accordance with the requirements of the LTCHQRP under section 1886(m)(5) of the Act, we proposed an LTCH PPS standard Federal payment rate of $41,480.12 (calculated as $41,762.85 × 0.9945 × 0.998723) for FY 2017.

In this final rule, as we proposed, based on the best available data, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 1.75 percent, which was determined using the methodology previously described. Accordingly, under § 412.523(c)(3)(xiii), we applied a factor of 1.0175 to the FY 2017 LTCH PPS standard Federal payment rate of $41,762.85 to determine the FY 2017 LTCH PPS standard Federal payment rate. These factors are based on IGI's second quarter 2016 forecast, which are the best available data at this time. For LTCHs that fail to submit quality reporting data for FY 2017 under the LTCH QRP, under § 412.523(c)(3)(xiii), in conjunction with the provisions of § 412.523(c)(4), as we proposed, we reduced the annual update to the LTCH PPS standard Federal payment rate by an additional 2.0 percentage points, consistent with section 1886(m)(5) of the Act. In those cases, the LTCH PPS standard Federal payment rate is updated by −0.25 percent (that is, an update factor of 0.9975) for FY 2017 for LTCHs that fail to submit the required quality reporting data for FY 2017 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we also applied an area wage level budget neutrality factor to the FY 2017 LTCH PPS standard Federal payment rate of 0.999593, which was determined using the methodology described below in section V.B.4. of this Addendum. We are applying this area wage level budget neutrality factor to the FY 2017 LTCH PPS standard Federal payment rate to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index values and labor-related share) will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, consistent with our proposal, we are establishing a LTCH PPS standard Federal payment rate of $42,476.41 (calculated as $41,762.85 × 1.0175 × 0.999593) for FY 2017. For LTCHs that fail to submit quality reporting data for FY 2017 in accordance with the requirements of the LTCHQRP under section 1886(m)(5) of the Act, we are establishing a LTCH PPS standard Federal payment rate of $41,641.49 (calculated as $41,762.85 × 0.9975 × 0.999593) for FY 2017. We note, as discussed in section VII.B. of the preamble of this final rule, under our application of the site neutral payment rate required under section 1886(m)(6) of the Act, this LTCH PPS standard Federal payment rate will only be used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be

excluded from the site neutral payment rate).

B. Adjustment for Area Wage Levels under the LTCH PPS for FY 2017

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

When we implemented the LTCH PPS, we established a 5-year transition to the full area wage level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable LTCH area wage index values are the full LTCH PPS area wage index values calculated based on acute care hospital inpatient wage index data without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. For additional information on the phase-in of the area wage level adjustment under the LTCH PPS, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56015 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

2. Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB and a ''rural area'' is defined as any area outside of an urban area. (Information on OMB's MSA delineations based on the 2010 standards can be found at: *http://www.whitehouse.gov/sites/default/files/omb/assets/fedreg_2010/06282010_metro_standards-Complete.pdf*).

The CBSA-based geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the OMB labor market area delineations based on the 2010 Decennial Census data. The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. We adopted these labor market area delineations because they are based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believe that these OMB delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) of the regulations (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. As discussed in the FY 2017 IPPS/LTCH proposed rule (81 FR 25282 through 25283), on July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. As discussed in section III.A.2. of the preamble of the proposed rule, the updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. A copy of this bulletin may be obtained on the Web site at: *https://www.whitehouse.gov/omb/bulletins_/*.

OMB Bulletin No. 15–01 made the following changes that are relevant to the LTCH PPS CBSA-based labor market area (geographic classification) delineations:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban area under new CBSA 21420 entitled Enid, OK.
- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA 31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City is now part of the county of Bedford, VA. The CBSA remains Lynchburg, VA, 31340.
- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

We believe that these revisions to the CBSA-based labor market area delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (81 FR 25282 through 25283). Therefore, as we proposed, we are adopting them under the LTCH PPS, effective October 1, 2016. Accordingly, the FY 2017 LTCH PPS wage index values in Tables 12A and 12B listed in section VI. of the Addendum of this final rule (which are available via the Internet on the CMS Web site) reflect the revisions to the CBSA-based labor market area delineations described above. We note that, as discussed in section III.C.2. of the preamble of this final rule, the revisions to the CBSA-based delineations also are being adopted under the IPPS, effective beginning October 1, 2016.

3. Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of

an LTCH's standard Federal payment rate payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs (Wages and Salaries; Employee Benefits; Professional Fees Labor-Related, Administrative and Business Support Services; and All-Other: Labor-Related Services) and a labor-related portion of capital costs using the applicable LTCH PPS market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we revised and rebased the market basket used under the LTCH PPS by adopting the newly created FY 2009-based LTCH-specific market basket. In addition, beginning in FY 2013, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH-specific market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) As noted previously, as we proposed, we are rebasing and revising the 2009-based LTCH-specific market basket to reflect a 2013 base year. In conjunction with that policy, as discussed in section VII.D.4.e. of the preamble of this final rule, we are establishing that the LTCH PPS labor-related share for FY 2017 is the sum of the FY 2017 relative importance of each labor-related cost category in the 2013-based LTCH market basket using the most recent available data. Specifically, as we discussed in the FY 2017 IPPS/LTCH proposed rule (81 FR 25283), we are establishing that the labor related share for FY 2017 will include the sum of the labor-related portion of operating costs from the 2013-based LTCH market basket (that is, the sum of the FY 2017 relative importance share of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) and a portion of the Capital-Related cost weight from the 2013-based LTCH PPS market basket. Based on IGI's second quarter 2016 forecast of the 2013-based LTCH market basket, as we proposed, we are establishing a labor-related share under the LTCH PPS for FY 2017 of 66.5 percent. This labor-related share is determined using the same methodology as employed in calculating all previous LTCH PPS labor-related shares. Consistent with our historical practice, as we proposed, we used more recent data to determine the final FY 2017 labor-related share in this final rule.

Table VII–9 in section VII.D.4.e. of the preamble of this final rule shows the FY 2017 relative importance labor-related share using the 2013-based LTCH market basket and the FY 2016 relative importance labor-related share using the 2009-based LTCH-specific market basket. The labor-related share for FY 2017 is the sum of the FY 2017 relative importance of each labor-related cost category, and will reflect the different rates of price change for these cost categories between the base year (2013) and FY 2017. The sum of the relative importance for FY 2017 for operating costs (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) is 62.2 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (the same percentage applied to the 2009-based LTCH-specific market basket). Because the relative importance for capital-related costs under our policies is 9.43 percent of the 2013-based LTCH market basket in FY 2017, as we proposed, we took 46 percent of 9.43 percent to determine the labor-related share of capital-related costs for FY 2017 (0.46×9.43). The result is 4.3 percent, which we added to 62.2 percent for the operating cost amount to determine the total labor-related share for FY 2017. Therefore, the labor-related share under the LTCH PPS for FY 2017 is 66.5 percent. We note that the FY 2017 labor-related share using the 2013-based LTCH market basket is 4.5 percentage points higher than the FY 2016 labor-related share using the 2009-based LTCH-specific market basket. This is primarily due to, as discussed in greater detail in section VII.D.4.e. of the preamble of this final rule, the change in the quantity of labor, particularly for professional services, outpacing the change in quantity of products (which are not included in the labor-related share) between 2009 and 2013, which more than offsets the faster relative growth in prices for products.

4. Wage Index for FY 2017 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49798 through 49799), we calculated the FY 2016 LTCH PPS area wage index values using the same data used for the FY 2016 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2012), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2016 LTCH PPS area wage index values, consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, as discussed in the FY 2017 IPPS/LTCH proposed rule (81 FR 25283 through 25284), to determine the applicable area wage index values for the FY 2017 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, as we proposed, we used wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2013, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, because these data are the most recent complete data available. We also note that these are the same data we are using to compute the FY 2017 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this final rule. We computed the FY 2017 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural''

geographic classifications (that is, labor market area delineations, including the proposed updates, as previously discussed in section V.B.2. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. As we also proposed, we are continuing to apportion wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2017, as we proposed, we are continuing to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data would be determined by using an average of all of the urban areas within the State and the LTCH PPS wage index value for rural areas with no IPPS wage data would be determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2013 IPPS wage data that we used to determine the FY 2017 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the FY 2017 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the state of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this final rule and available via the Internet on the CMS Web site). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

Based on the FY 2013 IPPS wage data that we used to determine the FY 2017 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no rural areas without IPPS hospital wage data. Therefore, as was the case in the proposed rule, it is not necessary to use our established methodology to calculate a LTCH PPS standard Federal payment rate wage index value for rural areas with no IPPS wage data for FY 2017. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future. The FY 2017 LTCH PPS standard Federal payment rate wage index values that are applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2016, through September 30, 2017, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum of this final rule and available via the Internet on the CMS Web site.

5. Budget Neutrality Adjustment for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage-level adjustment budget neutrality factor that will be applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we apply an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

In this final rule, for FY 2017 LTCH PPS standard Federal payment rate cases, in accordance with § 412.523(d)(4), as we proposed, we applied an area wage level adjustment budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using a methodology that is consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, as we proposed in the FY 2017 IPPS/LTCH proposed rule (81 FR 25284), we determined an area wage level adjustment budget neutrality factor that was applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2017 using the following methodology:

Step 1—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2016 wage index values and the FY 2016 labor-related share of 62.0 percent (as established in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49798 and 49799).

Step 2—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2017 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this rule and available via the Internet on the CMS Web site) and the FY 2017 labor-related share of 66.5 percent (based on the latest available data as previously discussed previously in this Addendum).

Step 3—We calculated the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2016 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the FY 2017 area wage level adjustments (calculated in Step 2) to determine the area wage level adjustment budget neutrality factor for FY 2017 LTCH PPS standard Federal payment rate payments.

Step 4—We then applied the FY 2017 area wage level adjustment budget neutrality factor from Step 3 to determine the FY 2017 LTCH PPS standard Federal payment rate after the application of the FY 2017 annual update (discussed previously in section V.A.2. of this Addendum).

We note that, with the exception of cases subject to the transitional blend payment rate provisions in the first 2 years, under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. Because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, we only used data from claims that

would have qualified for payment at the LTCH PPS standard Federal payment rate if such rate were in effect at the time of discharge to calculate the FY 2017 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor described above.

For this final rule, using the steps in the methodology previously described, we determined a FY 2017 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 0.999593. Accordingly, in section V.A.2. of the Addendum to this final rule, to determine the FY 2017 LTCH PPS standard Federal payment rate, we applied an area wage level adjustment budget neutrality factor of 0.999593, in accordance with § 412.523(d)(4). The FY 2017 LTCH PPS standard Federal payment rate shown in Table 1E of the Addendum to this final rule reflects this adjustment factor.

C. Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described.

Under our current methodology, we update the COLA factors for Alaska and Hawaii every 4 years (at the same time as the update to the labor-related share of the IPPS market basket) (77 FR 53712 through 53713). This methodology is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii, we refer readers to section VII.D.3. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482).)

As discussed in the FY 2017 IPPS/LTCH proposed rule (81 FR 25284 through 25285), we continue to believe that determining updated COLA factors using this methodology will appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii. Under our current policy, we update the COLA factors using the methodology described above every 4 years; the first year began in FY 2014 (77 FR 53482). Therefore, in this final rule for FY 2017, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, as we proposed, we are continuing to use the COLA factors based on the 2009 OPM COLA factors updated through 2012 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2014 IPPS/LTCH PPS final rule. (We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50998) for a discussion of the FY 2014 COLA factors.) Consistent with our historical practice, as we proposed, we are establishing that the COLA factors shown in the following table will be used to adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii under § 412.525(b).

COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS UNDER THE LTCH PPS FOR FY 2017

Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
All other areas of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.19
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the same rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8 percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases which would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO

threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

In order to maintain budget neutrality, consistent with the budget neutrality requirement for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulation for further details). We note during the 2-year transitional period, the site neutral payment rate HCO budget neutrality factor does not apply to the LTCH PPS standard Federal payment rate portion of the blended rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted above, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS, and are also used to determine payments for SSO cases under § 412.529 as well as payments for site neutral payment rate cases. (We note that the provisions of § 412.529 are only applicable to LTCH PPS standard Federal payment rate cases.) Therefore, this discussion is relevant to all HCO, SSO, and site neutral payment rate calculations.

As noted earlier, in determining HCO, SSO, and the site neutral payment rate (regardless of whether the case is also an HCO) payments, we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding HCO adjustments for either LTCH PPS payment rate, § 412.529(f)(4) for SSO adjustments, and § 412.522(c)(1)(ii) for the site neutral payment rate, respectively.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs above the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. LTCH Total CCR Ceiling

Consistent with our historical practice, we used more recent data to determine the LTCH total CCR ceiling for this FY 2017 in this final rule. Specifically, in this final rule, using our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the March 2016 update of the Provider Specific File (PSF), which is the most recent data available, we are establishing a LTCH total CCR ceiling of 1.297 under the LTCH PPS for FY 2017 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate, § 412.529(f)(4)(iii)(B) for SSOs, and § 412.522(c)(1)(ii) for the site neutral payment rate. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48118 through 48119).)

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(C)(2), the SSO policy at § 412.529(f)(4)(iii)(B), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data and as we proposed, in this final rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the March 2016 update of the PSF, we are establishing LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2016 through September 30, 2017, in Table 8C listed in section VI. of the Addendum to this final rule (and available via the Internet on the CMS Web site). Consistent with our historical practice, as we proposed, we used more recent data to determine the LTCH PPS statewide average total CCRs for FY 2017 in this final rule.

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71

FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut has areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there was no data available from short-term, acute care IPPS hospitals to compute a rural statewide average CCR or there were no short-term, acute care IPPS hospitals or LTCHs located in that area as of March 2016. (We note that, based on the best available data at the time of the proposed rule, there were no data available from short-term acute care IPPS hospitals (or LTCHs) located in the rural areas of North Dakota. However, based on the more recent data available for this final rule, there is now data available from short-term acute care IPPS hospitals in the rural areas of North Dakota from which to compute a rural statewide average CCR. Therefore, it is no longer necessary to use the national average total CCR for rural IPPS hospitals for rural North Dakota in Table 8C associated with this final rule, which is available via the Internet on the CMS Web site.) Therefore, consistent with our existing methodology, as we proposed, we used the national average total CCR for rural IPPS hospitals for rural Connecticut in Table 8C listed in section VI. of the Addendum to this final rule (and available via the Internet on the CMS Web site). Furthermore, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, as we proposed, we are continuing to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We used this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of HCO and SSO Payments

Under the HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(D) and the SSO policy at § 412.529(f)(4)(iv), the payments for HCO and SSO cases are subject to reconciliation. Specifically, any such payments are reconciled at settlement based on the CCR that is calculated based on the cost report coinciding with the discharge. (We note the existing reconciliation process for HCO payments is also applicable to LTCH PPS payments for site neutral payment rate cases (80 FR 49610).) For additional information on the reconciliation policy, we refer readers to Sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4) as added by Change Request 7192 (Transmittal 2111; December 3, 2010) and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

e. Technical Change to the Definition of ''Outlier Payment''

The existing regulations at § 412.503 includes a definition of ''outlier payment,'' which was adopted when the LTCH PPS was implemented (67 FR 56049). This definition does not account for the dual rate LTCH PPS payment structure that began in FY 2016. Therefore, in this final rule, to account for our HCO policy for LTCH cases paid under either payment rate, as we proposed, we are revising the definition of ''outlier payment'' at § 412.503 to mean an additional payment beyond the LTCH PPS standard Federal payment rate or the site neutral payment rate (including, when applicable, the transitional blended rate), as applicable, for cases with unusually high costs.

We did not receive any public comments on our proposed technical revisions to the definition of ''outlier payment'' at § 412.503 to account for the dual rate LTCH PPS payment structure that began in FY 2016. Therefore, we are adopting this revision as final, without modification.

3. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. Establishment of the Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2017

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, that the historical LTCH PPS HCO policy will continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount and target for LTCH PPS standard Federal payment rate cases is determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been a LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. The applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We use MedPAR claims data and CCRs based on data from the most recent PSF (or from the applicable statewide average CCR if an LTCH's CCR data are faulty or unavailable) to establish an applicable fixed-loss threshold amount for LTCH PPS standard Federal payment rate cases.

In the FY 2017 IPS/LTCH PPS proposed rule (81 FR 25286 through 25287), we proposed to continue to use our current methodology to calculate an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 using the best available data that would maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in that proposed rule). Specifically, based on the most recent complete LTCH data available (that is, LTCH claims data from the December 2015 update of the FY 2015 MedPAR file and CCRs from the December 2015 update of the PSF), we determined that a proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 of $22,728 would result in estimated outlier payments projected to be equal to 8 percent of estimated FY 2017 payments for such cases. Under this proposal, we would continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $22,728). We also noted that the proposed fixed-loss amount for HCO cases paid under the LTCH PPS standard Federal payment rate in FY 2017 of $22,728 is notably higher than the FY 2016 fixed-

loss amount for LTCH PPS standard Federal payment rate cases of $16,423, and explains that the increase is largely attributable to rate-of-change in the Medicare allowable charges on the claims data in the MedPAR file. Based on the most recent available data at the time of the proposed rule, we found that the current FY 2016 HCO threshold of $16,423 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 9.1 percent of the estimated total LTCH PPS payments in FY 2016, which exceeds the 8 percent target by 1.1 percentage points. We also noted that fluctuations in the fixed-loss amount occurred in the first few years after the implementation of the LTCH PPS, due, in part, to the changes in LTCH behavior (such as Medicare beneficiary treatment patterns) in response to the new payment system and the lack of data and information available to predict how those changes would affect the estimate costs of LTCH cases. As we gained more experience with the effects and implementation of the LTCH PPS, the annual changes on the fixed-loss amount generally stabilized relative to the fluctuations that occurred in the early years of the LTCH PPS. Therefore, we did not propose any changes to our method for the inflation factor applied to update the costs of each case (that is, an inflation factor based on the most recent estimate of the proposed 2013-based LTCH market basket as determined by the Office of the Actuary) in determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017. We stated our continued belief that it is appropriate to continue to use our historical approach until we gain experience with the effects and implementation of the dual rate LTCH PPS payment structure that began with discharges occurring in cost reporting periods beginning on or after October 1, 2015, and the types of cases paid at the LTCH PPS standard Federal payment rate under this dual rate payment structure. We stated that we may revisit this issue in the future if data demonstrate such a change is warranted, and would propose any changes in the future through the notice-and-comment rulemaking process. Furthermore, we invited public comments on potential improvements to the determination of the fixed-loss amount for LTCH PPS standard Federal payment rate cases, including the most appropriate method of determining an inflation factor for projecting the costs of each case when determining the fixed-loss threshold.

Comment: A few commenters expressed concern with the notable increase in the proposed FY 2017 fixed-loss amount for LTCH PPS standard Federal payment rate cases as compared to the current fixed-loss amount for such cases. Some of these commenters expressed general support for continuing to use a target amount of 8 percent for HCO payments for LTCH PPS standard Federal payment rate cases. Some commenters stated that they are concerned about the potential instability in the fixed-loss amount from year to year and requested that CMS continue to be transparent about the possible causes for such large year-to-year changes in the fixed-loss amount and how much of this variability may be attributable to the new dual rate LTCH PPS payment structure. Some commenters also expected that the fixed-loss amount would change in the final rule based on the use of more recent LTCH claims data from the MedPAR file and the latest CCRs from the PSF. In addition to using the most recent LTCH claims data and CCRs, some commenters suggested that CMS consider whether the new dual rate LTCH PPS payment structure warrants the use of other relevant data or a change in the inflation factor for projecting the costs of each case when determining the fixed-loss amount. One commenter stated that it is not reasonable for the HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases to increase to such a high level, and suggested that the increase in the HCO fixed-loss amount be established at 7 percent, which would reflect the LTCH industry's average increase in charges.

Response: We understand the commenters' concern with the proposed increase to the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017, and we appreciate the commenters' support for our proposed continued use of a HCO target amount of 8 percent for LTCH PPS standard Federal payment rate cases. (For information on the rationale for the existing 8 percent HCO ''target'' requirement, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56024).) As we discussed in the proposed rule, based on the best available data at that time, we estimated that the current FY 2016 HCO fixed-loss amount of $16,423 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases in excess of the 8 percent target by 1.1 percentage points. Similarly, based on the most recent available data for this final rule (discussed below), we found that the current FY 2016 HCO threshold of $16,423 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 9.0 percent of the estimated total LTCH PPS payments in FY 2016, which exceeds the 8 percent target by 1.0 percentage point. Maintaining the fixed-loss amount at the current level would result in HCO payments that are substantially more than the current regulatory 8 percent target that we apply to total payments for LTCH PPS standard Federal payment rate cases because a lower fixed-loss amount results in more cases qualifying as outlier cases, as well as higher HCO payments for qualifying cases because the maximum loss that an LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be smaller. For these reasons, we continue to believe it is necessary and appropriate to increase to the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 to maintain estimated HCO payments equal to 8 percent of estimated total LTCH PPS payments for such cases as required under § 412.525(a). In addition, for these reasons, we are not adopting the commenter's suggestion to only increase the fixed-loss amount for LTCH PPS standard Federal payment rate cases by the average increase in LTCHs' charges because the resulting fixed-loss amount would not maintain estimated HCO payments to equal 8 percent of estimated total LTCH PPS payments for such cases, as required under current policy.

As discussed in the proposed rule, fluctuations in the fixed-loss amount have occurred previously under the LTCH PPS, due, in part, to the changes in LTCH behavior in response to the changes in Medicare payments and the lack of data and information available to predict how those changes affect the estimate costs of LTCH cases. As was the case when there were fluctuations in the fixed-loss amount in the early years of the LTCH PPS, we expect annual changes to the fixed-loss amount to generally stabilize as experience is gained under the new dual rate LTCH PPS payment structure. We intend to continue to monitor annual changes in the HCO fixed-loss amount, including factors that cause any such changes. We appreciate the commenters' suggestions for potential improvements to the determination of the fixed-loss amount for LTCH PPS standard Federal payment rate cases, including the use of other relevant data or a change in the inflation factor for projecting the costs of each

case when determining the fixed-loss amount. As we indicated in the proposed rule, we may revisit this issue in the future if data demonstrate such a change is warranted, and would propose any changes in the future through the notice-and-comment rulemaking process. We note, as in greater detail discussed below, the fixed-loss amount for FY 2017 for LTCH PPS standard Federal payment rate cases we are establishing in this final rule, after consideration of public comments and based on the most recent LTCH claims data from the MedPAR file and the latest CCRs from the PSF, does result in a fixed-loss amount for such cases that is lower than the proposed fixed-loss amount, consistent with commenters' expectations.

After consideration of the public comments we received, for the reasons discussed above, we are finalizing our proposal to continue to use the current LTCH PPS HCO payment methodology for LTCH PPS standard Federal payment rate cases for FY 2017 without modification. Therefore, in this final rule, for FY 2017, we determined an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases using data from LTCH PPS standard Federal payment rate cases (or cases that would have been LTCH PPS standard Federal payment rate cases had the dual rate LTCH PPS payment structure been in effect at the time of those discharges). The fixed-loss amount for LTCH PPS standard Federal payment rate cases will continue to be determined so that estimated HCO payments will be projected to equal 8 percent of estimated total LTCH PPS standard Federal payment rate cases. Furthermore, in accordance with § 412.523(d)(1), a budget neutrality factor will continue to be applied to LTCH PPS standard Federal payment rate cases to offset that 8 percent so that HCO payments for LTCH PPS standard Federal payment rate cases will be budget neutral. Below we present our calculation of the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017, which is consistent with the methodology used to establish the FY 2016 LTCH PPS fixed-loss amount, as we proposed.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49803 through 49804), we presented our policies regarding the methodology and data we used to establish a fixed-loss amount of $16,423 for FY 2016 for LTCH PPS standard Federal payment rate cases, which was calculated based on the data and the rates and policies presented in that final rule in order to maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments. Consistent with our historical practice of using the best data available, as we proposed, in determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017, we used the most recent available LTCH claims data and CCR data, that is, LTCH claims data from the March 2016 update of the FY 2015 MedPAR file and CCRs from the March 2016 update of the PSF, as these data were the most recent complete LTCH data available at that time.

For FY 2017, as we proposed, we are continuing to use our current methodology to calculate an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 using the best available data that will maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the rates and policies for these cases presented in this final rule). Specifically, based on the most recent complete LTCH data available (that is, LTCH claims data from the March 2016 update of the FY 2015 MedPAR file and CCRs from the March 2016 update of the PSF), we determined a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 that will result in estimated outlier payments projected to be equal to 8 percent of estimated FY 2017 payments for such cases. Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are establishing a fixed-loss amount of $21,943 for LTCH PPS standard Federal payment rate cases for FY 2017. Under our policy, we will continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $21,943).

We note that the fixed-loss amount of $21,943 for FY 2017 for LTCH PPS standard Federal payment rate cases is somewhat lower than the proposed FY 2017 fixed-loss amount of $22,728 for FY 2017 for such cases, but notably higher than the FY 2016 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $16,423. As discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25287), the FY 2016 fixed-loss amount for LTCH PPS standard Federal payment rate cases was determined using LTCH claims data from the March 2015 update of the FY 2014 MedPAR file and CCRs from the March 2015 update of the PSF. Based on that data, the estimated outlier payments were projected to be equal to 8 percent of estimated FY 2016 payments for such cases (80 FR 49803). Using the more recent LTCH claims data (that is, FY 2015 LTCH discharges from the March 2016 update of the MedPAR file and CCRs from the March 2016 update of the PSF), we currently estimate that the FY 2016 fixed-loss amount of $16,423 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 9.0 percent of total estimated FY 2016 LTCH PPS payments to those cases, which exceeds the 8 percent target. While many factors contribute to this increase, we found that the rate-of-change in the Medicare allowable charges on the claims data in the MedPAR is a significant contributing factor. In the payment modeling used to estimate LTCH PPS payments for the FY 2016 IPPS/LTCH PPS final rule, for SSO and HCO cases paid as LTCH PPS standard Federal payment rate cases, we applied an inflation factor of 4.6 percent (determined by the Office of the Actuary) to update the 2014 costs of each case to 2016 (80 FR 49833). Upon examining FY 2014 LTCH and FY 2015 LTCH discharge data, we found that Medicare allowable charges for LTCH PPS standard Federal payment rate cases (had the dual rate LTCH PPS payment structure been in effect at the time of the discharges) increased approximately 7 percent. This higher inflation factor results in higher estimated costs for outlier cases and, therefore, more estimated outlier payments. For the reasons discussed above, we believe that it is necessary and appropriate to apply an increase to the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 to ensure that, for LTCH PPS standard Federal payment rate cases, estimated HCO payments will equal 8 percent of estimated total LTCH PPS payments for those cases as required under § 412.525(a).

b. Application of the High-Cost Outlier Policy to SSO Cases

Under our implementation of the dual rate LTCH PPS payment structure required by statute, LTCH PPS standard Federal payment rate cases (that is, LTCH discharges that meet the criteria for exclusion from the site neutral payment rate) will continue to be paid based on the LTCH PPS standard Federal payment rate, and will include all of the existing payment adjustments

under § 412.525(d), such as the adjustments for SSO cases under § 412.529. Under some rare circumstances, an LTCH discharge can qualify as an SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as an HCO case, as discussed in the August 30, 2002 final rule (67 FR 56026). In this scenario, a patient could be hospitalized for less than five-sixths of the geometric average length of stay for the specific MS–LTC–DRG, and yet incur extraordinarily high treatment costs. If the estimated costs exceeded the HCO threshold (that is, the SSO payment plus the applicable fixed-loss amount), the discharge is eligible for payment as an HCO. Therefore, for an SSO case in FY 2017, as we proposed, we are establishing that the HCO payment will be 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the fixed-loss amount of $21,943 and the amount paid under the SSO policy as specified in § 412.529).

4. High-Cost Outlier Payments for Site Neutral Payment Rate Cases

Under § 412.525(a), site neutral payment rate cases receive an additional HCO payment for costs that exceed the HCO threshold that is equal to 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold (80 FR 49618 through 49629). In the FY 2016 IPPS/LTCH PPS final rule, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary (OACT) projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. For FY 2016, at that time our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49618 through 49619). For those reasons, in the FY 2016 IPPS/LTCH PPS final rule (FR 80 49619), we stated that we believe that the most appropriate fixed-loss amount for site neutral payment rate cases for a given fiscal year, beginning with FY 2016, would be the IPPS fixed-loss amount for that fiscal year. Accordingly, we established that for FY 2016, a fixed-loss amount for site neutral payment rate cases of $22,544, which was the same as the FY 2016 IPPS fixed-loss amount. (We note that the FY 2016 fixed-loss amount under the IPPS was updated, applicable for discharges on or after January 1, 2016, as a conforming change to the implementation of section 601 of the Consolidated Appropriations Act, 2016, which modified the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016 (Change Request 9523, Transmittal 3449, dated February 4, 2016).) Consistent with this change, the FY 2016 fixed-loss amount for site neutral payment rate cases under the LTCH PPS was updated, applicable for discharges on or after January 1, 2016, to $22,538, which is the same as the updated IPPS outlier fixed-loss cost threshold for FY 2016. (We refer readers to Change Request 9527, Transmittal 3445, dated January 29, 2016, which also updated the IPPS comparable amount calculation, applicable to discharges occurring on or after January 1, 2016, consistent with the conforming changes made as a result of the new IPPS payment requirement.)

In developing a fixed-loss amount for site neutral payment rate cases for FY 2017, as discussed in the FY 2017 IPPS/LTCH proposed rule (81 FR 25288), we considered the same factors we did developing a fixed-loss amount for such cases for FY 2016. For FY 2017, our actuaries currently project that the proportion of cases that will qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the dual rate LTCH PPS payment structure provisions will remain consistent with what is reflected in the historical LTCH PPS claims data. Based on FY 2014 LTCH claims data, LTCH claims data, we found that approximately 55 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 45 percent of LTCH cases would have been paid the site neutral payment rate if those rates had been in effect at that time.) At this time, our actuaries continue to project no immediate change in these proportions. However, they do continue to project that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2017 is the IPPS fixed-loss amount for FY 2017.

Therefore, for FY 2017, we proposed that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we proposed a fixed-loss amount for site neutral payment rate cases of $23,681, which is the same FY 2017 IPPS fixed-loss amount discussed in section II.A.4.g.(1) of the Addendum to that proposed rule. We stated that we continued to believe that this policy will reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems. Accordingly, for FY 2017, we proposed to calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount,

which is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of site neutral payment rate payment and the fixed-loss amount for site neutral payment rate cases of $23,681).

Comment: Some commenters expressed support for our proposal to continue to use the FY 2017 IPPS fixed-loss amount and 5.1 percent HCO target for LTCH discharges paid at the site neutral payment rate in FY 2017. However, some commenters suggested that the IPPS fixed-loss amount and 5.1 percent HCO target not be used automatically for site neutral payment rate cases every year.

Response: We appreciate the commenters support for our proposal to continue to use the FY 2017 IPPS fixed-loss amount and 5.1 percent HCO target for LTCH discharges paid at the site neutral payment rate in FY 2017. Given the current expectation that cases paid at the site neutral payment rate would likely be similar to IPPS cases assigned to the same MS–DRG, we continue to believe the most appropriate fixed-loss amount for site neutral payment rate cases is the IPPS fixed-loss amount for that fiscal year. As we indicated in the FY 2016 IPPS/LTCH PS final rule (80 FR 49619), to the extent experience under the revised LTCH PPS indicates site neutral payment rate cases differ sufficiently from these expectations, we agree it would be appropriate to revisit in future rulemaking the most appropriate fixed-loss amount used to determine HCO payments for site neutral payment rate cases.

Comment: One commenter recommended that CMS apply geographic adjustments (that is, the wage index and COLA) to the fixed-loss amount when determining the HCO threshold for site neutral payment rate cases, consistent with the approach used under the IPPS.

Response: The LTCH PPS HCO policy does not include the application of geographic adjustments when determining the HCO threshold, and therefore, our current policy for determining the HCO threshold for site neutral payment rate cases, which we proposed to continue to use for FY 2017, is consistent with our longstanding LTCH PPS HCO policy. The LTCH PPS and IPPS HCO policies have historically differed with regard to this aspect of the HCO payment policy calculation. Moreover, the commenter offered little support to demonstrate that its recommended change, which we did not propose and are not accepting, would result in more appropriate HCO payments to site neutral payment rate cases paid under the LTCH PPS. We will keep this recommended change in mind as we consider potential refinements to the LTCH PPS HCO policy, including the HCO threshold for site neutral payment rate cases, in the future.

After consideration of the public comments we received, we are finalizing, without modification, our proposals to use the FY 2017 IPPS fixed-loss amount and 5.1 percent HCO target for LTCH discharges paid at the site neutral payment rate in FY 2017. Therefore, for FY 2017, as we proposed, we are establishing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we are establishing a fixed-loss amount for site neutral payment rate cases of $23,570, which is the same FY 2017 IPPS fixed-loss amount discussed in section II.A.4.g.(1) of the Addendum to this final rule. We continue to believe that this policy will reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems. Accordingly, under this policy, for FY 2017, we are calculating a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount, which is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of site neutral payment rate payment and the fixed-loss amount for site neutral payment rate cases of $23,570). (We note that any site neutral payment rate case that is paid 100 percent of the estimated cost of the case (because that amount is lower than the IPPS comparable per diem amount) will not be eligible to receive a HCO payment because, by definition, the estimated costs of such cases will never exceed the IPPS comparable per diem amount by any threshold.)

In establishing a HCO policy for site neutral payment rate cases, we established a budget neutrality requirement at § 412.522(c)(2)(i). We established this requirement because we believe that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases are budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments. Under § 412.522(c)(2)(i), we adjust all payments for site neutral payment rate cases by a budget neutrality factor so that the estimated HCO payments payable for site neutral payment rate cases do not result in any increase in aggregate LTCH PPS payments. Specifically, under § 412.522(c)(2)(i), we apply a budget neutrality factor to the site neutral payment rate portion of the transitional blended rate payment (that is applicable to site neutral payment rate cases during the 2-year transition period provided by the statute) that is established based on an estimated basis. (We refer readers to 80 FR 49621 through 49622 and 49805.)

Under the approach adopted for applying the budget neutrality adjustment to the site neutral payment rate portion of the transitional blended rate payment in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49805), we explained that there is no need to perform any calculation of the site neutral payment rate case HCO payment budget neutrality adjustment under our finalized policy. This is because, as discussed in the proposed rule (81 FR 25288), based on our actuarial assumptions we project that our proposal to use the IPPS fixed-loss threshold for the site neutral payment rate cases would result in HCO payments for those cases that are similar in proportion as is seen in IPPS cases assigned to the same MS–DRG; that is, 5.1 percent. In other words, we estimated that HCO payments for site neutral payment rate cases would be 5.1 percent of the site neutral payment rate payments. Under the statutory transition period, payments to site neutral payment rate cases in FY 2017 will be paid under the blended transitional rate. As such, we stated that estimated HCO payments for site neutral payment rate cases in the FY 2017 policy will be projected to be 5.1 percent of the portion of the blended rate payment that is based on the estimated site neutral payment rate payment amount (and will not include the LTCH PPS standard Federal payment rate payment amount as specified in § 412.522(c)(2)(i)). To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2017 will not result any increase in estimated aggregate FY 2017 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), we explained it is necessary to reduce the site neutral payment rate portion of the blended rate payment by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2017. In order to achieve this, for FY 2017, we proposed to continue to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0 − 5.1/100 =

0.949) to the site neutral payment rate portion of the blended rate payment (81 FR 25289). As stated previously, this adjustment is necessary so that the estimated HCO payments payable for site neutral payment rate cases do not result in any increase in aggregate LTCH PPS payments.

Comment: As was the case in the FY 2016 rulemaking cycle, commenters again objected to the proposed application of a high-cost outlier (HCO) budget neutrality adjustment to site neutral payment rate cases, stating that it results in savings to the Medicare program instead of being budget neutral. The commenters' primary objection was again based on their belief that, because the IPPS base rates used in the IPPS comparable per diem amount calculation of the site neutral payment rate include a budget neutrality adjustment for IPPS HCO payments (that is, a 5.1 percent adjustment on the operating IPPS standardized amount), an ''additional'' budget neutrality factor is not necessary and is, in fact, duplicative. Some of these commenters stated that, in addition to not applying a HCO budget neutrality adjustment to site neutral payment rate payments, its application in FY 2016 should be discontinued, and that a retroactive adjustment to the FY 2016 site neutral payment rate payments that have already occurred should be made to address this perceived error. In addition, some commenters also indicated that the HCO budget neutrality payment adjustment is inappropriate because it increases the payment difference between the IPPS payment amount for a case and the ''LTCH PPS payment amount'' (which we took to mean cases paid the IPPS comparable per diem amount under the site neutral payment rate) for similar cases. Other commenters stated that there is no statutory requirement for budget neutrality for HCO payments, and that any HCO budget neutrality adjustment for site neutral payment rate cases is therefore unwarranted. These commenters stated that there was nothing in their review of the rulemaking record that they read to mean that CMS would apply a HCO budget neutrality adjustment on an ongoing basis, and that they believed that a budget neutrality adjustment was only required for the first year of the LTCH PPS. A few other commenters stated that if CMS finalizes its proposal to apply a HCO budget neutrality adjustment for site neutral payment rate cases, then that budget neutrality adjustment should not be applied to site neutral payment rate cases that are paid at 100 percent of the estimated cost because they believed that doing so would violate the statute, which they understood to require payment at ''100 percent of the estimated cost for the services involved,'' without adjustment.

Response: We continue to disagree with the commenters who assert that a HCO budget neutrality adjustment for site neutral payment rate cases is inappropriate, unnecessary, or duplicative. We have made a budget neutrality adjustment for estimated HCO payments under the LTCH PPS under § 412.525 every year since its inception in FY 2003. Specifically, at § 412.523(d)(1), under the broad authority provided by section 123 of Public Law 106–113 and section 307 of Public Law 106–554, which includes the authority to establish adjustments, we established that the standard Federal rate (now termed the LTCH PPS standard Federal payment rate under the new dual rate system) would be adjusted by a reduction factor of 8 percent, the estimated proportion of outlier payments under the LTCH PPS (67 FR 56052). Thus, Congress was well aware of how we had implemented our HCO policy under the LTCH PPS under § 412.525 at the time of the enactment of section 1206 of Public Law 113–67.

Section 1206 of Public Law 113–67 defined the site neutral payment rate as the lower of the estimated cost of the case or the IPPS comparable per diem amount determined under paragraph (d)(4) of § 412.529, including any applicable outlier payments under § 412.525. The term ''IPPS comparable per diem amount'' was not new at the time of enactment. That term had already previously been defined under § 412.529(d)(4), which has been in effect since July 1, 2006, and used as a component of the payment adjustment formula for LTCH PPS SSO cases. From the July 1, 2006 inception of the IPPS comparable component of the LTCH PPS' SSO payment formula, we have budget neutralized the estimated HCO payments that we expected to pay to SSO cases including those paid based on the IPPS comparable per diem amount. Congress was also well aware of how we had implemented our ''IPPS comparable per diem amount'' concept in the SSO context at the time of the enactment of section 1206 of Public Law 113–67. As such, we believe Congress left us with the discretion to continue to treat the ''IPPS comparable per diem amount'' in the site neutral payment rate context as we have historically done with respect to LTCH PPS HCO payments made to discharges paid using the ''IPPS comparable per diem amount,'' that is, to adopt a policy in the site neutral context to budget neutralize HCO payments made to LTCH PPS discharges including those paid using the ''IPPS comparable per diem amount.''

In response to the commenters who believe that budget neutrality was only required in the first year of the LTCH PPS, we suspect that they are referencing the budget neutrality adjustment that was made to the LTCH PPS relative to the reasonable cost-based TEFRA payment system that preceded it. That initial budget neutrality adjustment is unrelated to our ongoing authority to make annual HCO budget neutrality adjustments for payments under the LTCH PPS, adjustments we adopted through prior notice-and-comment rulemaking using the broad authority provided by section 123 of Public Law 106–113 and section 307 of Public Law 106–554.

In response to commenters who stated that there is no statutory requirement to apply a budget neutrality adjustment for HCO payments, as discussed previously, the authorizing statutes grant the Secretary broad authority to determine appropriate adjustments under the LTCH PPS, and that although the statute did not ''require'' that a HCO policy be implemented in a budget neutral manner, we adopted such an approach through notice-and comment rulemaking when we initially implemented the LTCH PPS. As such, we have made a budget neutrality adjustment for estimated HCO payments under the LTCH PPS every year since its inception in FY 2003 under § 412.523(d)(1), where we established that the standard Federal rate is adjusted by a reduction factor of 8 percent, the estimated proportion of outlier payments under the LTCH PPS (67 FR 56052).

In response to commenters who indicated that the adjustment is inappropriate because it increases the payment difference between the IPPS comparable payment amount for a case and the LTCH PPS payment amount (that is, the site neutral payment rate) for similar cases, we note that the statutory requirement to take into account the estimated cost of the case if lower already creates a differential. In addition, the statute also specifies that the IPPS comparable amount is calculated as a per diem capped at the full amount as set forth under § 412.529(d)(4), which also creates a differential. Thus, the statute does not require or allow exact payment neutrality.

Finally, we disagree with the comment that applying the HCO budget neutrality adjustment to site neutral

payment rate payments that are paid at 100 percent of the estimated cost violates the statute. As noted above, CMS regularly uses its broad authorities under the authorizing statutes for the LTCH PPS to apply additional adjustments, where appropriate, to base payment amounts. For this reason, we are not adopting the commenter's request, and for FY 2017 we will apply a HCO budget neutrality adjustment factor to all site neutral payment rate cases (or the site neutral payment rate portion of the blended payment rate for all such cases), as proposed.

In summary, we continue to disagree with commenters that a HCO budget neutrality adjustment for site neutral payment rate cases is inappropriate, unnecessary or duplicative. As such, we will continue to use the IPPS comparable per diem amount (calculated in accordance with our historical practices, which predates enactment of section 1206 of Pub. L. 113–67), and we will continue to apply a HCO budget neutrality adjustment to all site neutral payment rate payments (or portion thereof in the blended payment rate context). For these reasons, we are not adopting the commenter's recommendation to discontinue the application of the HCO budget neutrality adjustment for site neutral payment rate cases in FY 2016, or their suggestion that we make a retroactive adjustment to the FY 2016 site neutral payment rate case payments that have already occurred.

Comment: One commenter noted that the HCO payment amount itself is being reduced under our proposed application of a budget neutrality factor to the site neutral payment rate portion of the blended payment rate, which is inconsistent with high-cost outlier payments for other LTCH PPS and IPPS cases, and requested that we treat all cases in the same manner.

Response: On review, we agree that our proposed application would be inconsistent with our budget neutrality treatment of HCO payments for other LTCH PPS and IPPS cases, and we agree with the commenter that we should remove this variance. As such, we are adopting a policy of not applying the 0.949 budget neutrality adjustment factor to any applicable HCO payment for the site neutral payment rate (or, during the transition, the site neutral payment rate portion of the blended payment rate).

After consideration of the public comments we received, we are finalizing our proposal to apply a budget neutrality adjustment for HCO payments made to site neutral payment rate cases, with one modification. That is, we will not apply the HCO budget neutrality adjustment to the HCO portion of the payment amount. To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2017 will not result any increase in estimated aggregate FY 2017 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate (or portion thereof in the blended payment rate context) by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2017. To effectuate this policy, for FY 2017, in this final rule we have adopted a budget neutrality policy under which we will apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as $1.0 - 5.1/100 = 0.949$) to the site neutral payment rate (or portion thereof in the blended payment rate context). This policy will be applied to cases paid at the IPPS comparable per diem amount and cases paid at 100 percent of the estimated cost.

E. Update to the IPPS Comparable/Equivalent Amounts to Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy for reflecting the changes to the Medicare IPPS DSH payment adjustment methodology provided for by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the 25-percent threshold payment adjustment policy at § 412.534 and § 412.536. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under the age of 65 who are uninsured, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating DSH payment amount that has historically been reflected in the LTCH PPS payments that is based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2017, as discussed in greater detail in section IV.D.3.d.(2) of the preamble of this final rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 55.36 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount was then used to determine the amount of uncompensated care payments that will be made to eligible IPPS hospitals in FY 2017. In other words, Medicare DSH payments prior to the amendments made by the Affordable Care Act will be adjusted to 41.52 percent (the product of 75 percent and 55.36 percent) and the

resulting amount will be used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2017, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 66.52 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of amendments made by the Affordable Care Act (that is, 25 percent + 41.52 percent = 66.52 percent).

In this final rule, for FY 2017, as we proposed, we are establishing that the calculation of the ''IPPS comparable amount'' under § 412.529 and the ''IPPS equivalent amount'' under new § 412.538 will include an applicable operating Medicare DSH payment amount that is equal to 66.52 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula but for the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, as we proposed, we used more recent data, to determine this factor in this final rule.

F. Computing the Adjusted LTCH PPS Federal Prospective Payments for FY 2017

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment for a case by the applicable LTCH PPS wage index (the FY 2017 values are shown in Tables 12A through 12B listed in section VI. of the Addendum of this final rule and are available via the Internet on the CMS Web site). The LTCH PPS standard Federal payment is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the FY 2017 factors are shown in the chart in section V.D. of this Addendum) in accordance with § 412.525(b). In this final rule, as we proposed, we are establishing an LTCH PPS standard Federal payment rate for FY 2017 of $42,476.41, as discussed in section V.A.2. of the Addendum to this final rule. We illustrate the methodology to adjust the LTCH PPS standard Federal payment rate for FY 2017 in the following example:

Example

During FY 2017, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in Chicago, Illinois (CBSA 16974). The FY 2017 LTCH PPS wage index value for CBSA 16974 is 1.0460 (obtained from Table 12A listed in section VI. of the Addendum of this final rule and available via the Internet on the CMS Web site). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a relative weight for FY 2017 of 0.9012 (obtained from Table 11 listed in section VI. of the Addendum of this final rule and available via the Internet on the CMS Web site). The LTCH submitted quality reporting data for FY 2017 in accordance with the LTCHQRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient case in FY 2017, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted FY 2017 LTCH PPS standard Federal payment rate ($42,476.41) by the labor-related share (66.5 percent) and the wage index value (1.0460). This wage-adjusted amount was then added to the nonlabor-related portion of the unadjusted LTCH PPS standard Federal payment rate (33.5 percent; adjusted for cost of living, if applicable) to determine the adjusted LTCH PPS standard Federal payment rate, which was then multiplied by the MS–LTC–DRG relative weight (0.9012) to calculate the total adjusted LTCH PPS standard Federal prospective payment for FY 2017 ($39,450.71). The table below illustrates the components of the calculations in this example.

LTCH PPS Standard Federal Prospective Payment Rate	$42,476.41
Labor-Related Share	× 0.665
Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $28,246.81
Wage Index (CBSA 16974)	× 1.0460
Wage-Adjusted Labor Share of LTCH PPS Standard Federal Payment Rate	= $29,546.16
Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($42,476.41x 0.335)	+ $14,229.60
Adjusted LTCH PPS Standard Federal Payment Amount	= $43,775.76
MS–LTC–DRG 189 Relative Weight	× 0.9012
Total Adjusted LTCH PPS Standard Federal Prospective Payment	= $39,450.71

VI. Tables Referenced in This Final Rule and Available Only Through the Internet on the CMS Web Site

This section lists the tables referred to throughout the preamble of this final rule and in this Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2016, for the FY 2017 rulemaking cycle, the IPPS and LTCH tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available only through the Internet. Specifically, all IPPS tables listed below, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E will be available only through the Internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules.

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49807), we streamlined and consolidated the wage index tables for FY 2016 and subsequent fiscal years.

As discussed in sections II.F.14., II.F.15.b., II.F.16., II.F.17.a., and II.F.19.a.1., a.3., and c.1. of the preamble of this final rule, we developed the following ICD–10–CM and ICD–10–PCS code tables for FY 2017: Table 6A—New Diagnosis Codes; Table 6B—New Procedure Codes; Table 6C—Invalid Diagnosis Codes; Table 6D—Invalid Procedure Codes; Table 6E—Revised Diagnosis Code Titles; Table 6F—Revised Procedure Code Titles; Table 6G.1—Secondary Diagnosis Order

Additions to the CC Exclusion List; Table 6G.2—Principal Diagnosis Order Additions to the CC Exclusion List; Table 6H.1—Secondary Diagnosis Order Deletions to the CC Exclusion List; Table 6H.2—Principal Diagnosis Order Deletions to the CC Exclusion List; Table 6I—Complete MCC List; Table 6I.1—Additions to the MCC List; Table 6I.2—Deletions to the MCC List; Table 6J.—Complete CC List; Table 6J.1—Additions to the CC List; Table 6J.2—Deletions to the CC List; Table 6K.—Complete List of CC Exclusions; Table 6L—Principal Diagnosis Is Its Own MCC List; Table 6M—Principal Diagnosis Is Its Own CC List; Table 6M.1—Additions to the Principal Diagnosis Is Its Own CC List; and Table 6P.—ICD–10–CM and ICD–10–PCS Codes for MCE and MS–DRG Changes. Table 6P contains multiple tables, 6P.1a through 6P.4k, that include the ICD–10–CM and ICD–10–PCS code lists and translations relating to specific MCE and MS–DRG changes. In addition, under the HAC Reduction Program established by section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. However, as discussed in section IV.I. of the preamble of this final rule, we are not providing the hospital-level data as a table associated with this final rule. The hospital-level data for the FY 2017 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

Finally, a hospital's Factor 3 is the proportion of the aggregate amount available for uncompensated care payments that a DSH eligible hospital will receive under section 3133 of the Affordable Care Act. For FY 2017, Factor 3 is the hospital's estimated number of Medicaid days and Medicare SSI days (or for a Puerto Rico hospital, a proxy for its Medicare SSI days) relative to the estimate of all DSH hospitals' Medicaid days and Medicare SSI days (or for Puerto Rico hospitals that are estimated to be eligible for DSH payments, a proxy for their Medicare SSI days). Table 18 associated with this final rule contains the FY 2017 uncompensated care payment Factor 3 for all hospitals and identifies whether or not a hospital is projected to receive DSH and, therefore, eligible to receive the additional payment for uncompensated care for FY 2017.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified below should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this FY 2017 final rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled, ''FY 2017 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download''.

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Hospital submitted quality data and is a meaningful EHR user (update = 1.65 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = −0.375 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 0.975 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −1.05 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,839.57	$1,677.06	$3,763.08	$1,643.65	$3,814.07	$1,665.92	$3,737.58	$1,632.51

TABLE 1B—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2017

Hospital submitted quality data and is a meaningful EHR user (update = 1.65 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = −0.375 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 0.975 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −1.05 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,420.31	$2,096.32	$3,352.17	$2,054.56	$3,397.59	$2,082.40	$3,329.46	$2,040.63

TABLE 1C—ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2017

Standardized amount	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National [1]	Not Applicable	Not Applicable	$3,420.31	$2,096.32

[1] For FY 2017, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D— CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2017

	Rate
National	$446.81

TABLE 1E—LTCH PPS STANDARD FEDERAL PAYMENT RATE—FY 2017

	Full Update (1.75 percent)	Reduced Update * (−0.25 percent)
Standard Federal Rate	$42,476.41	$41,641.49

* For LTCHs that fail to submit quality reporting data for FY 2017 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We have determined that this final rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the final changes for FY 2017 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this final rule, will result in an estimated $987 million increase in FY 2017 operating payments (or 0.9 percent change) and an estimated $66 million increase in FY 2017 capital payments (or 0.8 percent change). These changes are relative to payments made in FY 2016. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience

a decrease in payments by $363 million in FY 2017 relative to FY 2016.

Our operating impact estimate includes the −1.5 percent documentation and coding adjustment applied to the IPPS standardized amount, as discussed in section II.D. of the preamble of this final rule, which represents part of the recoupment required under section 631 of the ATRA. In addition, our operating payment impact estimate includes the 1.65 percent hospital update to the standardized amount (which includes the estimated 2.7 percent market basket update less 0.3 percentage point for the multifactor productivity adjustment and less 0.75 percentage point required under the Affordable Care Act). Our operating payment impact estimate also includes an adjustment of (1/0.998) to permanently remove the −0.2 percent reduction and a 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 as a result of the 2-midnight policy (we refer readers to section IV.P. of the preamble of this final rule for an explanation of these adjustments). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this final rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This final rule will affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this final rule.

B. Statement of Need

This final rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This final rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS.

C. Objectives of the IPPS

The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule will further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes, as well as statutory changes effective for FY 2017, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but, generally, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 32 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland All-Payer Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 5 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of July 2016, there were 3,330 IPPS acute care hospitals included in our analysis. This represents approximately 55 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,336 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, 11 cancer hospitals, and 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this final rule. The impact of the update and policy changes to the LTCH PPS for FY 2017 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of July 2016, there were 98 children's hospitals, 11 cancer hospitals, 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, and 18 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, 263 rehabilitation hospitals and 870 rehabilitation units, and approximately 430 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 513 psychiatric hospitals and 1,113 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this final rule. The impacts of the changes on LTCHs are discussed in section I.J. of this Appendix.

For children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2017 percentage increase in the IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. As discussed in section IV. of the preamble of the FY 2014 IPPS/LTCH PPS final rule, we rebased the IPPS operating market basket to a FY 2010 base year. Therefore, we are using the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for FY 2017 and subsequent fiscal years for children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs that are paid based on reasonable costs subject to the rate-of-increase limits. Consistent with current law, based on IHS Global Insight, Inc.'s second quarter 2016 forecast of the FY 2010-based IPPS market basket increase, we are estimating the FY 2017 update to be 2.7 percent (that is, the current estimate of the market basket rate-of-increase). However, the Affordable Care Act requires an adjustment for multifactor productivity (currently estimated to be 0.3 percentage point for FY 2017) and a 0.75 percentage point reduction to the market basket update, resulting in a 1.65 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section IV.B. of the preamble of this final rule. Children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the FY 2010-based IPPS operating market basket for FY 2017, estimated at 2.7 percent, without the reductions described previously under the Affordable Care Act.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect

is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this final rule, we are announcing final policy changes and final payment rate updates for the IPPS for FY 2017 for operating costs of acute care hospitals. The FY 2017 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2017 operating payments will increase by 0.9 percent compared to FY 2016. In addition to the applicable percentage increase, this amount reflects the FY 2017 recoupment adjustment for documentation and coding described in section II.D. of the preamble of this final rule of -1.5 percent to the IPPS national standardized amounts. This amount also reflects the adjustment of (1/0.998) to permanently remove the 0.2 percent reduction and the 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy, which are discussed in section IV.P. of the preamble of this final rule. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which will also affect overall payment changes.

We have prepared separate impact analyses of the changes to each system. This section deals with the changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available data to enable us to estimate the impacts on payments per case of certain changes in this final rule. However, there are other changes for which we do not have data available that will allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in payments per case presented in this section are taken from the FY 2015 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2015 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, or the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2017 are discussed in section I.I. of this Appendix.

We discuss the following changes:

- The effects of the application of the documentation and coding adjustment and the applicable percentage increase (including the market basket update, the multifactor productivity adjustment, and the applicable percentage reduction in accordance with the Affordable Care Act) to the standardized amount and hospital-specific rates.
- The effects of the adjustment of (1/0.998) to permanently remove the 0.2 percent reduction and the 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy, as discussed in section IV.P. of the preamble of this final rule.
- The effects of the changes to the relative weights and MS–DRG GROUPER.
- The effects of the changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2013, compared to the FY 2012 wage data, to calculate the FY 2017 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this final rule) that will be effective for FY 2017.
- The effects of the rural floor and imputed floor with the application of the national budget neutrality factor to the wage index.
- The effects of the last year of the 3-year transition for hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals that were deemed urban where the urban area became rural under the new OMB delineations.
- The effects of the frontier State wage index adjustment under the statutory provision that requires that hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. This provision is not budget neutral.
- The total estimated change in payments based on the FY 2017 policies relative to payments based on FY 2016 policies that include the applicable percentage increase of 1.65 percent (or 2.7 percent market basket update with a reduction of 0.3 percentage point for the multifactor productivity adjustment, and a 0.75 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the FY 2017 changes, our analysis begins with a FY 2016 baseline simulation model using: The FY 2016 applicable percentage increase of 1.7 percent and the documentation and coding recoupment adjustment of −0.8 percent to the Federal standardized amount; the FY 2016 MS–DRG GROUPER (Version 33); the FY 2016 CBSA designations for hospitals based on the new OMB definitions; the FY 2016 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, for FY 2017, we are establishing that hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act will receive an applicable percentage increase of 0.975 percent. At the time that this impact was prepared, 86 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2017 because they failed the quality data submission process or did not choose to participate but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the payment changes for FY 2017 using a reduced update for these hospitals.

For FY 2017, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user will be subject to a reduction of three-quarters of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, for FY 2017, we are establishing that hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act will receive an

applicable percentage increase of −0.375 percent. At the time that this impact analysis was prepared, 154 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2017 because they are identified as not meaningful EHR users that do submit quality information undersection 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the payment changes for FY 2017 using a reduced update for these 154 hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of −1.05 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user. At the time that this impact was prepared, 31 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2017 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2017 model incorporating all of the changes. This simulation allows us to isolate the effects of each change.

Our final comparison illustrates the percent change in payments per case from FY 2016 to FY 2017. Two factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are updating the standardized amounts for FY 2017 using an applicable percentage increase of 1.65 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.7 percent with a 0.3 percentage point reduction for the multifactor productivity adjustment and a 0.75 percentage point reduction as required under the Affordable Care Act. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users will receive an update of 0.975 percent. This update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users will receive an update of −0.375 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users will receive an update of −1.05 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs and MDHs also is equal to the applicable percentage increase, or 1.65 percent if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the changes in hospitals' payments per case from FY 2016 to FY 2017 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2016 that are no longer reclassified in FY 2017. Conversely, payments may increase for hospitals not reclassified in FY 2016 that are reclassified in FY 2017.

2. Analysis of Table I

Table I displays the results of our analysis of the changes for FY 2017. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,330 acute care hospitals included in the analysis.

The next four rows of Table I contain hospitals categorized according to their geographic location: All urban, which is further divided into large urban and other urban; and rural. There are 2,515 hospitals located in urban areas included in our analysis. Among these, there are 1,380 hospitals located in large urban areas (populations over 1 million), and 1,135 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 815 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The final groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2017 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban, large urban, other urban, and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 2,522, 1,372, 1,150, and 808, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 2,266 nonteaching hospitals in our analysis, 815 teaching hospitals with fewer than 100 residents, and 249 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next three rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs, RRCs, and MDHs). There were 189 RRCs, 324 SCHs, 148 MDHs, 126 hospitals that are both SCHs and RRCs, and 12 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total patient days. These data were taken from the FY 2013 or FY 2012 Medicare cost reports.

The next two groupings concern the geographic reclassification status of hospitals. The first grouping displays all urban hospitals that were reclassified by the MGCRB for FY 2017. The second grouping shows the MGCRB rural reclassifications.

TABLE I—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2017

	Number of hospitals [1]	Hospital rate update and documentation and coding adjustment (1) [2]	FY 2017 weights and DRG changes with application of recalibration budget neutrality (2) [3]	FY 2017 wage data under new CBSA designations with application of wage budget neutrality (3) [4]	FY 2017 MGCRB reclassifications (4) [5]	Rural and imputed floor with application of national rural and imputed floor budget neutrality (5) [6]	Application of the frontier wage index and out-migration adjustment (6) [7]	All FY 2017 changes (7) [8]
All Hospitals	3,330	1.0	0.0	0.0	0.0	0.0	0.1	0.9
By Geographic Location:								
Urban hospitals	2,515	0.9	0.0	0.0	−0.1	0.0	0.1	0.9
Large urban areas	1,380	0.9	0.1	0.0	−0.3	−0.1	0.0	0.8
Other urban areas	1,135	1.0	0.0	0.0	0.1	0.2	0.2	1.0
Rural hospitals	815	1.6	−0.4	0.1	1.4	−0.2	0.1	1.2
Bed Size (Urban):								
0–99 beds	659	0.9	−0.2	0.2	−0.5	0.1	0.2	0.9
100–199 beds	767	1.0	−0.1	0.0	0.0	0.3	0.2	0.7
200–299 beds	446	1.0	−0.1	−0.1	0.1	0.0	0.1	0.7

TABLE I—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2017—Continued

	Number of hospitals [1]	Hospital rate update and documentation and coding adjustment (1) [2]	FY 2017 weights and DRG changes with application of recalibration budget neutrality (2) [3]	FY 2017 wage data under new CBSA designations with application of wage budget neutrality (3) [4]	FY 2017 MGCRB reclassifications (4) [5]	Rural and imputed floor with application of national rural and imputed floor budget neutrality (5) [6]	Application of the frontier wage index and out-migration adjustment (6) [7]	All FY 2017 changes (7) [8]
300–499 beds	431	1.0	0.1	0.0	−0.2	0.0	0.2	0.9
500 or more beds	212	0.9	0.2	0.0	−0.2	−0.1	0.0	1.1
Bed Size (Rural):								
0–49 beds	317	1.5	−0.5	0.1	0.2	−0.2	0.3	1.0
50–99 beds	292	1.8	−0.6	0.1	0.8	−0.1	0.1	1.3
100–149 beds	120	1.6	−0.4	0.0	1.5	−0.2	0.2	1.0
150–199 beds	46	1.7	−0.2	0.2	1.7	−0.2	0.0	1.4
200 or more beds	40	1.6	−0.1	0.2	2.5	−0.2	0.0	1.5
Urban by Region:								
New England	116	0.8	0.0	−0.5	1.1	1.0	0.1	−0.4
Middle Atlantic	315	0.9	0.1	−0.1	0.8	−0.1	0.1	1.0
South Atlantic	407	1.0	0.0	−0.2	−0.5	−0.2	0.0	1.0
East North Central	390	0.9	0.0	−0.1	−0.2	−0.4	0.0	1.1
East South Central	147	1.0	0.0	−0.1	−0.4	−0.3	0.0	1.2
West North Central	163	1.1	0.1	−0.1	−0.8	−0.3	0.7	1.0
West South Central	385	0.9	0.0	0.2	−0.5	−0.3	0.0	1.3
Mountain	163	1.1	0.0	0.1	−0.4	0.0	0.2	0.9
Pacific	378	0.9	0.0	0.4	−0.4	1.0	0.1	0.6
Puerto Rico	51	0.9	0.1	−0.5	−1.0	0.1	0.1	0.3
Rural by Region:								
New England	21	1.3	−0.2	0.3	1.4	−0.3	0.2	1.7
Middle Atlantic	54	1.7	−0.4	0.1	0.8	−0.2	0.1	1.5
South Atlantic	128	1.7	−0.5	−0.1	2.3	−0.2	0.1	1.0
East North Central	115	1.7	−0.4	0.0	1.0	−0.1	0.1	1.2
East South Central	155	1.1	−0.3	0.4	2.2	−0.3	0.1	1.1
West North Central	98	2.2	−0.4	0.0	0.2	−0.1	0.3	1.5
West South Central	160	1.6	−0.4	0.4	1.3	−0.2	0.1	1.2
Mountain	60	1.7	−0.4	0.1	0.2	−0.1	0.2	1.3
Pacific	24	1.9	−0.4	−0.3	1.3	−0.1	0.0	1.3
By Payment Classification:								
Urban hospitals	2,522	0.9	0.0	0.0	−0.1	0.0	0.1	0.9
Large urban areas	1,372	0.9	0.1	0.0	−0.3	−0.1	0.0	0.8
Other urban areas	1,150	1.0	0.0	0.0	0.1	0.2	0.2	1.0
Rural areas	808	1.6	−0.4	0.1	1.4	−0.2	0.1	1.2
Teaching Status:								
Nonteaching	2,266	1.1	−0.2	0.0	0.1	0.1	0.1	0.8
Fewer than 100 residents	815	1.0	0.0	0.0	−0.1	0.0	0.2	0.9
100 or more residents	249	0.9	0.2	0.0	−0.1	−0.2	0.0	1.1
Urban DSH:								
Non-DSH	589	0.9	−0.1	−0.2	0.2	−0.1	0.2	0.8
100 or more beds	1,642	0.9	0.1	0.0	−0.2	0.0	0.1	0.9
Less than 100 beds	363	1.0	−0.3	0.0	−0.5	0.1	0.1	0.7
Rural DSH:								
SCH	240	2.0	−0.6	0.1	0.1	−0.1	0.0	1.4
RRC	325	1.7	−0.3	0.1	1.8	−0.2	0.1	1.3
100 or more beds	29	0.9	−0.4	0.1	2.9	−0.4	0.1	0.6
Less than 100 beds	142	0.8	−0.4	0.2	1.3	−0.4	0.7	0.3
Urban teaching and DSH:								
Both teaching and DSH	898	0.9	0.1	0.0	−0.2	−0.1	0.1	1.0
Teaching and no DSH	109	0.9	0.0	−0.1	1.1	−0.1	0.0	0.6
No teaching and DSH	1,107	1.0	−0.1	0.1	−0.1	0.2	0.1	0.7
No teaching and no DSH	408	1.0	−0.1	−0.2	−0.4	−0.1	0.2	0.9
Special Hospital Types:								
RRC	189	0.8	−0.1	0.1	1.9	0.1	0.5	1.3
SCH	324	2.1	−0.3	−0.1	0.0	0.0	0.0	1.7
MDH	148	1.7	−0.6	0.0	0.6	−0.1	0.1	1.3
SCH and RRC	126	2.2	−0.3	0.1	0.4	−0.1	0.0	1.8
MDH and RRC	12	2.1	−0.6	−0.1	1.3	−0.1	0.0	2.3
Type of Ownership:								
Voluntary	1,927	1.0	0.0	0.0	0.0	0.0	0.1	0.9
Proprietary	881	1.0	0.0	0.1	0.0	0.0	0.1	0.9
Government	522	1.0	0.0	−0.1	−0.2	0.0	0.1	0.9
Medicare Utilization as a Percent of Inpatient Days:								
0–25	523	0.8	0.1	0.1	−0.4	0.1	0.0	0.9
25–50	2,122	1.0	0.0	0.0	0.0	0.0	0.1	0.9
50–65	545	1.2	−0.2	−0.1	0.6	0.1	0.1	1.0
Over 65	89	1.3	−0.3	0.3	−0.4	0.3	0.2	1.1
FY 2017 Reclassifications by the Medicare Geographic Classification Review Board:								
All Reclassified Hospitals	792	1.1	−0.1	0.0	2.3	−0.1	0.0	1.0

TABLE I—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2017—Continued

	Number of hospitals [1]	Hospital rate update and documentation and coding adjustment (1) [2]	FY 2017 weights and DRG changes with application of recalibration budget neutrality (2) [3]	FY 2017 wage data under new CBSA designations with application of wage budget neutrality (3) [4]	FY 2017 MGCRB reclassifications (4) [5]	Rural and imputed floor with application of national rural and imputed floor budget neutrality (5) [6]	Application of the frontier wage index and out-migration adjustment (6) [7]	All FY 2017 changes (7) [8]
Non-Reclassified Hospitals	2,538	1.0	0.0	0.0	−0.8	0.0	0.1	0.9
Urban Hospitals Reclassified	533	1.0	0.0	−0.1	2.3	−0.1	0.0	0.9
Urban Nonreclassified Hospitals	1,938	0.9	0.1	0.0	−0.9	0.1	0.1	0.9
Rural Hospitals Reclassified Full Year	277	1.7	−0.3	0.1	2.2	−0.2	0.0	1.4
Rural Nonreclassified Hospitals Full Year	489	1.6	−0.4	0.2	−0.2	−0.2	0.3	1.1
All Section 401 Reclassified Hospitals:	69	1.7	−0.2	0.0	0.0	0.0	1.0	1.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	48	1.2	−0.4	0.1	3.1	−0.3	0.0	0.9

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2015, and hospital cost report data are from reporting periods beginning in FY 2012 and FY 2013.

[2] This column displays the payment impact of the hospital rate update and other adjustments, including the 1.65 percent adjustment to the national standardized amount and the hospital-specific rate (the estimated 2.7 percent market basket update reduced by 0.3 percentage point for the multifactor productivity adjustment and the 0.75 percentage point reduction under the Affordable Care Act), the -1.5 percent documentation and coding adjustment to the national standardized amount and the adjustment of (1/0.998) to permanently remove the -0.2 percent reduction, and the 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy.

[3] This column displays the payment impact of the changes to the Version 34 GROUPER, the changes to the relative weights and the recalibration of the MS–DRG weights based on FY 2015 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 0.999079 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the update to wage index data using FY 2013 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000209.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB) along with the effects of the continued implementation of the new OMB labor market area delineations on these reclassifications. The effects demonstrate the FY 2017 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2017. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.988224.

[6] This column displays the effects of the rural and imputed floor based on the continued implementation of the new OMB labor market area delineations. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The rural floor budget neutrality factor (which includes the imputed floor) applied to the wage index is 0.9932. This column also shows the effect of the 3-year transition for hospitals that were located in urban counties that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations, with a budget neutrality factor of 0.999997.

[7] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column shows the estimated change in payments from FY 2016 to FY 2017.

a. Effects of the Hospital Update, Documentation and Coding Adjustment, and Other Adjustments (Column 1)

As discussed in section IV.B. of the preamble of this final rule, this column includes the hospital update, including the 2.7 percent market basket update, the reduction of 0.3 percentage point for the multifactor productivity adjustment, and the 0.75 percentage point reduction in accordance with the Affordable Care Act. In addition, as discussed in section II.D. of the preamble of this final rule, this column includes the FY 2017 documentation and coding recoupment adjustment of −1.5 percent on the national standardized amount as part of the recoupment required by section 631 of the ATRA and, as discussed in section IV.P. of the preamble of this final rule, the adjustment of (1/0.998) to permanently remove the 0.2 percent reduction and the 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy. As a result, we are making a 1.0 percent update to the national standardized amount. This column also includes the 1.65 percent update to the hospital-specific rates which includes the 2.7 percent market basket update, the reduction of 0.3 percentage point for the multifactor productivity adjustment, and the 0.75 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the adjustment to the hospital-specific rates of (1/0.998) to permanently remove the −0.2 percent reduction and the 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016, which are discussed in section IV.P. of the preamble of this final rule. As a result, we are making a 2.45 percent update to the hospital-specific rates.

Overall, hospitals will experience a 1.0 percent increase in payments primarily due to the combined effects of the hospital update and the documentation and coding adjustment on the national standardized amount and the hospital update to the hospital-specific rate as well as the adjustment of (1/0.998) to permanently remove the −0.2 percent reduction and the 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy to both the national standardized amount and the hospital-specific rate. Hospitals that are paid under the hospital-specific rate will experience a 2.45 percent increase in payments; therefore, hospital categories containing hospitals paid under the hospital-specific rate will experience higher than average increases in payments.

b. Effects of the Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we are calculating a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this final rule, the FY 2017 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2017, the MS–DRGs are calculated using the FY 2015 MedPAR data grouped to the Version 34 (FY 2017) MS–DRGs. The methodology to calculate the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.G. of the preamble of this final rule.

The ''All Hospitals'' line in Column 2 indicates that changes due to the MS–DRGs

and relative weights will result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor of 0.999079 on to the standardized amount. Hospital categories that generally treat more surgical cases than medical cases will experience increases in their payments under the relative weights. Rural hospitals will experience a 0.4 percent decrease in payments because rural hospitals tend to treat fewer surgical cases than medical cases, while teaching hospitals with more than 100 residents will experience an increase in payments by 0.2 percent as those hospitals treat more surgical cases than medical cases.

c. Effects of the Wage Index Changes (Column 3)

Column 3 shows the impact of updated wage data using FY 2013 cost report data, with the application of the wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2017 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13–01), as updated in OMB Bulletin No. 15–01. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index and to section III.A.2. of the preamble of this final rule for a discussion of OMB Bulletin No. 15–01.)

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the wage index for acute care hospitals for FY 2017 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013. The estimated impact of the updated wage data using the FY 2013 cost report data and the OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other payment parameters constant in this simulation. That is, Column 3 shows the percentage change in payments when going from a model using the FY 2016 wage index, based on FY 2012 wage data, the labor-related share of 69.6 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the FY 2017 pre-reclassification wage index based on FY 2013 wage data with the labor-related share of 69.6 percent, under the OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters such as use of the Version 34 MS–DRG GROUPER constant. The FY 2017 occupational mix adjustment is based on the CY 2013 occupational mix survey.

In addition, the column shows the impact of the application of the wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2017, we are calculating the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share of 69.6 percent are budget neutral without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The FY 2017 wage budget neutrality factor is 1.000209, and the overall payment change is 0.0 percent.

Column 3 shows the impacts of updating the wage data using FY 2013 cost reports. Overall, the new wage data and the labor-related share, combined with the wage budget neutrality adjustment, will lead to no change for all hospitals as shown in Column 3.

In looking at the wage data itself, the national average hourly wage increased 1.02 percent compared to FY 2016. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the 1.02 percent increase in the national average hourly wage. Of the 3,309 hospitals with wage data for both FYs 2016 and 2017, 1,539 or 46.5 percent would experience an average hourly wage increase of 1.02 percent or more.

The following chart compares the shifts in wage index values for hospitals due to changes in the average hourly wage data for FY 2017 relative to FY 2016. Among urban hospitals, 4 will experience a decrease of 10 percent or more, and 14 urban hospitals will experience an increase of 10 percent or more. One hundred and nine urban hospitals will experience an increase or decrease of at least 5 percent or more but less than 10 percent. Among rural hospitals, 4 will experience an increase of at least 5 percent but less than 10 percent, but no rural hospitals will experience a decrease of greater than or equal to 5 percent but less than 10 percent. No rural hospital will experience increases of 10 percent or more, and no rural hospitals will experience decreases of 10 percent or more. However, 777 rural hospitals will experience increases or decreases of less than 5 percent, while 2,378 urban hospitals will experience increases or decreases of less than 5 percent. No urban hospitals but 23 rural hospitals will not experience any change to their wage index. These figures reflect changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural and imputed floors, the out-migration adjustment, and other wage index exceptions and adjustments. (We refer readers to sections III.G. through III.L. of the preamble of this final rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this final rule, which are available via the Internet on the CMS Web site) is used to adjust the labor-related share of a hospital's standardized amount, either 69.6 percent or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller change than will occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of changes in the area wage index values for urban and rural hospitals.

FY 2017 percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Increase 10 percent or more	14	0
Increase greater than or equal to 5 percent and less than 10 percent	70	4
Increase or decrease less than 5 percent	2,378	777
Decrease greater than or equal to 5 percent and less than 10 percent	39	0
Decrease 10 percent or more	4	0
Unchanged	0	23

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located). The changes in Column 4 reflect the per case payment impact of moving from this baseline to a

simulation incorporating the MGCRB decisions for FY 2017.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS Administrator. Further, hospitals have 45 days from publication of the IPPS proposed rule in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year.

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we are applying an adjustment of 0.988224 to ensure that the effects of the reclassifications under section 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this final rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification will increase payments to rural hospitals by an average of 1.4 percent. By region, all the rural hospital categories will experience increases in payments due to MGCRB reclassifications.

New Table 2 listed in section VI. of the Addendum to this final rule and available via the Internet on the CMS Web site reflects the reclassifications for FY 2017.

e. Effects of the Rural Floor and Imputed Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FYs 2011, 2012, 2013, 2014, 2015, 2016 IPPS/LTCH PPS final rules, and this final rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. We apply a uniform budget neutrality adjustment to the wage index. The imputed floor, which is also included in the calculation of the budget neutrality adjustment to the wage index, was extended in FY 2012 for 2 additional years and in FY 2014 and FY 2015 for 1 additional year. Prior to FY 2013, only urban hospitals in New Jersey received the imputed floor. As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53369), we established an alternative temporary methodology for the imputed floor, which resulted in an imputed floor for Rhode Island for FY 2013. For FY 2014 and FY 2015, we extended the imputed rural floor, as calculated under the original methodology and the alternative methodology. Due to the adoption of the new OMB labor market area delineations in FY 2015, the State of Delaware also became an all-urban State and thus eligible for an imputed floor. For FY 2016, we extended the imputed floor for 1 year, as calculated under the original methodology and the alternative methodology, through September 30, 2016. For FY 2017, we are extending the imputed rural floor for 1 year, as calculated under the original methodology and the alternative methodology, through September 20, 2017. As a result, New Jersey, Rhode Island, and Delaware will be able to receive an imputed floor through September 30, 2017. In New Jersey, 18 out of 64 hospitals will receive the imputed floor for FY 2017, 10 out of 11 hospitals in Rhode Island, and 2 out of 6 hospitals in Delaware.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally, and the imputed floor is part of the rural floor budget neutrality factor applied to the wage index nationally. We have calculated a FY 2017 rural floor budget neutrality factor to be applied to the wage index of 0.9930, which will reduce wage indexes by 0.7 percent.

Column 5 shows the projected impact of the rural floor and imputed floor with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the post-reclassification FY 2017 wage index of providers before the rural floor and imputed floor adjustment and the post-reclassification FY 2017 wage index of providers with the rural floor and imputed floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural and imputed floors. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) will experience a decrease in payments due to the budget neutrality adjustment that is applied nationally to their wage index.

We estimate that 397 hospitals will receive the rural and imputed floors in FY 2017. All IPPS hospitals in our model will have their wage index reduced by the rural floor budget neutrality adjustment of 0.9930 (or 0.7 percent). We project that, in aggregate, rural hospitals will experience a 0.2 percent decrease in payments as a result of the application of the rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in urban areas will experience no change in payments because increases in payments by hospitals benefitting from the rural floor offset decreases in payments by nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region will experience a 1.0 percent increase in payments primarily due to the application of the rural floor in Massachusetts and the imputed floor in Rhode Island. Fifteen urban providers in Massachusetts are expected to receive the rural floor wage index value, including the rural floor budget neutrality adjustment, increasing payments overall to Massachusetts by an estimated $24 million. We estimate that Massachusetts hospitals will receive approximately a 0.7 percent increase in IPPS payments due to the application of the rural floor in FY 2017.

Urban Puerto Rico hospitals are expected to experience a 0.1 percent increase in payments as a result of the application of the rural floor.

There are 18 hospitals out of the 64 hospitals in New Jersey that will benefit from the extension of the imputed floor and will receive the imputed floor wage index value under the OMB labor market area delineations. Overall, New Jersey will receive a net increase of $10 million in payments taking into account the 18 hospitals that will benefit from the imputed floor and the application of the national rural floor and imputed floor budget neutrality adjustment to all hospitals in the state. There are 10 hospitals out of the 11 hospitals in Rhode Island that will benefit from the extension of the imputed floor and will receive the imputed floor wage index value. Overall, Rhode Island will receive a net increase of $17 million in payments taking into account the 10 hospitals that will benefit from the imputed floor and the application of the national rural floor and imputed floor budget neutrality adjustment to all hospitals in the state. There are 2 hospitals out of the 6 hospitals in Delaware that will benefit from the extension of the imputed floor and will receive the imputed floor wage index value. Overall, Delaware will see no net increase in payments (to the nearest million) taking into account the 2 hospitals that will benefit from the imputed floor and the application of the national rural floor and imputed floor budget neutrality adjustment to all hospitals in the state.

Column 5 also shows the projected effects of the last year of the 3-year hold harmless provision for hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations. As discussed in section III.G.2. of the preamble of this final rule, under this transition, hospitals that were located in an urban county that became rural under the new OMB delineations were generally assigned the urban wage index value of the CBSA in which they were physically located in FY 2014 for a period of 3 fiscal years (that is, FYs 2015, 2016, and 2017). In addition, as discussed in section III.G.3. of the preamble of this final rule, under this transition, hospitals that were deemed urban where the urban area became rural under the new OMB delineations were generally assigned the area wage index value of hospitals reclassified to the urban CBSA (that is, the attaching wage index, if applicable) to which they were designated in FY 2014. For FY 2017, we are applying the 3-year transition wage index adjustments in a budget neutral manner, with a budget neutrality factor of 0.999994.

In response to a public comment addressed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), we are providing the payment impact of the rural floor and imputed floor with budget neutrality at the State level. Column 1 of the following table displays the number of IPPS hospitals located in each State. Column 2 displays the number of hospitals in each State that will receive the rural floor or imputed floor wage index for FY 2017. Column 3 displays the percentage of total payments each State will receive or contribute to fund the rural floor and imputed floor with national budget neutrality. The column compares the post-

reclassification FY 2017 wage index of providers before the rural floor and imputed floor adjustment and the post-reclassification FY 2017 wage index of providers with the rural floor and imputed floor adjustment. Column 4 displays the estimated payment amount that each State will gain or lose due to the application of the rural floor and imputed floor with national budget neutrality.

FY 2017 IPPS Estimated Payments Due to Rural and Imputed Floor With National Budget Neutrality

State	Number of hospitals (1)	Number of hospitals that will receive the rural floor or imputed floor (2)	Percent change in payments due to application of rural floor and imputed floor with budget neutrality (3)	Difference (in $ millions) (4)
Alabama	83	6	−0.3	−5
Alaska	6	4	2.1	4
Arizona	57	7	−0.1	−2
Arkansas	44	0	−0.3	−3
California	301	186	1.3	139
Colorado	48	3	0.3	3
Connecticut	31	8	0.3	5
Delaware	6	2	0	0
Washington, DC	7	0	−0.4	−2
Florida	171	16	−0.2	−14
Georgia	105	0	−0.3	−8
Hawaii	12	0	−0.3	−1
Idaho	14	0	−0.2	−1
Illinois	126	3	−0.4	−16
Indiana	89	0	−0.4	−9
Iowa	35	0	−0.3	−3
Kansas	53	0	−0.3	−3
Kentucky	65	0	−0.3	−5
Louisiana	95	2	−0.3	−4
Maine	18	0	−0.3	−2
Massachusetts	58	15	0.7	24
Michigan	95	0	−0.4	−15
Minnesota	49	0	−0.3	−5
Mississippi	62	0	−0.3	−3
Missouri	74	2	−0.3	−7
Montana	12	4	0.3	1
Nebraska	26	0	−0.3	−2
Nevada	24	3	−0.2	−1
New Hampshire	13	9	2.3	12
New Jersey	64	18	0.3	10
New Mexico	25	0	−0.2	−1
New York	154	21	−0.2	−15
North Carolina	84	1	−0.3	−10
North Dakota	6	1	−0.2	−1
Ohio	130	10	−0.3	−11
Oklahoma	86	2	−0.3	−4
Oregon	34	2	−0.3	−3
Pennsylvania	151	5	−0.4	−17
Puerto Rico	51	12	0.1	0
Rhode Island	11	10	4.5	17
South Carolina	57	5	−0.1	−1
South Dakota	18	0	−0.2	−1
Tennessee	92	20	−0.2	−6
Texas	320	3	−0.3	−22
Utah	33	1	−0.3	−1
Vermont	6	0	−0.2	0
Virginia	76	1	−0.3	−7
Washington	49	6	0	0
West Virginia	29	3	−0.1	−1
Wisconsin	65	6	−0.2	−4
Wyoming	10	0	−0.1	0

f. Effects of the Application of the Frontier State Wage Index and Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage-index of 1.00 for all hospitals located in ''frontier States,'' and the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. These two wage index provisions are not budget neutral and increase payments overall by 0.1 percent compared to the provisions not being in effect.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States and 50 hospitals located in those States will receive a frontier wage index of 1.0000. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $58 million. Rural and urban hospitals located in the West North Central region will experience an increase in payments by 0.3 and 0.7 percent, respectively, because many of the hospitals located in this region are frontier State hospitals.

In addition, section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 277 providers that will receive the out-migration wage adjustment in FY 2017. Rural hospitals generally qualify for the adjustment, resulting in a 0.1 percent increase in payments. This provision appears to benefit section 401 hospitals and RRCs in that they will experience a 1.0 percent and 0.5 percent increase in payments, respectively. This out-migration wage adjustment also is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase will be approximately $30 million.

g. Effects of All FY 2017 Changes (Column 7)

Column 7 shows our estimate of the changes in payments per discharge from FY 2016 and FY 2017, resulting from all changes reflected in this final rule for FY 2017. It includes combined effects of the year to year change of the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 0.9 percent for FY 2017 relative to FY 2016 and for this row is primarily driven by the changes reflected in Column 1. Column 7 includes the annual hospital update of 1.65 percent to the national standardized amount. This annual hospital update includes the 2.7 percent market basket update, the reduction of 0.3 percentage point for the multifactor productivity adjustment, and the 0.75 percentage point reduction under section 3401 of the Affordable Care Act. As discussed in section II.D. of the preamble of this final rule, this column also includes the FY 2017 documentation and coding recoupment adjustment of −1.5 percent on the national standardized amount as part of the recoupment required under section 631 of the ATRA. In addition, this column includes the adjustment of (1/0.998) to permanently remove the 0.2 percent reduction, and the 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy, which are discussed in section IV.P. of the preamble of this final rule. Hospitals paid under the hospital-specific rate will receive a 1.65 percent hospital update in addition to the adjustment of (1/0.998) to permanently remove the 0.2 percent reduction, and the 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 previously described. As described in Column 1, the annual hospital update with the documentation and coding recoupment adjustment for hospitals paid under the national standardized amount, the adjustment of (1/0.998) to permanently remove the 0.2 percent reduction and the 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 for hospitals paid under the national standardized amount and hospitals paid under the hospital-specific rates, which are discussed in section IV.P. of the preamble of this final rule, combined with the annual hospital update for hospitals paid under the hospital-specific rates will result in a 1.0 percent increase in payments in FY 2017 relative to FY 2016. There are also interactive effects among the various factors comprising the payment system that we are not able to isolate which contribute to our estimate of the changes in payments per discharge from FY 2016 and FY 2017 in Column 7.

Overall payments to hospitals paid under the IPPS due to the applicable percentage increase and changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 0.9 percent for FY 2017. Hospitals in urban areas will experience a 0.9 percent increase in payments per discharge in FY 2017 compared to FY 2016. Hospital payments per discharge in rural areas are estimated to increase by 1.2 percent in FY 2017.

3. Impact Analysis of Table II

Table II presents the projected impact of the changes for FY 2017 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2016 with the estimated average payments per discharge for FY 2017, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 7 of Table I.

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2017 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments per discharge]

	Number of hospitals	Estimated average FY 2016 payment per discharge	Estimated average FY 2017 payment per discharge	FY 2017 changes
	(1)	(2)	(3)	(4)
All Hospitals	3,330	11,542	11,648	0.9
By Geographic Location:				
Urban hospitals	2,515	11,890	11,996	0.9
Large urban areas	1,380	12,698	12,805	0.8
Other urban areas	1,135	10,922	11,028	1.0
Rural hospitals	815	8,602	8,709	1.2
Bed Size (Urban):				
0–99 beds	659	9,392	9,476	0.9

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2017 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals	Estimated average FY 2016 payment per discharge	Estimated average FY 2017 payment per discharge	FY 2017 changes
	(1)	(2)	(3)	(4)
100–199 beds	767	10,050	10,118	0.7
200–299 beds	446	10,757	10,836	0.7
300–499 beds	431	12,092	12,200	0.9
500 or more beds	212	14,613	14,775	1.1
Bed Size (Rural):				
0–49 beds	317	7,208	7,281	1.0
50–99 beds	292	8,192	8,295	1.3
100–149 beds	120	8,434	8,518	1.0
150–199 beds	46	9,243	9,370	1.4
200 or more beds	40	10,171	10,324	1.5
Urban by Region:				
New England	116	12,957	12,909	-0.4
Middle Atlantic	315	13,471	13,604	1.0
South Atlantic	407	10,498	10,602	1.0
East North Central	390	11,190	11,312	1.1
East South Central	147	10,042	10,167	1.2
West North Central	163	11,578	11,698	1.0
West South Central	385	10,693	10,827	1.3
Mountain	163	12,279	12,388	0.9
Pacific	378	15,372	15,464	0.6
Puerto Rico	51	8,491	8,515	0.3
Rural by Region:				
New England	21	11,818	12,015	1.7
Middle Atlantic	54	8,655	8,781	1.5
South Atlantic	128	8,043	8,125	1.0
East North Central	115	8,918	9,025	1.2
East South Central	155	7,639	7,721	1.1
West North Central	98	9,420	9,561	1.5
West South Central	160	7,243	7,332	1.2
Mountain	60	10,100	10,229	1.3
Pacific	24	12,045	12,200	1.3
By Payment Classification:				
Urban hospitals	2,522	11,886	11,993	0.9
Large urban areas	1,372	12,695	12,801	0.8
Other urban areas	1,150	10,928	11,035	1.0
Rural areas	808	8,602	8,708	1.2
Teaching Status:				
Nonteaching	2,266	9,600	9,677	0.8
Fewer than 100 residents	815	11,133	11,233	0.9
100 or more residents	249	16,764	16,952	1.1
Urban DSH:				
Non-DSH	589	10,055	10,132	0.8
100 or more beds	1,642	12,247	12,360	0.9
Less than 100 beds	363	8,853	8,916	0.7
Rural DSH:				
SCH	240	8,584	8,703	1.4
RRC	325	9,006	9,125	1.3
100 or more beds	29	7,018	7,059	0.6
Less than 100 beds	142	6,823	6,843	0.3
Urban teaching and DSH:				
Both teaching and DSH	898	13,344	13,477	1.0
Teaching and no DSH	109	11,361	11,424	0.6
No teaching and DSH	1,107	10,047	10,119	0.7
No teaching and no DSH	408	9,455	9,536	0.9
Special Hospital Types:				
RRC	189	9,709	9,831	1.3
SCH	324	10,344	10,517	1.7
MDH	148	7,321	7,417	1.3
SCH and RRC	126	10,767	10,956	1.8
MDH and RRC	12	8,822	9,022	2.3
Type of Ownership:				
Voluntary	1,927	11,719	11,829	0.9
Proprietary	881	10,130	10,216	0.9
Government	522	12,485	12,600	0.9

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2017 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2016 payment per discharge (2)	Estimated average FY 2017 payment per discharge (3)	FY 2017 changes (4)
Medicare Utilization as a Percent of Inpatient Days:				
0–25	523	14,996	15,135	0.9
25–50	2,122	11,460	11,565	0.9
50–65	545	9,343	9,435	1.0
Over 65	89	6,948	7,023	1.1
FY 2017 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	792	11,395	11,507	1.0
Non-Reclassified Hospitals	2,538	11,596	11,701	0.9
Urban Hospitals Reclassified	533	12,001	12,113	0.9
Urban Nonreclassified Hospitals	1,938	11,856	11,959	0.9
Rural Hospitals Reclassified Full Year	277	8,984	9,104	1.4
Rural Nonreclassified Hospitals Full Year	489	8,173	8,266	1.1
All Section 401 Reclassified Hospitals	69	11,084	11,269	1.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	48	7,889	7,958	0.9

H. Effects of Other Policy Changes

In addition to those policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are making various other changes in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes. Our estimates of the likely impacts associated with these other changes are discussed in this section.

1. Effects of Policy Relating to New Medical Service and Technology Add-On Payments

In section II.I. of the preamble to this final rule, we discuss seven applications (MAGEC® Spinal Bracing and Distraction System (MAGEC® Spine), MIRODERM Biologic Wound Matrix (MIRODERM), Idarucizumab, Titan Spine (Titan Spine Endoskeleton® nanoLOCK™ Interbody Device), Defitelio® (Defibrotide), GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE), Vistogard™ (Uridine Triacetate)) for add-on payments for new medical services and technologies for FY 2017, as well as the status of the new technologies that were approved to receive new technology add-on payments in FY 2016. We note that two of the applications (Andexanet Alfa and EDWARDS INTUITY Elite™ Valve System) discussed in the proposed rule did not receive FDA approval by July 1, 2016 in accordance with the regulations under § 412.87(c), and, therefore, are ineligible for consideration for new technology add-on payments for FY 2017.

As explained in the preamble to this final rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.I.4. of the preamble of this final rule, we are approving five of the seven applications (MAGEC® Spine, Idarucizumab, Defitelio®, GORE® EXCLUDER® IBE and Vistogard™) for new technology add-on payments for FY 2017. As we proposed, in this final rule, we also are continuing to make new technology add-on payments in FY 2017 for CardioMEMS™ HF (Heart Failure) Monitoring System, Blinatumomab (BLINCYTO™), and the LUTONIX® Drug Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) and IN.PACT™ Admiral™ Pacliaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter (because all of these technologies are still within the 3-year anniversary of the product's entry onto the market). We note that new technology add-on payments per case are limited to the lesser of: (1) 50 Percent of the costs of the new technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case. Because it is difficult to predict the actual new technology add-on payment for each case, our estimates below are based on the increase in new technology add-on payments for FY 2017 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. Based on the applicant's estimate for FY 2015, we currently estimate that new technology add-on payments for the CardioMEMS™ HF Monitoring System will increase overall FY 2017 payments by $11,315,625. Based on the applicant's estimate for FY 2016, we currently estimate that new technology add-on payments for BLINCYTO™ will increase overall FY 2017 payments by $4,593,034 (maximum add-on payment of $27,017.85 * 170 patients). Based on the weighted cost average for FY 2016 described in the FY 2016 IPPS/LTCH final rule (80 FR 49469 through 49470), we currently estimate that new technology add-on payments for LUTONIX® DCB PTA and IN.PACT™Admiral™ Pacliaxel Coated PTA Balloon Catheter will increase overall FY 2017 payments by $36,120,735 (maximum add-on payment of $1,035.72 * 8,875 patients for LUTONIX® DCB PTA Balloon Catheter; maximum add-on payment of $1,035.72 * 26,000 patients for IN.PACT™Admiral™ Pacliaxel Coated PTA Balloon Catheter). Based on the applicant's estimate for FY 2017, we currently estimate that new technology add-on payments for MAGEC® Spine will increase overall FY 2017 payments by $267,750 (maximum add-on payment of $15,750 * 17 patients). Based on the applicant's estimate for FY 2017, we currently estimate that new technology add-on payments for Idarucizumab will increase overall FY 2017 payments by $14,766,500 (maximum add-on payment of $1,750 * 8,438 patients). Based on the applicant's estimate for FY 2017, we currently estimate that new technology add-on payments for Defitelio® will increase overall FY 2017 payments by $5,161,200 (maximum add-on payment of $75,900 * 68 patients). Based on the applicant's estimate for FY 2017, we currently estimate that new technology add-on payments for the GORE® EXCLUDER® IBE will increase overall FY 2017 payments by $5,685,750 (maximum add-on payment of $5,250 * 1,083 patients). Based on the applicant's estimate for FY 2017, we currently estimate that new technology add-on payments for Vistogard™ will increase overall FY 2017 payments by $2,812,500 (maximum add-on payment of $37,500 * 75 patients).

2. Effects of the Changes to Medicare DSH Payments for FY 2017

As discussed in section IV.F. of the preamble of this final rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the former statutory formula for Medicare DSH payments. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of individuals under age 65 who are uninsured and additional statutory adjustments (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's uncompensated care relative to the uncompensated care for all hospitals eligible for Medicare DSH payments (Factor 3). For FY 2017, we are continuing to use low-income insured patient days as a proxy for uncompensated care, and the uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's low-income insured patient days (sum of Medicaid patient days and Medicare SSI patient days) relative to the low-income insured patient days for all hospitals eligible for DSH payments. The reduction to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this FY 2017 IPPS/LTCH PPS final rule, we are establishing the amount to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2017 is $5,977,483,146.86, or 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 55.36 percent. For FY 2016, the amount available to be distributed for uncompensated care was $6,406,145,534.04, or 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 63.69 percent. To calculate Factor 3 for FY 2017, we are using an average of data computed using Medicaid days from hospitals' 2011, 2012, and 2013 cost reports, Medicaid days from 2011 and 2012 cost report data submitted to CMS by IHS hospitals, and SSI days from the FY 2012, FY 2013, and FY 2014 SSI ratios. That is, for each hospital we are calculating an individual Factor 3 for cost reporting periods beginning during FYs 2011, 2012, and 2013, adding the individual amounts, and dividing the sum by three in order to calculate an average Factor 3 for the hospital.

The final FY 2017 policy of using data on low-income insured days from 3 years of cost reports to determine Factor 3, as described earlier, is in contrast to the methodology used in FY 2016, when we used Medicaid days from the more recent of a hospital's full year 2012 *or* 2011 cost report from the March 2015 update of the HCRIS database, Medicaid days from 2012 cost report data submitted to CMS by IHS hospitals, and SSI days from the FY 2013 SSI ratios to calculate Factor 3. In addition, as explained in section IV.F. of the preamble of this final rule, we are making two additional modifications to the Factor 3 methodology: (1) To create proxy Medicare SSI values for Puerto Rico hospitals and (2) to include all hospitals' cost reports that begin during FYs 2011, 2012, and 2013, even in the instance where a hospital has more than one cost report beginning during a given fiscal year. Because residents of Puerto Rico are not eligible for SSI benefits, we are imputing a Medicare SSI value for each Puerto Rico hospital equal to 14 percent of its Medicaid days. The final FY 2017 uncompensated care payment methodology is discussed in more detail in section IV.F. of the preamble of this final rule.

To estimate the impact of the combined effect of reductions in the percent of individuals under age 65 who are uninsured and additional statutory adjustments (Factor 2) and changes in Medicaid and SSI patient days (components of Factor 3) on the calculation of Medicare DSH payments, including both empirically justified Medicare DSH payments and uncompensated care payments, we compared total DSH payments estimated in the FY 2016 IPPS/LTCH PPS final rule to total DSH payments estimated in this FY 2017 IPPS/LTCH PPS final rule. For FY 2016, for each hospital, we calculated the sum of: (1) 25 percent of the estimated amount of what would have been paid as Medicare DSH in FY 2016 in the absence of section 3133 of the Affordable Care Act; and (2) 75 percent of the estimated amount of what would have been paid as Medicare DSH payments in the absence of section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 63.69 percent and multiplied by a Factor 3 as stated in the FY 2016 IPPS/LTCH PPS final rule. For FY 2017, we calculated the sum of: (1) 25 percent of the estimated amount of what would be paid as Medicare DSH payments in FY 2017 absent section 3133 of the Affordable Care Act; and (2) 75 percent of the estimated amount of what would have been paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 55.36 percent and multiplied by a Factor 3 as previously stated.

Our analysis included 2,426 hospitals that are projected to be eligible for DSH in FY 2017. It did not include hospitals that terminated their participation from the Medicare program as of July 1, 2016, Maryland hospitals, and SCHs that are expected to be paid based on their hospital-specific rates. In addition, low-income insured days from merged or acquired hospitals were combined into the surviving hospital's CCN, and the nonsurviving CCN was excluded from the analysis. In contrast to FY 2016, hospitals participating in the Rural Community Hospital Demonstration program, which is scheduled to end in FY 2017, are included in the analysis if projected to be eligible for DSH payments during FY 2017. The estimated impact of the changes in Factors 1, 2, and 3 across all hospitals projected to be eligible for DSH payments in FY 2017, by hospital characteristic, is presented in the following table.

MODELED DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR ESTIMATED FY 2017 DSHS BY HOSPITAL TYPE: MODEL DSH $ (IN MILLIONS) FROM FY 2016 TO FY 2017

	Number of estimated DSHs (FY 2017)	FY 2016 final rule estimated DSH $* (in millions)	FY 2017 Final rule estimated DSH $* (in millions)	Dollar difference: FY 2017–FY 2016 (in millions)	Percent change**
	(1)	(2)	(3)	(4)	(5)
Total	2,426	$9,767	$9,549	−$217	−2.2%
By Geographic Location:					
Urban Hospitals	1,927	9,294	9,1067	−187	−2.0
Large Urban Areas	1,050	5,885	5,766	−120	−2.0
Other Urban Areas	877	3,408	3,341	−67	−2.0
Rural Hospitals	499	473	443	−30	−6.4
Bed Size (Urban):					
0 to 99 Beds	340	189	185	−4	−2.2
100 to 249 Beds	839	2,211	2,154	−57	−2.6
250+ Beds	748	6,894	6,768	−126	−1.8
Bed Size (Rural):					
0 to 99 Beds	369	206	190	−16	−7.8

MODELED DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR ESTIMATED FY 2017 DSHS BY HOSPITAL TYPE: MODEL DSH $ (IN MILLIONS) FROM FY 2016 TO FY 2017—Continued

	Number of estimated DSHs (FY 2017) (1)	FY 2016 final rule estimated DSH $* (in millions) (2)	FY 2017 Final rule estimated DSH $* (in millions) (3)	Dollar difference: FY 2017–FY 2016 (in millions) (4)	Percent change** (5)
100 to 249 Beds	117	211	200	−11	−5.2
250+ Beds	13	56	53	−3	−5.9
Urban by Region:					
East North Central	322	1,273	1,252	−22	−1.7
East South Central	130	574	566	−8	−1.3
Middle Atlantic	232	1,614	1,570	−44	−2.7
Mountain	125	448	448	0	−0.0
New England	90	394	385	−9	−2.3
Pacific	314	1,459	1,448	−10	−0.7
Puerto Rico	42	104	116	12	11.4
South Atlantic	314	1,777	1,721	−55	−3.2
West North Central	104	451	440	−11	−2.5
West South Central	254	1,200	1,161	−39	−3.2
Rural by Region:					
East North Central	64	49	45	−4	−8.3
East South Central	142	149	141	−8	−5.2
Middle Atlantic	27	34	32	−2	−7.0
Mountain	21	16	15	0	−0.2
New England	11	15	16	1	7.2
Pacific	7	9	7	−3	−27.4
South Atlantic	86	98	92	−6	−6.4
West North Central	31	20	19	−1	−6.3
West South Central	110	83	76	−7	−8.3
By Payment Classification:					
Urban Hospitals	1,892	9,243	9,056	−187	−2.0
Large Urban Areas	1,048	5,884	5,764	−120	−2.0
Other Urban Areas	844	3,359	3,292	−68	−2.0
Rural Hospitals	534	523	493	−30	−5.8
Teaching Status:					
Nonteaching	1,550	3,117	3,050	−67	−2.1
Fewer than 100 residents	638	3,213	3,132	−80	−2.5
100 or more residents	238	3,437	3,367	−71	−2.1
Type of Ownership:					
Voluntary	1,404	6,044	5,909	−136	−2.2
Proprietary	546	1,672	1,631	−41	−2.4
Government	474	2,023	1,984	−39	−1.9
Unknown	2	27	25	−2	−6.1
Medicare Utilization Percent:					
0 to 25	429	3,013	2,975	−38	−1.3
25 to 50	1,617	6,356	6,189	−167	−2.6
50 to 65	318	385	374	−11	−2.9
Greater than 65	51	12	11	−1	−8.2

Source: Dobson | DaVanzo analysis of 2011–2013 Hospital Cost Reports.

*Dollar DSH calculated by [0.25 * estimated section 1886(d)(5)(F) payments] + [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, DSH payments are estimated to be $9,767 million in FY 2016 and $9,549 million in FY 2017.

**Percentage change is determined as the difference between Medicare DSH payments modeled for the FY 2017 IPPS/LTCH PPS final rule (column 3) and Medicare DSH payments modeled for the FY 2016 IPPS/LTCH final rule (column 2) divided by Medicare DSH payments modeled for the FY 2016 final rule (column 2) 1 times 100 percent.

Changes in projected FY 2017 DSH payments from DSH payments in FY 2016 are primarily driven by three factors: (1) An increase in Factor 1 from $10.058 billion to $10.798 billion; (2) a reduction in the percent of uninsured (Factor 2) from 63.69 percent to 55.36 percent; and (3) a revised proxy methodology for calculating Factor 3 values. The impact analysis found that, across all projected DSH eligible hospitals, FY 2017 DSH payments are estimated at approximately $14.397 billion, or an increase of approximately 7.4 percent from FY 2016 DSH payments (approximately $13.411 billion). Although Factor 1 increased substantially, the reduction in Factor 2 offsets this and results in a net decrease in the amount available to be distributed in uncompensated care payments.

As seen in the above table, percent reductions greater than 2.2 percent indicate that hospitals within the specified category are projected to experience a greater reduction in DSH payments, on average, compared to the universe of FY 2017 projected DSH hospitals. Conversely, percent reductions that are less than 2.2 percent indicate a hospital type is projected to have a smaller reduction than the overall average. The variation in the distribution of payments by hospital characteristic is largely dependent on the change in a given hospital's number of Medicaid days and SSI days used in the Factor 3 computation.

Rural hospitals, grouped by geographic location, payment classification, and bed size, are projected to experience a larger reduction in DSH payments than urban hospitals. Overall, urban hospitals are projected to receive a 2.0 percent decrease in DSH payments, and rural hospitals are projected to receive a 6.4 percent decrease in

DSH payments. The smaller the rural hospital, the larger the projected reduction in DSH payments, with rural hospitals that have 0–99 beds projected to experience a 7.8 percent payment reduction, and larger rural hospitals with 100–249 beds and greater than 250 beds projected to experience a 5.2 and 5.9 percent payment reductions respectively. In contrast, the smallest urban hospitals (0–99 beds) are projected to receive a decrease in DSH payments of 2.2 percent. Larger urban hospitals (100–250 beds and 250+ beds) are projected to receive reductions of 2.6 and 1.8 percent respectively.

By region, projected DSH payment reductions for urban hospitals are largest in the South Atlantic and West South Central, with New England, Middle Atlantic, and West North Central hospitals also projected to receive reductions in DSH payments greater than the overall average. Urban hospitals in the East North Central, East South Central, Mountain, and Pacific regions are projected to receive reductions less than the overall average. Puerto Rico hospitals are expected to receive an 11.4 percent increase in DSH payments.

Teaching hospitals with fewer than 100 residents are projected to receive relatively larger reductions than nonteaching hospitals or hospitals with 100 or more residents, although all are fairly consistent with the national average. Voluntary, proprietary, and government hospitals are projected to receive payment reductions generally consistent with the national average, where government hospitals are projected to receive slightly smaller reductions in DSH payments and proprietary hospitals are projected to receive slightly larger reductions than the overall average. Hospitals with over 65 percent Medicare utilization are projected to receive a significant reduction in DSH payments, while lower Medicare utilization percentiles show smaller reductions.

Puerto Rico hospitals are projected to receive an increase in overall DSH payments, including both empirically justified DSH payments and uncompensated care payments, due to the finalized policy to create proxy values for SSI days for hospitals in Puerto Rico for purposes of calculating Factor 3 of the uncompensated care payment methodology. For FY 2017, Puerto Rico hospitals are projected to receive $116 million in overall DSH and uncompensated care payments, or an 11.4 percent increase from FY 2016 payments ($104 million). Of the estimated $116 million for FY 2017, we estimate that $78 million will be uncompensated care payments to Puerto Rico hospitals. This represents an increase of approximately 13.8 percent, or $9.5 million, in FY 2017 compared to the estimated $68 million in uncompensated care payments to Puerto Rico hospitals in FY 2016. Moreover, we estimate that uncompensated care payments to Puerto Rico hospitals for FY 2017 are 19.8 percent, or $12.9 million, higher with the finalized SSI proxy than they otherwise would have been without the finalized SSI proxy for FY 2017. In other words, without the finalized SSI proxy, we would have expected uncompensated care payments to Puerto Rico hospitals to decline by approximately $3.4 million between FY 2016 and FY 2017. We note that because the finalized SSI proxy for Puerto Rico hospitals increases the number of days in the denominator of Factor 3, this affects hospitals nationally. We estimate that uncompensated care payments to non-Puerto Rico hospitals for FY 2017 are approximately 0.15 percent lower with the finalized SSI proxy than they otherwise would have been without the finalized SSI proxy.

3. Effects of Reduction Under the Hospital Readmissions Reduction Program

In section IV.G. of the preamble of this final rule, we discuss our proposed and final policies for the FY 2017 Hospital Readmissions Reduction Program (established under section 3025 of the Affordable Care Act), which requires a reduction to a hospital's base operating DRG payments to account for excess readmissions. For FY 2017, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). This provision is not budget neutral. A hospital's readmission adjustment is the higher of a ratio of the hospital's aggregate payments for excess readmissions to their aggregate payments for all discharges, or a floor, which has been defined in the statute as 0.97 (or a 3.0 percent reduction). A hospital's base operating DRG payment (that is, wage-adjusted DRG payment amount, as discussed in section IV.G. of the preamble of this final rule) is the portion of the IPPS payment subject to the readmissions payment adjustment (DSH, IME, outliers and low-volume add-on payments are not subject to the readmissions adjustment). In this final rule, we estimate that 2,588 hospitals will have their base operating DRG payments reduced by their proxy FY 2017 hospital-specific readmissions adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program will save approximately $528 million in FY 2017, an increase of $108 million over the estimated FY 2016 savings.

4. Effects of Changes Under the FY 2017 Hospital Value-Based Purchasing (VBP) Program

In section IV.H. of the preamble of this final rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2017 through a reduction to the FY 2017 base operating DRG payment amounts for all discharges for participating hospitals for such fiscal year, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2017 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary.

In section IV.H. of the preamble of this final rule, we estimate the available pool of funds for value-based incentive payments in the FY 2017 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, will be 2.00 percent of base operating DRG payments, or a total of approximately $1.8 billion. This estimated available pool for FY 2017 is based on the historical pool of hospitals that were eligible to participate in the FY 2016 program year and the payment information from the March 2016 update to the FY 2015 MedPAR file.

The estimated impacts of the FY 2017 program year by hospital characteristic, found in the table below, are based on historical TPSs. We used the FY 2016 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the March 2016 update to the FY 2015 MedPAR file. The proxy adjustment factors can be found in Table 16A associated with this final rule (available via the Internet on the CMS Web site).

The impact analysis shows that, for the FY 2017 program year, the number of hospitals that will receive an increase in their base operating DRG payment amounts is higher than the number of hospitals that will receive a decrease. Among urban hospitals, those in the New England, South Atlantic, East North Central, East South Central, West North Central, West South Central, Mountain, and Pacific regions will have an increase, on average, in their base operating DRG payment amounts. Urban hospitals in the Middle Atlantic region will receive an average decrease in their base operating DRG payment amounts. Among rural hospitals, those in all regions will have an increase, on average, in their base operating DRG payment amounts.

On average, hospitals that receive a higher (50–65) percent of DSH payments will receive decreases in base operating DRG payment amounts. With respect to hospitals' Medicare utilization as a percent of inpatient days (MCR), those hospitals with an MCR above 65 percent will have the largest average increase in base operating DRG payment amounts.

Nonteaching hospitals will have an average increase, and teaching hospitals will experience an average decrease in base operating DRG payment amounts.

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT CHANGES RESULTING FROM THE FY 2017 HOSPITAL VBP PROGRAM

	Number of hospitals	Average percentage change
By Geographic Location:		
All Hospitals	3,041	0.244
Large Urban	1,247	0.117
Other Urban	1,048	0.202
Rural Area	746	0.515
Urban hospitals	2,295	0.156
0–99 beds	518	0.709
100–199 beds	716	0.141
200–299 beds	434	−0.031
300–499 beds	420	−0.147
500 or more beds	207	−0.170
Rural hospitals	746	0.514
0–49 beds	267	0.692
50–99 beds	285	0.540
100–149 beds	113	0.308
150–199 beds	44	0.150
200 or more beds	37	0.103
By Region:		
Urban by Region	2,295	0.156
New England	110	0.152
Middle Atlantic	297	−0.065
South Atlantic	389	0.108
East North Central	368	0.205
East South Central	141	0.126
West North Central	155	0.370
West South Central	326	0.212
Mountain	159	0.128
Pacific	350	0.225
Rural by Region	746	0.515
New England	20	0.528
Middle Atlantic	53	0.373
South Atlantic	117	0.621
East North Central	112	0.515
East South Central	138	0.389
West North Central	94	0.623
West South Central	133	0.418
Mountain	55	0.714
Pacific	24	0.677
By MCR Percent:		
0–25	372	0.116
25–50	2,036	0.208
50–65	501	0.405
Over 65	125	0.580
Missing	7	0.114
By DSH Percent:		
0–25	1,307	0.393
25–50	1,412	0.162
50–65	169	−0.015
Over 65	153	0.012
By Teaching Status:		
Non-Teaching	2,022	0.388
Teaching	1,019	−0.041

Actual FY 2017 program year's TPSs will not be reviewed and corrected by hospitals until after this FY 2017 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2016 program year are used for the updated impact analysis in this final rule.

5. Effects of Changes to the HAC Reduction Program for FY 2017

In section IV.I. of the preamble of this final rule, we discuss the changes to the HAC Reduction Program for FY 2017. The table and analysis below show the estimated cumulative effect of the measures and scoring system for the HAC Reduction Program in this final rule. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49575 through 49576), we finalized a Total HAC Score methodology that assigns, for FY 2017, weights for Domain 1 and Domain 2 at 15 percent and 85 percent, respectively. Based on this methodology, the table below presents data on the estimated proportion of hospitals in the worst-performing quartile of the Total HAC Scores by hospital characteristic. We note that because scores will undergo a 30-day review and correction period by the hospitals that will not conclude until after the publication of this FY 2017 IPPS/LTCH PPS final rule, we are not providing hospital-level data or a hospital-level payment impact in conjunction with this FY 2017 IPPS/LTCH PPS final rule.

To estimate the impact of the FY 2017 HAC Reduction Program, we used, as previously finalized, AHRQ PSI 90 measure results based on Medicare FFS discharges from July 2013 through June 2015 and version 5.0.1 (recalibrated) of the AHRQ software. For the CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and

CDI measure results, we used standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the NHSN for infections occurring between January 1, 2013 and December 31, 2014.

To analyze the results by hospital characteristic, we used the FY 2017 Proposed Rule Impact File. This table includes 3,215 non-Maryland hospitals with a Total HAC Score FY 2017. Of these, 3,200 hospitals had information for geographic location, region, bed size, DSH percent, and teaching status; 3,178 had information for ownership; and 3,176 had information for MCR percent. Maryland hospitals and hospitals without a Total HAC Score are not included in the table below.

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORE FOR THE FY 2017 HAC REDUCTION PROGRAM

[By hospital characteristic]

Hospital characteristic	Number of hospitals [a]	Number of hospitals in the worst-performing quartile [b]	Percent of hospitals in the worst-performing quartile [c]
Total [d]	3,215	771	24.0
By Geographic Location:			
All hospitals:			
Urban	2,404	653	27.2
Rural	796	107	13.4
Urban hospitals:			
1–99 beds	592	91	15.4
100–199 beds	734	166	22.6
200–299 beds	440	134	30.5
300–399 beds	276	101	36.6
400–499	150	61	40.7
500 or more beds	212	100	47.2
Rural hospitals:			
1–49 beds	303	48	15.8
50–99 beds	289	29	10.0
100–149 beds	118	11	9.3
150–199 beds	45	9	20.0
200 or more beds	41	10	24.4
By Region:			
New England	134	42	31.3
Mid-Atlantic	365	131	35.9
South Atlantic	519	133	25.6
East North Central	494	96	19.4
East South Central	295	45	15.3
West North Central	259	38	14.7
West South Central	511	104	20.4
Mountain	226	55	24.3
Pacific	397	116	29.2
By DSH Percent: [e]			
0–24	1,387	321	23.1
25–49	1,454	324	22.3
50–64	181	58	32.0
65 and over	178	57	32.0
By Teaching Status: [f]			
Non-teaching	2,160	381	17.6
Fewer than 100 residents	790	237	30.0
100 or more residents	250	142	56.8
By Type of Ownership:			
Voluntary	1,868	478	25.6
Proprietary	825	154	18.7
Government	485	121	24.9
By MCR Percent:			
0–24	472	148	31.4
25–49	2,106	481	22.8
50–64	518	104	20.1
65 and over	80	18	22.5

Source: FY 2017 HAC Reduction Program Final Rule results are based on AHRQ PSI 90 data from July 2013 through June 2015 and CDC CLABSI, CAUTI, SSI, CDI, and MRSA results from January 2014 to December 2015. Hospital Characteristics are based on the FY 2017 Proposed Rule Impact File updated on April 27, 2016.

[a] The total number of non-Maryland hospitals with a Total HAC Score with hospital characteristic data (3,200 for geographic location, bed size, and teaching status; 3,178 for type of ownership; and 3,176 for MCR) does not add up to the total number of non-Maryland hospitals with a Total HAC Score for the FY 2017 HAC Reduction Program (3,215) because 15 hospitals are not included in the FY 2017 Proposed Rule Impact File and not all hospitals have data for all characteristics.

[b] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[c] This column is the percent of hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[d] Total excludes 47 Maryland hospitals and 64 non-Maryland hospitals without a Total HAC Score for FY 2017.

[e] A hospital is considered to be a DSH hospital if it has a DSH patient percentage greater than zero.

[f] A hospital is considered to be a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

6. Effects of Policy Changes Relating to Direct GME and IME Payments for Rural Training Tracks at Urban Hospitals

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25308) and section IV.J. of the preamble of this final rule, we discuss our proposed and finalized policy to extend the period for establishing rural track FTE limitations from 3 years to 5 years for purposes of direct GME and IME payments to urban hospitals with rural track training programs. Specifically, we are revising the regulations to permit that, in the first 5 program years (rather than the first 3 program years) of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents training in the rural training track at the urban hospital, and beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural training track's existence, the rural track FTE limitation will take effect. This change addresses concerns expressed by the hospital community that rural training tracks, like any program, should have a sufficient amount of time for a hospital to ''grow'' and to establish a rural track FTE limitation that reflects the number of FTE residents that it will actually train, once the program is fully grown. In the proposed rule (81 FR 25308) and in section IV.J. of the preamble of this final rule, we explain that because we inadvertently did not also amend the separate direct GME and IME regulations regarding the growth window and effective date of FTE limitations for rural track training programs when we amended the regulations regarding the 5-year growth window in the FY 2013 IPPS/LTCH PPS final rule and regarding the additional changes we made in the FY 2015 IPPS/LTCH PPS final rule, we are making the effective date regarding the change in the growth window also effective for rural track training programs started on or after October 1, 2012. As stated in the proposed rule, mostly due to the relatively small size of rural track programs, we estimate that the proposal would cost approximately $1 million by the end of the 10-year period, a negligible cost. We are finalizing this policy as proposed, and therefore our estimate remains unchanged for the final rule.

7. Effects of Implementation of Rural Community Hospital Demonstration Program

In section IV.K. of the preamble of this final rule, for FY 2017, we discuss our implementation of section 410A of Public Law 108–173, as amended, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural community hospitals. Section 410A(c)(2) requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.

As discussed in section IV.K. of the preamble of this final rule, in the IPPS final rules for each of the previous 12 fiscal years, we have estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we have adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented but does not identify the range across which aggregate payments must be held equal.

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25130), we proposed a different methodology as compared to previous years for analyzing the costs attributable to the demonstration for FY 2017. The demonstration will have substantially phased out by the beginning of FY 2017. The 7 ''originally participating hospitals'', that is, those hospitals that were selected for the demonstration in 2004 and 2008, ended their participation in the 5-year extension period authorized by the Affordable Care Act prior to the start of FY 2016. In addition, we stated in the proposed rule that the participation period for the 14 hospitals that entered the demonstration following the extension of the demonstration mandated by the Affordable Care Act and that were still participating would end on a rolling basis according to the end dates of the hospitals' cost report periods, respectively, from April 30, 2016 through December 31, 2016. Of these 14 hospitals, 10 hospitals will end participation on or before September 30, 2016, leaving 4 hospitals participating for the last 3 months of CY 2016 (that is, the first 3 months of FY 2017). Given the small number of participating hospitals and the limited time of participation, we proposed to forego the process of estimating the costs attributable to the demonstration for FY 2017 and to instead analyze the set of finalized cost reports for reporting periods beginning in FY 2016 when they become available.

In previous IPPS/LTCH PPS final rules, we have determined the amount by which the actual costs of the demonstration for an earlier, previous year differed from the estimated costs of the demonstration set forth in the corresponding final rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We note that we have calculated this difference between the actual costs of the demonstration for FYs 2005 through 2010, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years. In the proposed rule (81 FR 25130), we proposed to conduct this analysis for FYs 2011 through 2016 at one time, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available. Given the general lag of 3 years in finalizing cost reports, we stated in the proposed rule that we expect any such analysis to be conducted in FY 2020.

Because, as discussed earlier, we proposed that we would not calculate and apply an estimated budget neutrality offset amount for FY 2017, but instead analyze the set of finalized cost reports for cost reporting periods beginning in FY 2016 when they become available, and proposed to reconcile the budget neutrality offset amounts for FYs 2011 through 2016 with the actual costs of the demonstration once the finalized cost reports for all of these years are available, we stated in the proposed rule that there would be no impact from the demonstration on the national IPPS rates for FY 2017 (81 FR 25308).

In this final rule, we are finalizing these proposals without modification. Thus, in this final rule, we are applying no budget neutrality offset amount to the national IPPS rates for FY 2017.

8. Effects of Implementation of the Notice of Observation Treatment and Implications for Care Eligibility Act (NOTICE Act)

In the proposed rule (81 FR 25131 through 25134) and in section IV.L. of the preamble of this final rule, we discuss implementation of section 1866(a)(1)(Y) of the Act as amended by the NOTICE Act (Pub. L. 114–42) and revisions to the basic commitments providers agree to as part of participating in Medicare under a provider agreement. These revisions specify a process for hospitals and CAHs to notify an individual, orally and in writing, regarding the individual's receipt of observation services as an outpatient for more than 24 hours and the implications of receiving such services. The statute mandates the Secretary develop a plain language written notice for this purpose. The written notice must be delivered no later than 36 hours after observation services are initiated (or, if sooner, upon release).

We developed a standardized format for the notice, which is undergoing OMB approval. The notice will be disseminated during the normal course of related business activities. In 2014, there were approximately 1,399,999 claims for Medicare outpatient observation services lasting greater than 24 hours furnished by 6,142 hospitals and CAHs.[400] We refer readers to section IX.B. of the preamble of this final rule for a discussion of the burden associated with this notice requirement.

9. Effects of Technical Changes and Correction of Typographical Errors in Certain Regulations Under 42 CFR Part 413 Relating to Costs to Related Organizations and Medicare Cost Reports

In the FY 2017 IPPS/LTCH proposed rule (81 FR 25134 through 25135) and in section IV.M. of the preamble of this final rule, we discuss a number of technical changes or corrections of typographical errors in 42 CFR part 413 relating to costs to related organizations and Medicare cost reports that need to be made. We believe that the impact of these technical changes and corrections is negligible.

[400] Source: CMS Office of Enterprise and Data Analytics.

10. Effects of Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25140 through 25141) and in section VI.C. of the preamble of this final rule, we discuss the implementation of the FCHIP demonstration, which will allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care, and other health care services to Medicare beneficiaries in no more than four States. Budget neutrality estimates for CAHs selected for the demonstration will be based on the demonstration period, August 1, 2016 through July 31, 2019. The demonstration design includes three intervention prongs, under which specific waivers of Medicare payment rules will allow for enhanced payment: Telemedicine, nursing facility, and ambulance services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

We have specified the payment enhancements for the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration will produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration program and uncertainty associated with projected Medicare utilization and costs, we proposed a contingency plan (81 FR 25141) to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. Accordingly, if analysis of claims data for the Medicare beneficiaries receiving services at each of the participating CAHs, as well as of other data sources, including cost reports, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. Thus, in the event that we determine that aggregate payments under the demonstration exceed the payments that would otherwise have been made, we proposed that CMS would recoup payments through reductions of Medicare payments to all CAHs under both Medicare Part A and Part B. Because of the small scale of the demonstration, it would not be feasible to implement budget neutrality by reducing payments only to the participating CAH providers. We proposed to make the reduction to payments to all CAHs, not just those participating in the demonstration, because the FCHIP program is specifically designed to test innovations that affect delivery of services by this provider category. We believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of the Act permits the agency to implement the budget neutrality provision in this manner. The statutory language refers merely to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Given the 3-year period of performance of the FCHIP demonstration and the time needed to conduct the budget neutrality analysis, we proposed that, in the event the demonstration is found not to have been budget neutral, any excess costs would be recouped over a period of three cost report periods, beginning in CY 2020. Therefore, in this final rule, we are finalizing this proposal, which has no impact for any national payment system for FY 2017.

I. Effects of Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the March 2016 update of the FY 2015 MedPAR file and the March 2016 update of the Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the capital prospective payment system do not incorporate cost data, we used the March 2016 update of the most recently available hospital cost report data (FYs 2013 and 2014) to categorize hospitals. Our analysis has several qualifications. We use the best data available and make assumptions about case-mix and beneficiary enrollment as described later in this section.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the March 2016 update of the FY 2015 MedPAR file, we simulated payments under the capital IPPS for FY 2016 and FY 2017 for a comparison of total payments per case. Any short-term, acute care hospitals not paid under the general IPPS (for example, Indian Health Service hospitals and hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the capital IPPS payments in FY 2017 is as follows:

(Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- We estimate that the Medicare case-mix index will increase by 0.5 percent in both FYs 2016 and 2017.
- We estimate that Medicare discharges will be approximately 11.0 million in FY 2016 and 11.1 million in FY 2017.
- The capital Federal rate was updated beginning in FY 1996 by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1.a. of the Addendum to this rule, the update is 0.9 percent for FY 2017.
- In addition to the FY 2017 update factor, the FY 2017 capital Federal rate was calculated based on a GAF/DRG budget neutrality adjustment factor of 0.9991, a outlier adjustment factor of 0.9386, and an adjustment of (1/0.998) to permanently remove the 0.2 percent adjustment, as well as a temporary 2-midnight adjustment of 1.006. The 2-midnight adjustments are discussed in section V.C. of the preamble of this final rule and are consistent with the 2-midnight adjustments on the operating Federal rate. As discussed in section V.C. of the preamble of this final rule, we are not making an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rates for FY 2017.

2. Results

We used the actuarial model previously described in section I.I. of Appendix A of this final rule to estimate the potential impact of our changes for FY 2017 on total capital payments per case, using a universe of 3,330 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the March 2016 update of the FY 2015 MedPAR file, the March 2016 update to the PSF, and the most recent cost report data from the March 2016 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2016 and estimated total payments per case for FY 2017 based on the FY 2017 payment policies. Column 2 shows estimates of payments per case under our model for FY 2016. Column 3 shows estimates of payments per case under our model for FY 2017. Column 4 shows the total percentage change in payments from FY 2016 to FY 2017. The change represented in Column 4 includes the 0.9 percent update to the capital Federal rate and other changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2017 are expected to increase as compared to capital payments per case in FY 2016. This expected increase overall is due primarily to the approximately 1.84 percent increase in the capital Federal rate for FY 2017 as compared to the FY 2016 capital Federal rate. (For a discussion of the determination of the capital Federal rate, we refer readers to section III.A. of the Addendum to this final

rule.) Less than half of the hospitals in urban areas are expected to experience a slight increase in capital payments per case due to the effects of changes to the GAFs, while the remainder of these urban area hospitals would experience no change or a decrease in capital payments per case due to changes in the GAFs. For most hospitals in rural areas, changes in the GAFs are expected to increase capital payments, to a greater or lesser extent, except for two rural areas where changes in the GAFs are expected to decrease capital payments per case. These regional effects of the changes to the GAFs on capital payments are consistent with the projected changes in payments due to changes in the wage index (and policies affecting the wage index) as shown in Table I in section I.G. of this Appendix A.

The net impact of these changes is an estimated 0.8 percent change in capital payments per case from FY 2016 to FY 2017 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, most hospitals in all classifications (urban and rural) will experience an increase in capital IPPS payments per case in FY 2017 as compared to FY 2016. Capital IPPS payments per case for hospitals in ''large urban areas'' have an estimated increase of 0.7 percent, while hospitals in rural areas, on average, are expected to experience a 0.8 percent increase in capital payments per case from FY 2016 to FY 2017. Capital IPPS payments per case for ''other urban hospitals'' are estimated to increase 0.9 percent. The primary factor contributing to the small difference in the projected increase in capital IPPS payments per case for urban hospitals as compared to rural hospitals is the changes to the GAFs.

The comparisons by region show that the estimated increases in capital payments per case from FY 2016 to FY 2017 in urban areas range from a 4.2 percent increase for the Puerto Rico urban hospitals, and a 1.4 percent increase for the West South Central urban region to a 0.7 percent increase for the Mountain urban region. The New England urban region is expected to experience a 0.6 percent decrease in capital payments per case, largely due to changes in the GAFs as compared to the other urban hospitals. The 4.2 percent increase in capital payments per case for the Puerto Rico urban region is in part due to the change in the capital payment rate to 100 percent of the capital Federal rate rather than a blend of the capital Puerto Rico rate and the capital Federal rate, as discussed in section V.B.3. of the preamble of this final rule. For rural regions, the Middle Atlantic rural region is projected to experience the largest increase in capital IPPS payments per case of 1.6 percent, while the Mountain rural region is projected to experience a small decrease in capital IPPS payments per case of 0.4 percent. The change in the GAFs is the main factor for the projected decrease in the capital IPPS payments for the Mountain rural region compared to the other rural regions, as it is for the projected decrease in capital IPPS payments for the New England urban region.

Hospitals of all types of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are expected to experience an increase in capital payments per case from FY 2016 to FY 2017. The increase in capital payments for voluntary and proprietary hospitals is estimated to be 0.8 percent and for government hospitals, the increase is estimated to be 0.7 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2017. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this rule for FY 2017, we show the average capital payments per case for hospitals for FY 2017. Urban reclassified hospitals are expected to experience an increase in capital payments of 1.0 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 0.7 percent. The estimated percentage increase for rural reclassified hospitals is 1.0 percent, and for rural nonreclassified hospitals, the estimated percentage increase is 0.2 percent. Other reclassified hospitals (section 1886(d)(8)(B) of the Act) are expected to experience an increase in capital payments of 0.5 percent.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2016 payments compared to FY 2017 payments]

	Number of hospitals	Average FY 2016 payments/case	Average FY 2017 payments/case	Change
By Geographic Location:				
All hospitals	3,330	912	920	0.8
Large urban areas (populations over 1 million)	1,380	1,011	1,018	0.7
Other urban areas (populations of 1 million of fewer)	1,135	870	878	0.9
Rural areas	815	618	623	0.8
Urban hospitals	2,515	947	955	0.8
0–99 beds	659	768	774	0.7
100–199 beds	767	824	829	0.6
200–299 beds	446	865	871	0.7
300–499 beds	431	958	967	0.9
500 or more beds	212	1,139	1,149	0.9
Rural hospitals	815	618	623	0.8
0–49 beds	317	520	524	0.7
50–99 beds	292	577	582	0.8
100–149 beds	120	610	614	0.5
150–199 beds	46	669	673	0.7
200 or more beds	40	738	746	1.0
By Region:				
Urban by Region	2,515	947	955	0.8
New England	116	1,031	1,025	−0.6
Middle Atlantic	315	1,056	1,065	0.8
South Atlantic	407	840	847	0.9
East North Central	390	908	916	0.9
East South Central	147	793	804	1.4
West North Central	163	923	930	0.8
West South Central	385	858	868	1.2
Mountain	163	977	984	0.7
Pacific	378	1,219	1,228	0.8
Puerto Rico	51	435	453	4.2
Rural by Region	815	618	623	0.8
New England	21	868	878	1.2
Middle Atlantic	54	591	600	1.6
South Atlantic	128	584	584	0.1

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2016 payments compared to FY 2017 payments]

	Number of hospitals	Average FY 2016 payments/case	Average FY 2017 payments/case	Change
East North Central	115	638	644	0.9
East South Central	155	562	567	0.9
West North Central	98	666	669	0.4
West South Central	160	536	543	1.3
Mountain	60	718	714	−0.4
Pacific	24	804	813	1.0
By Payment Classification:				
All hospitals	3,330	912	920	0.8
Large urban areas (populations over 1 million)	1,372	1,012	1,019	0.7
Other urban areas (populations of 1 million of fewer)	1,150	869	878	0.9
Rural areas	808	619	623	0.7
Teaching Status:				
Non-teaching	2,266	771	776	0.7
Fewer than 100 Residents	815	885	892	0.8
100 or more Residents	249	1,287	1,299	0.9
Urban DSH:				
100 or more beds	1,642	968	976	0.8
Less than 100 beds	363	696	701	0.7
Rural DSH:				
Sole Community (SCH/EACH)	240	575	580	1.0
Referral Center (RRC/EACH)	325	649	654	0.7
Other Rural:				
100 or more beds	29	538	540	0.5
Less than 100 beds	142	526	528	0.4
Urban teaching and DSH:				
Both teaching and DSH	898	1,043	1,053	0.9
Teaching and no DSH	109	942	947	0.5
No teaching and DSH	1,107	813	819	0.8
No teaching and no DSH	408	815	820	0.6
Rural Hospital Types:				
Non special status hospitals	2,529	948	955	0.7
RRC/EACH	189	772	783	1.4
SCH/EACH	324	706	715	1.3
SCH, RRC and EACH	126	748	755	1.0
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2017 Reclassifications:				
All Urban Reclassified	533	953	962	1.0
All Urban Non-Reclassified	1,938	948	955	0.7
All Rural Reclassified	277	650	656	1.0
All Rural Non-Reclassified	489	578	580	0.2
Other Reclassified Hospitals (Section 1886(d)(8)(B))	42	599	602	0.5
Type of Ownership:				
Voluntary	1,927	926	933	0.8
Proprietary	881	820	827	0.8
Government	522	963	969	0.7
Medicare Utilization as a Percent of Inpatient Days:				
0–25	523	1,103	1,113	0.9
25–50	2,122	916	923	0.8
50–65	545	745	751	0.8
Over 65	89	529	531	0.5

J. Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this final rule and section V. of the Addendum to this final rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2017. In the preamble of this final rule, we specify the statutory authority for the provisions that are presented, identify the proposed and final policies, and present rationales for our decisions as well as alternatives that were considered. In this section of Appendix A to this final rule, we discuss the impact of the changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this final rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 420 LTCHs included in this impacts analysis, which includes data for 78 nonprofit (voluntary ownership control) LTCHs, 325 proprietary LTCHs, and 17 LTCHs that are government-owned and operated. (We note that, although there are currently approximately 430 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2017 MS–LTC–DRG relative weights (discussed in section VII.C.3.c. of the preamble of this final rule).) In the impact analysis, we used the payment rate, factors, and policies presented in this final rule, which includes the continued transition to the site neutral payment rate required by section 1886(m)(6)(A) of the Act (discussed in section VII.B. of the preamble of this final rule), the 1.75 percent annual update to the LTCH PPS standard Federal payment rate in accordance with section 1886(m)(5)(C) of the Act (which is based on the full estimated increase of the revised and rebased LTCH

PPS market basket and the reductions required by sections 1886(m)(3) and (m)(4) of the Act), the update to the MS–LTC–DRG classifications and relative weights, the update to the wage index values and labor-related share, and the best available claims and CCR data to estimate the change in payments for FY 2017.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a); or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, there are two separate HCO targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. The statute also establishes a transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 and FY 2017. The transitional payment amount for site neutral payment rate cases is a blended payment rate, which is calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under new § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge determined under § 412.523.

Based on the best available data for the 420 LTCHs in our database that were considered in the analyses used for this final rule, we estimate that overall LTCH PPS payments in FY 2017 will decrease by approximately 7.1 percent (or approximately $363 million). This projection takes into account estimated payments for LTCH cases in our database that would have met the patient-level criteria and been paid the LTCH PPS standard Federal payment rate if those criteria had been in effect at the time of the discharge, and estimated payments for LTCH cases that would not have met the patient-level criteria and been paid under the site neutral payment rate if that rate had been in effect at the time of the discharge, as described in the following paragraph.

The statutory transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017 uses a blended payment rate, which is determined as 50 percent of the site neutral payment rate amount for the discharge and 50 percent of the standard Federal prospective payment rate amount for the discharge (§ 412.522(c)(3)). The transitional blended payment rate uses the same blend percentages (that is, 50 percent) for both years of the 2-year transition period. Therefore, when estimating FY 2017 LTCH PPS payments for site neutral payment rate cases for this impact analysis, the transitional blended payment rate was applied to all such cases because all discharges in FY 2017 will either be in the hospital's cost reporting period that began during FY 2016 or in the hospital's cost reporting period that will begin during FY 2017. However, when estimating FY 2016 LTCH PPS payments for site neutral payment rate cases for this impact analysis because the statute specifies that the site neutral payment rate effective date for a given LTCH is determined based on the date on which that LTCH's cost reporting period begins during FY 2016, we included an adjustment to account for this rolling effective date, consistent with the approach used for the LTCH PPS impact analysis presented in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49831). This approach accounts for the fact that LTCHs with discharges in FY 2016 that are in cost reporting periods that begin *before* October 1, 2015, continued to be paid for all discharges (including those that did not meet the patient-level criteria for exclusion from the site neutral payment rate) at the LTCH PPS standard Federal payment rate until the start of their first cost reporting period beginning *after* October 1, 2015.

For purposes of this impact analysis, to estimate total FY 2016 LTCH PPS payments for site neutral payment rate cases, we used the same approach as was used in the FY 2016 IPPS/LTCH PPS final rule. In summary, under this approach, we grouped LTCHs based on the quarter of FY 2016 their cost reporting periods began during FY 2016. For example, LTCHs with cost reporting periods that began during October through December 2015 began during the first quarter of FY 2016. For LTCHs grouped in each quarter of FY 2016, we modeled those LTCHs' estimated FY 2016 site neutral payment rate payments under the transitional blended payment rate based on the quarter in which the LTCHs in each group become subject to the site neutral payment rate. Then, we modeled for LTCHs grouped in each quarter of FY 2016, estimated FY 2016 payments under the LTCH PPS standard Federal payment rate based on the quarter in which the LTCHs in each group become subject to the site neutral payment rate. (For additional details on our method of taking into account the rolling effective date of the application of the site neutral payment rate when estimating payments for FY 2016, we refer readers to the description presented in FY 2016 IPPS/LTCH PPS final rule (80 FR 49831).) We continue to believe that this approach is a reasonable means of taking the rolling effective date into account when estimating FY 2016 payments.

Based on the fiscal year start dates recorded in the March 2016 update of the PSF, of the 420 LTCHs in our database of LTCH claims from the March 2016 update of the FY 2015 MedPAR files used for this final rule, the following percentages apply in the approach previously described: 9.9 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the first quarter of FY 2016; 26.4 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the second quarter of FY 2016; 10.3 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the third quarter of FY 2016; and 53.4 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the fourth quarter of FY 2016.

Comment: Some commenters requested that additional information be added to the publically available IPPS and LTCH PPS MedPAR files because they were made available in the FY 2016 rulemaking cycle, such as encrypted patient identifiers, encrypted admission and discharge dates, and the number of days the patient spent in the ICU in the immediately preceding IPPS hospital stay prior to admission to the LTCH. These commenters believed that such additional information is needed to determine which historical discharges were immediately preceded by a qualifying IPPS hospital stay and could be used to verify the payment rate designation (that is, site neural or standard) CMS has included in the publically available IPPS and LTCH MedPAR file.

Response: We understand that, for commenters who would like to replicate the proposed LTCH PPS payment rates, factors, and payment estimates presented in the proposed rule, it is necessary to be able to identify the LTCH discharges in the historical data that would be the LTCH PPS standard Federal payment rate cases and the ones that would be site neutral payment rate cases (had the statutory criteria been in effect at the time of the discharge). In response to a similar comment in the FY 2016 rule-making cycle, as requested by commenters, we have added the number of days that the patient spent in the ICU in an immediately preceding IPPS hospital stay prior to admission to the LTCH because this aggregated count of days conforms with CMS' privacy and security standards and does not result in the identification of specific beneficiaries. We believe that including the number of days spent in the ICU from the immediately preceding IPPS hospital stay to the publically available MedPAR file will allow the public to adequately corroborate the indicator of the historical LTCH discharges as a LTCH PPS standard Federal payment rate case or a site neutral payment rate case (had the statutory criteria been in effect at the time of the discharge).

As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49603), currently the publically available IPPS and LTCH PPS MedPAR files do not contain any specified direct patient identifiers consistent with CMS' privacy and security standards and as outlined in the HIPAA Privacy Rule. (For additional information on CMS' privacy and security standards under the HIPAA Privacy Rule, we refer readers to the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/PrivacyandSecurityInformation.html*, and for additional information on CMS' publically available LDS files, we refer readers to the CMS Web site at: *http://cms.hhs.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/index.html*.) It is for these reasons that, as noted by commenters, we added an identifier to the publically available FY 2014 LTCH MedPAR File to identify the historical LTCH discharges in that file as LTCH PPS standard Federal payment rate cases or site neutral

payment rate cases (had the statutory dual rate LTCH PPS payment structure been in effect at the time of the discharge). These are the same payment rate identifiers we used to develop the FY 2017 proposed payment rates, factors, and payment estimates as described in the proposed rule. We believe that the addition of this payment rate identifier to the publically available LTCH MedPAR file provides sufficient information for commenters to replicate and evaluate the proposed payment rates, factors, and payment estimates in the proposed rule. We will continue to consider adding the encrypted information requested by commenters to the publically available IPPS and LTCH PPS MedPAR files. However, we are not able to do so at this time because to add such specific direct patient identifiers would need to be done in conformance with CMS' privacy and security standards, including any requirements outlined in the HIPAA Privacy and Security Rules.

Based on the FY 2015 LTCH cases that were used for the analyses in this final rule, approximately 45 percent of those LTCH cases would have been classified as site neutral payment rate cases if the site neutral payment rate had been in effect in FY 2015 (that is, 45 percent of such LTCH cases would not have met the patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2017 will not change significantly from the historical data. Taking into account the transitional blended payment rate and other changes that will apply to the site neutral payment rate cases in FY 2017, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will decrease by approximately 23 percent (or approximately $388 million).

Approximately 55 percent of LTCH cases are expected to meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2017, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2017 will increase approximately 0.7 percent (or approximately $24 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2017 is primarily due to the combined effects of the 1.75 percent annual update to the LTCH PPS standard Federal payment rate for FY 2017 (discussed in section V.A. of the Addendum to this final rule) and an estimated decrease in HCO payments for these cases (discussed in section V.D.3. of the Addendum to this final rule).

Based on the 420 LTCHs that were represented in the FY 2015 LTCH cases that were used for the analyses in this final rule, we estimate that aggregate FY 2017 LTCH PPS payments will be approximately $4.771 billion, as compared to estimated aggregate FY 2016 LTCH PPS payments of approximately $5.134 billion, resulting in an estimated overall decrease in LTCH PPS payments of approximately $363 million. Because the combined distributional effects and estimated payment changes exceed $100 million, this final rule is a major economic rule. We note that this estimated $363 million decrease in LTCH PPS payments in FY 2017 (which includes estimated payments for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases) does not reflect changes in LTCH admissions or case-mix intensity, which would also affect the overall payment effects of the policies in this final rule.

The LTCH PPS standard Federal payment rate for FY 2016 is $41,762.85. For FY 2017, we are establishing an LTCH PPS standard Federal payment rate of $42,476.41 (as compared to the proposed payment rate of $42,314.31), which reflects the 1.75 percent annual update to the LTCH PPS standard Federal payment rate and the area wage budget neutrality factor of 0.999593 to ensure that the changes in the wage indexes and labor-related share do not influence aggregate payments. For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $41,641.49. This reduced LTCH PPS standard Federal payment rate reflects the updates previously described as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP. We note that the factors previously described to determine the FY 2017 LTCH PPS standard Federal payment rate are applied to the FY 2016 LTCH PPS standard Federal rate set forth under § 412.523(c)(3)(xii) (that is, $41,762.85).

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the annual update to the LTCH PPS standard Federal payment rate is projected to result in an increase of 1.5 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, on average, for all LTCHs (Column 6). In addition to the annual update to the LTCH PPS standard Federal payment rate for FY 2017, the estimated increase of 1.5 percent shown in Column 6 of Table IV also includes estimated payments for SSO cases that will be paid using special methodologies that are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update of LTCHs that do not submit the required LTCH QRP data. Therefore, for all hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases is somewhat less than the 1.75 percent annual update for FY 2017.

For FY 2017, we are updating the wage index values based on the most recent available data, and we are continuing to use labor market areas based on the OMB CBSA delineations (as discussed in section V.B. of the Addendum to this final rule). In addition, we are increasing the labor-related share from 62.0 percent to 66.5 percent under the LTCH PPS for FY 2017, based on the most recent available data on the relative importance of the labor-related share of operating and capital costs of the 2013-based LTCH market basket (as discussed in section VII.D. of the preamble of this final rule). We also are applying an area wage level budget neutrality factor of 0.999593 to ensure that the changes to the wage data and labor-related share do not result in a change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases, which decreases the LTCH PPS standard Federal payment rate by approximately 0.04 percent.

We currently estimate total HCO payments for LTCH PPS standard Federal payment rate cases will decrease from FY 2016 to FY 2017. Based on the FY 2015 LTCH cases that were used for the analyses in this final rule, we estimate that the FY 2016 HCO threshold of $16,423 (as established in the FY 2016 IPPS/LTCH PPS final rule) will result in estimated HCO payments for LTCH PPS standard Federal payment rate cases in FY 2016 that are above the estimated 8 percent target. Specifically, we currently estimate that HCO payments for LTCH PPS standard Federal payment rate cases will be approximately 9.0 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2016. Combined with our estimate that FY 2017 HCO payments for LTCH PPS standard Federal payment rate cases will be 8.0 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2017, this results in the estimated decrease in HCO payments of approximately 1.0 percent between FY 2016 and FY 2017.

In calculating these estimated HCO payments, we increased estimated costs by our actuaries' projected market basket percentage increase factor. This increase in estimated costs also results in a projected increase in SSO payments in FY 2017 (because 100 percent of the estimated cost of the case is an option in the SSO payment formula (§ 412.529)). We estimate that these increased SSO payments in FY 2017 will increase total payments for LTCH PPS standard Federal payment rate cases by approximately 0.25 percent. (Payments for SSO cases represent approximately 14 percent of the estimated total FY 2017 payments for LTCH PPS standard Federal payment rate cases.)

Table IV shows the estimated impact of the payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2017 by comparing estimated FY 2016 LTCH PPS payments to estimated FY 2017 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) The projected increase in payments from FY 2016 to FY 2017 for LTCH PPS standard Federal payment rate cases of 0.7 percent is attributable to the impacts of the change to the LTCH PPS standard Federal payment rate (1.5 percent in Column 6) and the effect of the estimated decrease in HCO payments for LTCH PPS standard Federal payment cases (− 1.0 percent), and the estimated increase in payments for SSO cases (0.25 percent). We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.3. of this Appendix.

As we discuss in detail throughout this final rule, based on the most recent available data, we believe that the provisions of this

final rule relating to the LTCH PPS, which are projected to result in an overall decrease in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 0.7 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases. This estimated impact is based on the FY 2015 data for the 21 rural LTCHs (out of 420 LTCHs) that were used for the impact analyses shown in Table VI.

3. Anticipated Effects of LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, including any applicable HCO payments, or 100 percent of the estimated cost of the case. The statute also establishes a transitional payment method for cases that are paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017, under which the site neutral payment rate cases are paid based on a blended payment rate calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge.

As discussed in section I.J.1. of this Appendix, we project a decrease in aggregate LTCH PPS payments in FY 2017 of approximately $363 million. This estimated decrease in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $25 million and the projected decrease in payments to site neutral payment rate cases of approximately $388 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section VII.B.7.b. of the preamble of this final rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this final rule to project estimated FY 2017 LTCH PPS payments (that is, FY 2015 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3. of this Appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

Under the dual rate LTCH PPS payment structure, there are two distinct payment rates for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2016. Under that statute, any discharges that occur on or after October 1, 2015, but prior to the start of the LTCH's FY 2016 cost reporting period, will be paid at the LTCH PPS standard Federal payment rate. On or after the start of an LTCH's FY 2017 cost reporting period, discharges are paid based on the nature of the case. As described previously, LTCH PPS standard Federal payment rate cases are defined as LTCH discharges that meet the patient-level criteria to be excluded from the typically lower site neutral payment rate, and site neutral payment rate cases are defined as LTCH discharges that do not meet the patient-level criteria and generally will be paid the lower site neutral payment rate. However, for discharges occurring in cost reporting periods beginning in FY 2016 or 2017, the statute specifies that site neutral payment rate cases are paid based on a transitional payment method that is calculated as 50 percent of the applicable site neutral payment rate amount and 50 percent of the applicable LTCH PPS standard Federal payment rate.

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.536. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this final rule on different categories of LTCHs for FY 2017, it is necessary to estimate payments per discharge for FY 2016 using the rates, factors, and the policies established in the FY 2016 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2017 using the rates, factors, and the policies in this FY 2017 IPPS/LTCH PPS final rule (as discussed in section VII. of the preamble of this final rule and section V. of the Addendum to this final rule). As discussed elsewhere in this final rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for SSO and HCO cases in each year. The resulting analyses can then be used to compare how our policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, FY 2012 through FY 2013 cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: Large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FYs 2016 and 2017 payments on a case-by-case basis using historical LTCH claims from the FY 2015 MedPAR files that would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for those cases. For modeling FY 2016 LTCH PPS payments, we used the FY 2016 standard Federal payment rate of $41,762.85, or $40,941.55 for LTCHs that failed to submit

quality data as required under the requirements of the LTCH QRP. Similarly, for modeling payments based on the FY 2017 LTCH PPS standard Federal payment rate, we used the FY 2017 standard Federal payment rate of $42,476.41, or $41,641.49 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP. In each case, we applied the applicable adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2016 LTCH PPS payments, we used the current FY 2016 labor-related share (62.0 percent); the wage index values established in the Tables 12A through 12D listed in the Addendum to the FY 2016 IPPS/LTCH PPS final rule (which are available via the Internet on the CMS Web site); the FY 2016 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $16,423 (as discussed in section V.D. of the Addendum to that final rule) and the FY 2016 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2016 nonlabor-related share (38.0 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling FY 2017 LTCH PPS payments, we used the FY 2017 LTCH PPS labor-related share (66.5 percent), the FY 2017 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this final rule (which are available via the Internet on the CMS Web site), the FY 2017 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $21,943 (as discussed in section V.D.3. of the Addendum to this final rule), and the FY 2017 COLA factors (shown in the table in section V.C. of the Addendum to this final rule) to adjust the FY 2017 nonlabor-related share (33.5 percent) for LTCHs located in Alaska and Hawaii.

As previously discussed, our impact analysis reflects an estimated change in payments for SSO cases, as well as an estimated decrease in HCO payments for LTCH PPS standard Federal payment rate cases (as described previously in section I.J.1. of this Appendix). In modeling payments for SSO and HCO cases for LTCH PPS standard Federal payment rate cases, we applied an inflation factor of 4.8 percent (determined by the Office of the Actuary) to update the 2015 costs of each case.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2016 to FY 2017 based on the payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2016 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated FY 2017 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2016 to FY 2017 due to the annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this final rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 for changes to the area wage level adjustment (that is, the wage indexes and the labor-related share), including the application of the area wage level budget neutrality factor (as discussed in section V.B. of the Addendum to this final rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 (Column 4) to FY 2017 (Column 5) for all changes (and includes the effect of estimated changes to HCO and SSO payments).

TABLE IV—IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR STANDARD PAYMENT RATE CASES FOR FY 2017

[Estimated FY 2016 payments compared to estimated FY 2017 payments]

LTCH Classification	Number of LTCHS	Number of LTCH PPS standard payment rate cases	Average FY 2016 LTCH PPS payment per standard payment rate	Average FY 2017 LTCH PPS payment per standard payment rate [1]	Percent change due to change to the annual update to the standard Federal rate [2]	Percent change due to changes to area wage adjustment with wage budget neutrality [3]	Percent change due to all standard payment rate changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
All providers	420	72,932	$46,898	$47,236	1.5	0.0	0.7
By location:							
Rural	21	2,289	38,941	39,061	1.6	−0.4	0.3
Urban	399	70,643	47,156	47,501	1.5	0.0	0.7
Large	202	42,000	49,427	49,909	1.5	0.2	1.0
Other	197	28,643	43,827	43,971	1.6	−0.3	0.3
By Participation Date:							
Before Oct. 1983	12	1,983	43,329	43,653	1.5	0.0	0.8
Oct. 1983–Sept. 1993	42	8,977	52,907	53,392	1.5	0.3	0.9
Oct. 1993–Sept. 2002	174	31,903	45,562	45,890	1.5	0.0	0.7
After October 2002	192	30,069	46,758	47,063	1.6	−0.2	0.7
By Ownership Type:							
Voluntary	78	10,160	47,907	48,026	1.6	−0.3	0.3
Proprietary	325	61,057	46,526	46,902	1.5	0.0	0.8
Government	17	1,715	54,179	54,461	1.5	0.0	0.5
By region:							
New England	13	2,865	44,083	44,424	1.5	0.0	0.8
Middle Atlantic	26	5,548	51,520	52,247	1.5	0.5	1.4
South Atlantic	63	12,193	46,984	47,085	1.5	−0.4	0.2
East North Central	69	11,693	46,882	47,154	1.6	−0.3	0.6
East South Central	34	5,440	44,505	44,522	1.6	−0.6	0.0
West North Central	29	3,942	46,564	46,555	1.6	−0.4	0.0
West South Central	128	18,800	42,182	42,362	1.6	−0.1	0.4
Mountain	33	4,329	48,465	48,823	1.6	0.2	0.7
Pacific	25	8,122	56,475	57,737	1.5	1.2	2.2
By Bed Size:							
Beds: 0–24	26	1,508	44,462	44,812	1.6	−0.1	0.8
Beds: 25–49	194	24,853	43,902	44,061	1.6	−0.4	0.4

TABLE IV—IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR STANDARD PAYMENT RATE CASES FOR FY 2017—Continued

[Estimated FY 2016 payments compared to estimated FY 2017 payments]

LTCH Classification	Number of LTCHS	Number of LTCH PPS standard payment rate cases	Average FY 2016 LTCH PPS payment per standard payment rate	Average FY 2017 LTCH PPS payment per standard payment rate [1]	Percent change due to change to the annual update to the standard Federal rate [2]	Percent change due to changes to area wage adjustment with wage budget neutrality [3]	Percent change due to all standard payment rate changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Beds: 50–74	119	19,819	48,784	49,127	1.5	0.1	0.7
Beds: 75–124	48	13,490	49,594	50,141	1.5	0.2	1.1
Beds: 125–199	23	8,100	46,771	47,179	1.5	0.1	0.9
Beds: 200+	10	5,162	47,952	48,474	1.5	0.3	1.1

[1] Estimated FY 2017 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this final rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 for the annual update to the LTCH PPS standard Federal payment rate. The temporary exclusion from the site neutral payment rate provided by section 231 of Public Law 114–113 is not reflected in these estimated FY 2017 LTCH PPS payments.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 for changes to the area wage level adjustment under § 412.525(c) (as discussed in section V.B. of the Addendum to this final rule).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 (shown in Column 4) to FY 2017 (shown in Column 5), including all of the changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this final rule. We note that this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the LTCH PPS standard Federal payment rate (Column 6) and the changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in both estimated payments to SSO cases that are paid based on estimated costs and aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

d. Results

Based on the FY 2015 LTCH cases (from 420 LTCHs) that were used for the analyses in this final rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and policy changes for LTCH PPS standard Federal payment rate cases presented in this final rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are expected to increase 0.7 percent, on average, for all LTCHs from FY 2016 to FY 2017 as a result of the payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. This estimated 0.7 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2017 LTCH PPS payments (using the payment rates and factors discussed in this final rule) to estimated FY 2016 LTCH PPS payments for LTCH discharges which will be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge (as described in section I.J.3. of this Appendix).

As stated previously, we are updating the LTCH PPS standard Federal payment rate for FY 2017 by 1.75 percent based on the estimate of the 2013-based LTCH PPS market basket increase (2.8 percent), the reduction of 0.3 percentage point for the MFP adjustment, and the 0.75 percentage point reduction consistent with sections 1886(m)(3) and (m)(4) of the Act. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. As explained earlier in this section, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the 1.75percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 1.5 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2016 to FY 2017. This is because our estimate of the changes in payments due to the update to the LTCH PPS standard Federal payment rate also reflects estimated payments for SSO cases that are paid using special methodologies that are not affected by the update to the LTCH PPS standard Federal payment rate. Consequently, for certain hospital categories, we estimate that payments to LTCH PPS standard Federal payment rate cases may increase by less than 1.75 percent due to the annual update to the LTCH PPS standard Federal payment rate for FY 2017.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 3 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 for all hospitals is 0.7 percent. For rural LTCHs, the overall percent change for LTCH PPS standard Federal payment rate cases is estimated to be a 0.3 percent increase, while for urban LTCHs, we estimate the increase will be 0.7 percent. Large urban LTCHs are projected to experience an increase of 1 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, and other urban LTCHs are projected to experience an increase of 0.3 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, as shown in Table IV.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the most recent available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 44 percent) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002, and they are projected to experience a 0.7 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, as shown in Table IV.

Approximately 2.9 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience an average percent increase (0.8 percent) in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, as shown in Table IV. Approximately 10 percent of LTCHs began participating in the Medicare program between October 1983 and September 1993. These LTCHs are projected to experience a larger than average increase (0.9 percent) in estimated payments for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, which is primarily due to a projected larger than average increase in payments due to the changes to the area wage adjustment. LTCHs that began participating in the Medicare program after October 1, 2002, which treat approximately 41 percent of all LTCH PPS standard Federal payment rate cases, are projected to experience a 0.7 percent increase in estimated payments from FY 2016 to FY 2017.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: Voluntary, proprietary, and government. Based on the most recent available data, approximately 19 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 77 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 4 percent of LTCHs. Based on ownership type, voluntary LTCHs are expected to experience a lower than average increase in payments to LTCH PPS standard Federal payment rate cases of 0.3 percent. Proprietary LTCHs are expected to experience an average increase of 0.8 percent in payments to LTCH PPS standard Federal payment rate cases, while government owned and operated LTCHs are expected to experience a smaller than average increase of 0.5 percent in payments to LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017.

(4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2017 are projected to experience no change from FY 2016 for LTCHs located in the East South Central and West North Central regions, while LTCHs located in all other regions are projected to experience an increase in estimated payments per discharge in comparison to FY 2016. Of the 9 census regions, we project that the increase in estimated payments per discharge to LTCH PPS standard Federal payment rate cases will have the largest positive impact on LTCHs in the Pacific and Middle Atlantic regions (2.2 percent and 1.4 percent, respectively, as shown in Table IV), which is largely attributable to the changes in the area wage level adjustment.

In contrast, LTCHs located in the South Atlantic and West South Central regions are projected to experience the smallest increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017. The lower than national average estimated increase in payments of 0.2 percent among LTCHS located in the South Atlantic region and 0.4 percent among LTCHS located in the West South Central region is primarily due to estimated decreases in payments associated with the changes to the area wage level adjustment.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. All bed size categories are projected to receive an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017. We project that LTCHs with 75 or more beds and fewer than 125 beds, as well as LTCHs with more than 200 beds (that is, LTCHs in the 75–124 beds and 200+ beds categories), will experience a larger than average increase in payments for LTCH PPS standard Federal payment rate cases (1.1 percent). LTCHs with 25 or more beds but fewer than 50 beds (that is, LTCHs in the 25–49 beds category) are expected to experience a smaller than average increase in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 (0.4 percent), mostly due to estimated decreases in payments from the area wage level adjustment.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2017 relative to FY 2016 of approximately $25 million (or approximately 0.7 percent) for the 420 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this final rule will result in a decrease in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2017 relative to FY 2016 of approximately $388 million (or approximately 23 percent) for the 420 LTCHs in our database. Therefore, we project that the provisions of this final rule will result in a decrease in estimated aggregate LTCH PPS payments to all LTCH cases in FY 2017 relative to FY 2016 of approximately $363 million (or approximately 7.1 percent) for the 420 LTCHs in our database.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this final rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program.

K. Effects of Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section VIII.A. of the preamble of this final rule, we discuss our requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2019 payment determination.

In section VIII.A.3.b. of the preamble of this final rule, we discuss finalizing our proposals to remove 15 measures: 13 eCQMs (2 of which we are also finalizing to remove in their chart-abstracted form) and 2 structural measures. We are finalizing our proposal to remove the electronic versions of: (1) AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142); (2) AMI–7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival; (3) AMI–10: Statin Prescribed at Discharge; (4) HTN: Healthy Term Newborn (NQF #0716); (5) PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147); (6) SCIP–Inf–1a: Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision (NQF #0527); (7) SCIP–Inf–2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528); (8) SCIP Inf–9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero; (9) STK–4: Thrombolytic Therapy (NQF #0437); (10) VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373); (11) VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram); (12) VTE–5: Venous Thromboembolism Discharge Instructions; and (13) VTE–6: Incidence of Potentially Preventable Venous Thromboembolism.

We are also finalizing our proposal to remove: (1) STK–4: Thrombolytic Therapy (NQF #0437); and (2) VTE–5: Venous Thromboembolism Discharge Instructions in their chart-abstracted form. Finally, we are also finalizing our proposal to remove two structural measures: (1) Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and (2) Participation in a Systematic Clinical Database Registry for General Surgery.

As further explained in section X.B.7. of the preamble of this final rule, we believe that there will be a reduction in burden for hospitals due to the removal of two chart-abstracted measures (STK–4 and VTE–5). Due to the burden associated with the collection of chart-abstracted data, we estimate that the removal of STK–4 will result in a burden reduction of approximately 303,534 hours across all hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. We estimate that the removal of VTE–5 will result in a burden reduction of approximately 1,437,843 hours across all hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. We believe that removing 13 eCQMs will reduce burden for hospitals. However, as we stated in the proposed rule, even though we are requiring hospitals to submit data on 8 of the available eCQMs included in the Hospital IQR Program measure set (discussed below), the modest reduction in burden associated with removing 13 eCQMs from which hospitals may choose to report will be offset by the increased burden associated with submitting data on 8 eCQMs, instead of 4 eCQMs as previously finalized. We also believe that there will be a negligible burden reduction due to the removal of the two structural measures.

Also, we are finalizing refinements to two previously adopted measures: (1) Expanding the population cohort for the Hospital-Level, Risk-Standardized 30-Day Episode-of-Care Payment Measure for Pneumonia; and (2) Patient Safety and Adverse Events Composite (NQF #0531). As further explained in section X.B.7. of the preamble of this final rule, we believe no additional burden on hospitals will result from the refinements to these two claims-based measures.

In addition, we are finalizing our proposals to add four claims-based measures to the Hospital IQR Program measure set beginning with the FY 2019 payment determination: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure; (3) Spinal Fusion Clinical Episode-Based Payment Measure; and (4) Excess Days in Acute Care after Hospitalization for Pneumonia. We believe no additional burden on hospitals will result from the addition of these four claims-based measures.

We are finalizing a modified version of our eCQM proposals; instead of requiring hospitals to submit data for all available eCQMs in the Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years as proposed, we are finalizing a lesser amount. For the FY 2019 payment determination and the FY 2020 payment determination, we are requiring hospitals to submit data for 8 of the available eCQMs included in the Hospital IQR Program measure set in a manner that will permit eligible hospitals to align Hospital IQR Program requirements with some requirements under the Medicare and Medicaid EHR Incentive Programs. Specifically, hospitals will be required to submit a full calendar year of data for 8 eCQMs, on an annual basis, for CY 2017 reporting for the FY 2019 payment determination and CY 2018 reporting for the FY 2020 payment determination, as further explained in section X.B.7. of the preamble of this final rule. We believe that the burden associated with submitting a full year of eCQM data will not be substantially greater than the burden associated with transmission of a single quarter of data. As described in section VII.A.10.d of the preamble of this final rule, the CMS data receiving system requires that each QRDA I file include data for one patient, per quarter, per reporting CCN. Once hospitals establish their protocols to ensure this is maintained, hospitals and vendors should not experience much added burden reporting an additional 3 quarters of data. However, in our conservative estimates here, we calculate as if burden is four times as much in an abundance of caution. In total, we expect that this newly finalized proposal will increase burden by 15,400 hours across all hospitals participating in the Hospital IQR Program. This figure was derived by calculating the difference between the FY 2017 burden estimate of 17,600 hours (80 minutes per record/60 minutes per hour × 4 reporting quarters per year × 1 record per hospital per quarter × 3,300 hospitals) and the FY 2016 burden estimate of 2,200 hours (20 minutes per record/60 minutes per hour × 1 reporting quarter per year × 1 record per hospital per quarter × 3,300 hospitals) (80 FR 49763), for an incremental increase of 15,400 hours.

As we noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49763), for validation of chart-abstracted data, we require hospitals to provide 72 charts per hospital per year (with an average page length of 1,500), including 40 charts for HAI validation and 32 charts for clinical process of care validation, for a total of 108,000 pages per hospital per year. We reimburse hospitals at 12 cents per photocopied page for a total per hospital cost of $12,960. For hospitals providing charts digitally via a re-writable disc, such as encrypted CD–ROMs, DVDs, or flash drives, we will reimburse hospitals at a rate of 40 cents per disc, and additionally hospitals will be reimbursed $3.00 per record. For hospitals providing charts via secure file transfer, we will reimburse hospitals at a rate of $3.00 per record. We will maintain these requirements for the FY 2019 payment determination and subsequent years.

In this final rule, we are expanding the existing validation process for Hospital IQR Program data to include a random sample of up to 200 hospitals for validation of eCQMs in the Hospital IQR Program. As further explained in section X.B.7. of the preamble of this final rule, we estimate that 43 hours of work for up to 200 hospitals reflects a total burden increase of 8,533 labor hours. We estimate an hourly labor cost of $32.84. Therefore, we estimate a cost increase of $280,224 (8,533 additional burden hours × $32.84 per hour) across the up to 200 hospitals selected for eCQM validation, on an annual basis.

Finally, we are updating our Extraordinary Circumstances Extensions or Exemptions (ECE) policy. We believe the updates will have no effect on burden for hospitals.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the requirements of this program. We anticipate that, because of the new requirements for reporting we are finalizing for the FY 2019 payment determination, the number of hospitals not receiving the full annual percentage increase may be higher than average. At this time, information is not available to determine the precise number of hospitals that will not meet the requirements to receive the full annual percentage increase for the FY 2019 payment determination. If the number of hospitals failing to receive the full annual percentage increase does increase because of the new requirements, we anticipate that, over the long run, this number will decline as hospitals gain more experience with these requirements.

Under OMB number 0938–1022, considering the newly finalized policies above, we estimate a total burden decrease of 1,717,444 hours, at a total cost decrease of approximately $56.4 million across approximately 3,300 hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries.

L. Effects of Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section VIII.B. of the preambles of the proposed rule (81 FR 25205 through 25213) and this final rule, we discuss our policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act.

In section VIII.B.3. of the preamble of this final rule, we are finalizing our proposed updates to one of the measures on which PCHs currently submit data: Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382). In addition, in section VIII.B.4.b. of the preamble of this final rule, we are finalizing our proposal to add one claims-based quality measure for the PCHQR Program: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.

The impact of the newly finalized requirements for the PCHQR Program is expected to be minimal overall since beginning with Q1 2016 events, PCHs have been reporting Clinical Process/Oncology Care Measures using a sampling methodology which requires reporting no more than 25 cases per facility (79 FR 28259). As the measure cohort expansion for Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) does not expand the maximum required sample, we do not anticipate that this cohort expansion will significantly impact the operational burden for PCHs.

In addition, the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure is a claims-based measure and, therefore, poses no additional burden for PCHs to submit data beyond that which they currently submit as part of the claims process.

One expected effect of the PCHQR Program is to keep the public informed of the quality of care provided by PCHs. We will display publicly the quality measure data collected under the PCHQR Program as required under the Act. These data will be displayed on the *Hospital Compare* Web site. The goals of making these data available to the public in a user-friendly and relevant format include, but are not limited to: (1) Allowing the public to compare PCHs in order to make informed health care decisions regarding care setting; and (2) providing information about current trends in health care. Furthermore, PCHs can use their own health care quality data for many purposes such as in risk management programs, healthcare associated infection prevention programs, and research and development activities, among others.

M. Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) for the FY 2018 Payment Determination and Subsequent Years

In section VIII.C.1. of the preambles of the proposed rule (81 FR 25213) and this final rule, we discuss the implementation of section 1886(m)(5) of the Act, which was added by section 3004(a) of the Affordable Care Act. Section 1886(m)(5) of the Act provides that, for rate year 2014 and each subsequent year, any LTCH that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) and (F) of the Act shall receive a 2 percentage point reduction to the annual update to the standard Federal rate for discharges for the hospital during the applicable fiscal year.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49838 through 49839), we estimated that only a few LTCHs will not receive the full annual percentage increase in any fiscal year as a result of failure to submit data under the LTCH QRP. There are approximately 432 LTCHs currently reporting quality data to CMS. At the time that this analysis was prepared, 39, or approximately 9.5 percent, of 412 eligible LTCHs were determined to be noncompliant and therefore received a 2 percentage point reduction to their FY 2016 annual payment update.

Information is not available to determine the precise number of LTCHs that will not meet the requirements to receive the full annual percentage increase for the FY 2017 payment determination.

We believe that a majority of LTCHs will continue to collect and submit data for the FY 2017 payment determination and subsequent years because they will continue to view the LTCH QRP as an important step in improving the quality of care patients receive in the LTCHs. We believe that the burden associated with the LTCH QRP is the time and effort associated with data collection.

Currently, LTCHs use two separate data collection mechanisms to report quality data to CMS: The CDC's NHSN, which is used to report all Healthcare Associated Infections (HAI) (CAUTI, CLABSI, MRSA Bacteremia, CDI, VAE) and vaccination data, (Influenza Vaccination Coverage Among Healthcare Personnel measure); and the LTCH CARE Data Set, which is submitted to the QIES ASAP system.

The data collection burden associated with reporting quality measures via the CDC's NHSN is discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49838 through 49839). These measures are stewarded by the CDC, and the reporting burden is approved under OMB control number 0920–0666.

The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals (NQF #2512) measure is calculated based on Medicare FFS claims data, and therefore does not have any associated data reporting burden for LTCHs.

The remaining assessment-based quality measure data are reported to CMS by LTCHs using the LTCH CARE Data Set. As of April 1, 2016, LTCHs use the LTCH CARE Data Set Version 3.00 (approved under OMB control number 0938–1163) which includes data elements related to the following quality measures: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678), Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680); Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674); Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632).

In this final rule, we are retaining 13 previously finalized quality measures and are adding 4 measures for use in the LTCH QRP. In section VII.C.7. of the preamble of this final rule, we are finalizing our proposals to add three measures for the FY 2018 payment determination and subsequent years: (1) MSPB–PAC LTCH QRP; (2) Discharge to Community- PAC LTCH QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for the PAC LTCH QRP. These three measures are Medicare claims-based measures, and because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there will be no additional burden for any of these newly finalized measures.

In section VIII.C.9.d. of the preamble of this final rule, we are finalizing our proposal to expand the data collection timeframe for the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) (77 FR 53624 through 53627), beginning with the FY 2019 payment determination. The data collection time frame and associated data submission deadlines are currently aligned with the Influenza Vaccination Season (IVS) (October 1 of a given year through March 31 of the subsequent year), and only require data collection during the two calendar year quarters that align with the IVS. We are finalizing our proposal to expand the data collection timeframe from just two quarters (covering the IVS) to a full four quarters or 12 months. We refer readers to section VIII.C.9.d. of the preamble of this final rule for further details on the expansion of data collection for this measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), including data collection timeframes and associated submission deadlines. We originally finalized this measure for use in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627). Although we finalized data collection for this measure to coincide with the IVS, we originally proposed year-round data collection. The associated PRA package, which was approved under OMB control number 0938–1163, included burden calculations that aligned with our original proposal for year-round data collection. All subsequent PRA packages, and the PRA package that is currently under review by OMB, included burden calculations reflecting year-round (12 month) data collection for this measure. Because of this, the newly finalized change in the data collection timeframe for this measure, and any associated burden related to increased data collection, has already been accounted for in the total burden figures included in this section of the preamble of this final rule.

In section VIII.C.7. of the preamble of this final rule, we are finalizing our proposal to adopt one measure for the FY 2020 payment determination and subsequent years: Drug Regimen Review Conducted with Follow-Up for Identified Issues- PAC LTCH QRP. In addition, we are finalizing our proposal that data for this measure will be collected and reported using the LTCH CARE Data Set Version 4.00 (effective April 1, 2018).

While reporting quality measure data involves collecting information, we believe that the burden associated with modifications to the LTCH CARE Data Set discussed in this final rule fall under the PRA exceptions provided in section 1899B(m) of the Act. Section 1899B(m) of the Act, which was added by the IMPACT Act, states that the PRA requirements do not apply to section 1899B of the Act and the sections referenced in section 1899B(a)(2)(B) of the Act that require modifications in order to achieve standardized patient assessment data. However, the PRA requirements and burden estimates will be submitted to OMB for review and approval when modifications to the LTCH CARE Data Set or other applicable PAC assessment instruments are not used to achieve standardized patient assessment data.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49838 through 49840), we discussed burden estimates for the 13 previously finalized quality measures which we are retaining in this final rule using the LTCH CARE Data Set Version 2.01. Based on a revised PRA package for the LTCH CARE Data Set Version 3.00, we estimate the total cost for the previously finalized assessment-based measures was $13,929 per LTCH annually or $6,017,146 for all LTCHs annually. In addition, we estimate that the cost to report the previously finalized quality measures via the CDC's NHSN was $10,896 per LTCH annually or $4,706,857 for all LTCHs annually. The revised total estimate for all 13 previously finalized measures was $24,825 per LTCH annually or $10,724,003 for all LTCHs annually. The two estimates discussed above, as well as the comprehensive estimate discussed below, include overhead; however, obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and firm sizes. In addition, the precise cost elements assigned as ''indirect'' or ''overhead'' costs, as opposed to direct costs or employee wages, are subject to some interpretation at the firm level. Therefore, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Because we are finalizing our proposal to add the Drug Regimen Review Conducted with Follow-Up for Identified Issues- PAC LTCH QRP measure in the LTCH CARE Data Set Version 4.00, the estimated burden and cost will increase. The additional data elements for this quality measure will take 6 minutes of nursing/clinical staff time to report data on admission and 4 minutes of nursing/clinical staff time to report data on discharge, for a total of 10 minutes. We believe that the additional LTCH CARE Data Set items we are newly finalizing will be completed by registered nurses and pharmacists. As a result, we estimate that the total cost related to the newly finalized Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP measure will be $3,080 per LTCH annually, or $1,330,721 for all LTCHs annually. Because the three measures newly finalized in section VII.C.6. of the preamble of this final rule are claims-based and will be calculated based on data that are already reported to the Medicare program for payment purposes, we believe

that there will be no additional LTCH burden for any of these newly finalized measures.

Overall, we estimate the total cost for the 13 previously adopted measures and the 4 newly finalized measures will be $27,905 per LTCH annually or $12,054,724 for all LTCHs annually. This is an average increase of 14 percent to all LTCHs over the burden discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49838 through 49840), which included all quality measures that LTCHs are required to report under the LTCH QRP, with the exception of those 4 newly finalized measures in this final rule.

We intend to continue to closely monitor the effects of the LTCH QRP on LTCHs and help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, LTCH announcements, Web site postings, CMS Open Door Forums, and general and technical help desks.

We received comments about the effects of requirements for the LTCH QRP, which we summarize and respond to below.

Comment: One commenter expressed concern about the burden associated with the development of new measures, data-collection and operational and technical data extraction. The commenter suggested that any of the quality reporting or pay-for-performance programs weigh the value of the data generated in proportion to the intensity of the data-collection effort and that the data be the most clinically relevant and actionable to the facility and its patients.

Response: Burden on providers is always a consideration for CMS, and we take this into account when developing quality measures for inclusion into our quality reporting programs. When developing new measures, we try to leverage existing data items whenever possible, and only include new items in existing data sets, when necessary to inform the calculation of these metrics. We will continue to take these and future stakeholder inputs into consideration to inform our ongoing measure development and refinement efforts.

Comment: One commenter expressed concerns about the complexities of the LTCH CARE Data Set transmittal process and associated costs implementing the LTCH CARE Data Set Version 4.00, effective April 1, 2018 after implementation of LTCH CARE Data Set Version 3.00.

Response: We thank the commenter for its comment and will consider the data transmittal process and associated cost burden as we develop the LTCH CARE Data Set Version 4.00. We have leveraged CMS claims as the data source, whenever possible and appropriate for newly introduced measures, in order to limit the burden on LTCHs. In addition, when possible, we leverage the use of existing data elements, again in an attempt to limit burden. Beyond this, we offer free software for LTCHs (LASER), allowing LTCHs to record and transmit the required LTCH CARE Data Set assessment based data. This free software, including instructions for installing and using the software, is located at: *https://www.qtso.com/laser.html*.

N. Effects of Updates to the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

As discussed in section VIII.D. of the preambles of the proposed rule (81 FR 25238 through 25244) and this final rule and in accordance with section 1886(s)(4)(A)(i) of the Act, we will implement a 2.0 percentage point reduction in the FY 2019 market basket update for IPFs that have failed to comply with the IPFQR Program requirements for FY 2019, including reporting on the required measures. In section VIII.D. of the preamble of this final rule, we discuss how the 2 percentage point reduction will be applied. For FY 2016, of the 1,684 IPFs eligible for the IPFQR Program, 51 did not receive the full market basket update because of the IPFQR Program; 24 of these IPFs chose not to participate and 27 did not meet the requirements of the program. We anticipate that even fewer IPFs will receive the reduction for FY 2017 as IPFs become more familiar with the requirements. Thus, we estimate that this policy will have a negligible impact on overall IPF payments for FY 2017.

Based on the proposals we are finalizing in this final rule, we estimate a total increase in burden due to the newly finalized addition of a chart-abstracted measure set of 212 hours per IPF or 357,008 hours across all IPFs, resulting in a total increase in financial burden of approximately $6,962 per IPF or $11,724,143 across all IPFs. We also are finalizing that we will make the data for the IPFQR Program available as soon as possible and to no longer specify in rulemaking when measure data will be publicly available, when the approximately 30-day preview period will occur, or that the preview period will begin approximately 12 weeks before the public display date, but rather to announce these using subregulatory guidance. Lastly, for the FY 2017 payment determination only, we are also finalizing our proposal that, if it is technically feasible to display the data in December 2016, we will provide data to IPFs for a 2-week preview period that will start on October 1, 2016. Moreover, we are finalizing as proposed that, as a courtesy, for the FY 2017 payment determination only, if we are able to display the data in December 2016, we will ensure that IPFs have approximately 30 days for review if they so choose by providing IPFs with their data as early as mid-September.. However, we do not expect this will change the burden on IPFs. In addition, we are finalizing our proposal to include SUB–3: Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and subset measure SUB–3a: Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664) in the list of measures covered by the global sample for the FY 2019 payment determination and subsequent years as proposed. Because the population for the SUB–3 and SUB–3a measure is nearly identical to the population for both the SUB–1 measure and the SUB–2 and SUB–2a measure (measures previously adopted into the IPFQR Program), we believe that the addition of 1 chart-abstracted measure will lead to a negligible change in burden associated with nonmeasure data collection. We also are finalizing our proposal to update the denominator exclusions for Screening for Metabolic Disorders to align with other measures eligible for the global sample. As this will not alter the number of cases that facilities are required to report on, we do not anticipate a change in IPF burden. We also estimate a total increase in burden for training personnel on chart abstraction and data collection for the newly finalized measures of 2 hours per IPF or 3,368 hours across all IPFs, resulting in a total increase in financial burden of $65.68 per IPF or $110,605 across all IPFs. Our estimate for the total increase in burden, including the newly finalized chart-abstracted measure set and training, is 360,376 hours across all IPFs, which at $32.84 labor cost per hour, totals $11,834,748. As discussed in section X.B.11. of the preamble of this final rule, we will attribute the costs associated with the newly finalized policies to the year in which these costs begin; for the purposes of all the changes made in this final rule, that year is FY 2017. Further information on these estimates can be found in section X.B.11. of the preamble of this final rule.

We intend to closely monitor the effects of this quality reporting program on IPFs and help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, and a technical help desk.

O. Effects of Requirements Regarding the Electronic Health Record (EHR) Incentive Programs and Meaningful Use

In section VIII.E. of the preambles of the proposed rule (81 FR 25244 through 25247) and this final rule, we discuss requirements for the Medicare and Medicaid EHR Incentive Programs. For CY 2017, we are finalizing the proposed CQM reporting period requirements pertaining to the Medicare and Medicaid EHR Incentive Programs; the number of CQMs eligible hospitals and CAHs are required to report by attestation; the removal of 13 CQMs from the set of CQMs available for eligible hospitals and CAHs to report; and the policy determining that the electronic submission of CQMs will require the use of the most recent version of the CQM electronic specification for each CQM to which the EHR is certified. In addition, we are finalizing a modified version of our proposed submission period requirements and the number of CQMs eligible hospitals and CAHs are required to report electronically for CY 2017. We note that these requirements will only apply for eligible hospitals and CAHs submitting CQMs electronically in CY 2017. Because these requirements for data collection will align with the reporting requirements in place for the Hospital IQR Program and because eligible hospitals and CAHs will still have the option to submit their clinical quality measures via attestation for the Medicare and Medicaid EHR Incentive Programs, we do not believe these requirements will have a significant impact.

P. Alternatives Considered

This final rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for

our decisions and, where relevant, alternatives that were considered.

Q. Overall Conclusion

1. Acute Care Hospitals

Table I of section I.G. of this Appendix demonstrates the estimated distributional impact of the IPPS budget neutrality requirements for the MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB. Table I also shows a projected overall increase of 0.9 percent in operating payments. As discussed in section I.G. of this Appendix, we estimate that operating payments will increase by approximately $987 million in FY 2017 relative to FY 2016. However, when we account for the impact of the changes in Medicare DSH payments and the impact of the additional payments based on uncompensated care in accordance with section 3133 of the Affordable Care Act, based on estimates provided by the CMS Office of the Actuary, consistent with our policy discussed in section IV.F. of the preamble of this final rule, we estimate that operating payments will increase by approximately $809 million relative to FY 2016. We currently estimate that the changes in new technology add-on payments for FY 2017 will decrease spending by approximately $20 million. In addition, the changes to the Hospital Readmissions Reduction Program for FY 2017 are estimated to decrease spending by $108 million, as a result of the inclusion of the refinement to the pneumonia readmissions measure that expanded the measure cohort, along with the addition of the CABG readmission measure, in the calculation of the FY 2017 payment adjustment factor. These estimates, combined with our estimated increase in FY 2017 operating payment of $809 million, will result in an estimated increase of approximately $680 million for FY 2017. We estimate that hospitals will experience a 0.8 percent increase in capital payments per case, as shown in Table III of section I.I. of this Appendix. We project that there will be a $66 million increase in capital payments in FY 2017 compared to FY 2016. The cumulative operating and capital payments will result in a net increase of approximately $746 million to IPPS providers. The discussions presented in the previous pages, in combination with the rest of this final rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience a decrease in estimated payments per discharge in FY 2017. In the impact analysis, we are using the rates, factors, and policies presented in this final rule, including updated wage index values and relative weights, and the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2017. Accordingly, based on the best available data for the 420 LTCHs in our database, we estimate that FY 2017 LTCH PPS payments will decrease approximately $363 million relative to FY 2016 as a result of the payment rates and factors presented in this final rule.

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the following Table V, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

The costs to the Federal Government associated with the policies in this final rule are estimated at $746 million.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2016 TO FY 2017

Category	Transfers
Annualized Monetized Transfers	$746 million.
From Whom to Whom	Federal Government to IPPS Medicare Providers.

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the payment rates and factors presented in this final rule under the LTCH PPS is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2017 relative to FY 2016 of approximately $363 million based on the data for 420 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table VI, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to the changes to the LTCH PPS. Table VI provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the payment rates and factors and other provisions presented in this final rule based on the data for the 420 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

The savings to the Federal Government associated with the policies for LTCHs in this final rule are estimated at $363 million.

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2016 LTCH PPS TO THE FY 2017 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	−$363 million.
From Whom to Whom	Federal Government to LTCH Medicare Providers.

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this final rule relating to acute care hospitals will have a significant impact on small entities as explained in this Appendix. Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. MACs are not considered to be small entities. Because we acknowledge that many of the affected

entities are small entities, the analysis discussed throughout the preamble of this final rule constitutes our regulatory flexibility analysis. In the FY 2017 IPPS/LTCH PPS proposed rule, we solicited public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we received and our responses are presented throughout this final rule.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I in section I.G. of this Appendix for the quantitative effects of the policy changes under the IPPS for operating costs.)

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately $146 million. This final rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

VI. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this final rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules, respectively. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we have made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2017 consistent with approach for FY 2016, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2017

A. FY 2017 Inpatient Hospital Update

As discussed in section IV.B. of the preamble to this final rule, for FY 2017, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment), and an additional reduction of 0.75 percentage point as required by section 1886(b)(3)(B)(xii) of the Act. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2017 adjustment of 0.75 percentage point may result in the applicable percentage increase being less than zero.

In the FY 2017 IPPS/LTCH PPS proposed rule, based on the most recent data available at that time, in accordance with section 1886(b)(3)(B) of the Act, we proposed to establish the FY 2017 market basket update used to determine the applicable percentage increase for the IPPS based on IHS Global Insight, Inc.'s (IGI's) first quarter 2016 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through fourth quarter 2015, which was estimated to be 2.8 percent. Based on the most recent data available for this FY 2017 IPPS/LTCH PPS final rule, in accordance with section 1886(b)(3)(B) of the Act, we are establishing the FY 2017 market basket update used to determine the applicable percentage increase for the IPPS on the IHS Global Insight, Inc. (IGI's) second quarter 2016 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through first quarter 2016, which is estimated to be 2.7 percent.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25077), we proposed a multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2017) of 0.5 percent. Therefore, based on IGI's first quarter 2016 forecast of the FY 2010-based IPPS market basket, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we presented in the proposed rule four possible applicable percentage increases that could be applied to the standardized amount. Based on the most recent data available for this FY 2017 IPPS/LTCH PPS final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of this final rule, we are establishing a MFP adjustment (the 10-year moving average of MFP for the period ending FY 2017) of 0.3 percent.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, as discussed in section IV.B. of the preamble of this final rule, we are establishing the applicable percentages increases for the FY 2017 updates based on IGI's second quarter 2016 forecast of the FY 2010-based IPPS market basket, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, as outlined in the table below.

FY 2017	Hospital submitted quality data and is a meaningful EHR User	Hospital submitted quality data and is NOT a meaningful EHR User	Hospital did NOT submit quality data and is a meaningful EHR User	Hospital did NOT submit quality data and is NOT a meaningful EHR User
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.025	0.0	−2.025
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.3	−0.3	−0.3	−0.3
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Applicable Percentage Increase Applied to Standardized Amount	1.65	−0.375	0.975	−1.05

B. Update for SCHs and MDHs for FY 2017

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2017 applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS).

As discussed in section IV.N. of the preamble of this final rule, section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017).

As previously mentioned, the update to the hospital-specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are establishing the same four possible applicable percentage increases in the table above for the hospital-specific rate applicable to SCHs and MDHs.

C. FY 2017 Puerto Rico Hospital Update

As discussed in section IV.A. of the preamble of this final rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this final rule. Accordingly, for FY 2017, we are establishing an applicable percentage increase of 1.65 percent to the standardized amount for hospitals located in Puerto Rico.

D. Update for Hospitals Excluded From the IPPS for FY 2017

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. As we finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50156 through 50157), we are applying the FY 2017 percentage increase in the IPPS operating market basket to the target amount for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. For this final rule, the current estimate of the IPPS operating market basket percentage increase for FY 2017 is 2.7 percent.

E. Update for LTCHs for FY 2017

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this final rule, we are establishing an update to the LTCH PPS standard Federal rate for FY 2017 based on the full revised and rebased 2013-based LTCH PPS market basket increase estimate subject to an adjustment based on changes in economy-wide productivity and an additional reduction required by sections 1886(m)(3)(A)(ii)(I), 1886(m)(3)(A)(ii), and 1886(m)(4)(F) of the Act. In accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are reducing the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of an LTCH to submit the required quality data. The MFP adjustment described in section 1886(b)(3)(B)(xi)(i) of the Act is currently estimated to be 0.3 percent for FY 2017. In addition, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) Act require that the annual update for FY 2017 be reduced by the ''other adjustment,'' which is 0.75 percentage point. Based on the most recent data available for this final rule, that is, IGI's second quarter 2016 forecast of the FY 2017 LTCH PPS market basket increase, we are establishing an annual update to the LTCH PPS standard Federal rate of 1.75 percent (that is, the current FY 2017 estimate of the market basket rate-of-increase of 2.8 percent less an adjustment of 0.3 percentage point for MFP and less 0.75 percentage point). Accordingly, we are applying an update factor of 1.0175 percent in determining the LTCH PPS standard Federal rate for FY 2017. For LTCHs that fail to submit quality data for FY 2017, we are applying an annual update to the LTCH PPS standard Federal rate of -0.25 percent (that is, the annual update for FY 2017 of 1.75 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying an update factor of 0.9975 percent in determining the LTCH PPS standard Federal rate for FY 2017.

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update in the amount specified in current law for FY 2017. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to

the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa of 2.7 percent.

For FY 2017, consistent with policy set forth in section VII. of the preamble of this final rule, for LTCHs that submit quality data, we are recommending an update of 1.75 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2017, we are recommending an annual update to the LTCH PPS standard Federal rate of −0.25 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2016 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates in the amount specified in current law. We refer the reader to the March 2016 MedPAC report, which is available for download at *www.medpac.gov* for a complete discussion on this recommendation. MedPAC expects Medicare margins to remain low in 2016. At the same time, MedPAC's analysis finds that efficient hospitals have been able to maintain positive Medicare margins while maintaining a relatively high quality of care.

Response: We agree with MedPAC and, consistent with current law, we are applying an applicable percentage increase for FY 2017 of 1.65 percent, provided the hospital submits quality data and is a meaningful EHR user, consistent with statutory requirements.

We note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The update to the capital rate is discussed in section III. of the Addendum to this final rule.

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Part III

Department of Justice

28 CFR Part 32
Public Safety Officers' Benefits Program; Proposed Rule

DEPARTMENT OF JUSTICE

28 CFR Part 32

[Docket No.: OJP (BJA) 1722]

RIN 1121–AA86

Public Safety Officers' Benefits Program

AGENCY: Office of Justice Programs, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This rulemaking proposes to make the following changes to current regulations implementing the Public Safety Officers' Benefits (PSOB) Act: Revising provisions pertaining to the filing of an application for benefits, revising provisions that define when an individual is a public safety officer, when an officer has sustained a line-of-duty injury, when payment of benefits is prohibited, and when individuals are ineligible for payment; revising provisions pertaining to the admissibility, sufficiency, and evaluation of evidence submitted in PSOB claims; revising provisions concerning the fees that may be charged for representation in PSOB claims, establishing provisions that prescribe the scope of legal review of PSOB claims and the completeness of applications for benefits, and revising provisions pertaining to the definitions of permanent and total disability, payment of benefits, educational assistance, and other matters necessary to implement the aforementioned changes.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before October 21, 2016. Comments received by mail will be considered timely if they are postmarked on or before that date. The electronic Federal Docket Management System (FDMS) will accept comments until Midnight Eastern Time at the end of that day.

ADDRESSES: Please address all comments regarding this rule by U.S. mail, to: Hope Janke, Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street NW., Washington, DC 20531; or by telefacsimile to (202) 354–4135. To ensure proper handling, please reference OJP Docket No. [insert number] on your correspondence. Comments may also be sent electronically through *http://regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://regulations.gov* Web site. OJP will accept attachments to electronic comments in Microsoft Word, WordPerfect, or Adobe PDF formats only.

FOR FURTHER INFORMATION CONTACT: Hope Janke, BJA, OJP, at (202) 514–6278, or toll-free at 1 (888) 744–6513.

SUPPLEMENTARY INFORMATION:

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I. Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov.* Information made available for public inspection includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

The Office of Justice Programs (OJP) does not require you to submit personal identifying information (such as your name, address, medical information etc.) as part of your comment. However, if you wish to submit such information, but do not wish it to be posted online, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also locate all the personal identifying information that you do not want posted online in the first paragraph of your comment and identify what information you want the agency to redact. Personal identifying information identified and located as set forth above will be placed in the agency's public docket file, but not posted online.

If you wish to submit confidential business information as part of your comment but do not wish it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, the agency may choose not to post that comment (or to only partially post that comment) on *http://www.regulations.gov.* Confidential business information identified and located as set forth above will not be placed in the public docket file, nor will it be posted online.

If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

II. Executive Summary

A. Purpose of the Regulatory Action

1. Need for Regulatory Action

The Public Safety Officers' Benefits Act of 1976 (PSOB Act) was enacted to address the emotional and economic burden placed on the families of deceased public safety officers by providing the assurance of a federal benefit to such survivors.[1] As recently as 2012, the House Committee on the Judiciary reaffirmed this purpose stating ''[t]he [Public Safety Officers' Benefits Act] . . . is an important resource for the public safety officers and their families who would potentially face financial disaster because of the death or incapacitation of the public safety officer.'' [2]

As of February 1, 2016, 931 claims for benefits were pending before the agency: 761 initial claims for benefits pending at the PSOB Office, 123 appeals of PSOB Office determinations pending with Hearing Officers, and 47 appeals of Hearing Officer determinations pending with the BJA Director. A recent audit by the Department of Justice's Office of the Inspector General (OIG) found that although the PSOB Program processed 56% of determined claims within one year of filing, other claims took significantly longer to resolve.[3] A Business Process Improvement (BPI) review of the PSOB Program completed by an independent contractor in October 2015 noted, among other things, that ''the combination of the lengthy processing times and the growing backlog of open claims indicates significant changes are needed for the program to operate efficiently and process existing and new claims in a timely manner.''

To fulfill Congress' intent that the PSOB Program remain ''an important resource'' for public safety officers and their families, the proposed rulemaking would amend regulations implementing the Act to implement recommendations from the OIG audit and BPI review, simplify the process for claimants to establish eligibility, simplify the program, and implement statutory changes to the PSOB Act.

2. Statement of Authority for Regulatory Action

Under 42 U.S.C. 3796(a)–(b) (authorizing the agency to promulgate

[1] *See* S. Rep. No. 94–816, at 3–4, as reprinted in 1976 U.S.C.C.A.N. 2504, 2505.

[2] H.R. Rpt. 112–548 at 6 (Jun. 25, 2012).

[3] U.S. Dept. of Justice, Office of the Inspector General, *Audit of the Office of Justice Programs' Processing of Public Safety Officers' Benefit Programs Claims,* Audit Division 15–21 at 8 (July 7, 2015).

regulations for the determination of PSOB Program death and disability claims), 3796c(a) (authorizing the agency to promulgate regulations for (1) the determination of PSOB Program death and disability claims, (2) ''the recognition of agents or other persons representing claimants'' in PSOB death and disability claims, and (3) the establishment of ''the maximum fees which may be charged for services performed in connection with any claim''), 3796d–3(a) (authorizing the agency to promulgate regulations for implementing PSOB Educational Assistance programs), and 3782(a) (authorizing the agency to establish regulations ''necessary to the exercise of [its] functions''), the agency is authorized to promulgate regulations necessary to implement the PSOB Act. The agency has previously exercised its regulatory authority to define in regulations many of the terms essential to this rulemaking including ''public agency,'' ''injury,'' ''line of duty,'' ''line of duty injury,'' ''official capacity,'' ''firefighter,'' ''involvement [in crime and juvenile delinquency control or reduction],'' ''gross negligence,'' and ''voluntary intoxication.''

B. Summary of Major Provisions

The proposed rule would make the following changes in response to the Dale Long Public Safety Officers' Benefits Improvement Act of 2012 (Dale Long Act), as provided in sec. 1086 of Public Law 112–239:

- Revise the definition of ''child of a public safety officer;''
- Define ''line of duty activity or action'' for members of rescue squads and ambulance crews;
- Revise the definition of ''officially recognized or designated public employee member of a squad or crew;''
- Remove the definition of ''public employee member of a squad or crew;'' and
- Remove for purposes of educational assistance definitions of ''dependent,'' ''eligible dependent,'' and ''tax year.''

The proposed rule would make the following changes in response to identified ambiguities and gaps in existing regulations, as well as opportunities to simplify and improve the program's administration:

- Expand the definitions of ''firefighter,'' and ''involvement [in crime and juvenile delinquency control or reduction]'' (a necessary component to qualify as a ''law enforcement officer'') to include firefighter and law enforcement officer trainees who are participants in an official training program required for employment or certification as a firefighter or a law enforcement officer;
- Expand the definitions of ''line of duty activity or action'' and ''official capacity'' to include a public safety officer's actions to save human life in certain limited circumstances but without regard to jurisdiction;
- Introduce a definition of ''volunteer fire department'' which provides that a department satisfying the definition qualifies as an ''instrumentality'' of a public agency thereby enabling otherwise qualified volunteer firefighters to more easily establish ''public safety officer'' status;
- Replace the current standard for determining admissibility of evidence (the Federal Rules of Evidence) with the requirement that evidence be ''credible, probative, and substantial;''
- Replace existing prerequisite certification requirements for death and disability claims with a single provision authorizing PSOB determining officials to require that a claimant provide any evidence necessary to determine eligibility;
- Establish a limited exception to the requirement that a claimant must establish all issues by the standard of proof of ''more likely than not;'' when evidence is equivalent on a particular issue, the determining official will resolve such issue in the claimant's favor;
- Change from ''clear and convincing'' to ''more likely than not'' the standard of proof required to establish (1) an officer was injured because of his or her status as a public safety officer, (2) total and permanent disability, and (3) parent-child relationship;
- Expand the types of permissible fee arrangements for representative services, establish a definition for ''attorney'' and limit paid representation in PSOB claims to such individuals;
- Establish, consistent with authority in 42 U.S.C. 3796c(a) providing that the Bureau of Justice Assistance may prescribe in regulations ''the maximum fees which may be charged for services performed in connection with any claim,'' a cap on fees of 12 percent of the total payment available to a claimant and establish fee amounts that are presumptively reasonable in claims determined at the PSOB Office level (8 percent) and at the Hearing Officer or BJA Director level (10 percent);
- Revise the definition of ''totally disabled'' and related provisions to address circumstances when a claimant performs work that is compensated but not substantial; and
- Require individuals seeking benefits to file minimum required documents (a complete application) before the agency will treat the application as a claim for benefits.

C. Projected Costs and Benefits

The proposed rule is not economically significant as defined in Executive Orders 12866 and 13563. The estimated annual increase in PSOB Program death and disability benefit costs is $3,398,810, which equates to 10 additional determinations approving death or disability benefits as compared to the number of annual approvals under existing rules. There is no significant projected increase in administrative or personnel costs. OJP estimates that the rulemaking will result in (1) reduced burden for claimants in establishing eligibility for benefits, (2) timelier processing of all claims for death and disability benefits, and (3) improved delivery of benefits to eligible claimants.

III. Background

The Public Safety Officers' Benefits (PSOB) Program, 42 U.S.C. 3796 *et seq.* (established pursuant to the Public Safety Officers' Benefits Act of 1976), is administered by the Bureau of Justice Assistance (BJA) of the Office of Justice Programs (OJP), U.S. Department of Justice. Generally speaking, the PSOB Program provides a one-time financial benefit, currently adjusted for inflation at $339,881, to the statutorily-eligible survivors of public safety officers who die as the direct and proximate result of personal injuries sustained in the line of duty, as well as educational assistance for their spouses and eligible children. Alternatively, the PSOB Program also provides the same inflation-adjusted one-time financial benefit directly to public safety officers determined to be permanently and totally disabled as the direct and proximate result of personal injury sustained in the line of duty, as well as educational assistance for their spouses and eligible children.

Under 42 U.S.C. 3796(a), an individual seeking PSOB Program death benefits must establish the following: (1) That the deceased was a public safety officer as defined in 42 U.S.C. 3796b, (2) that the officer died as the direct and proximate result of an injury, (3) that the officer's injury was sustained in the line of duty, (4) that the claimant is an eligible beneficiary as identified in 42 U.S.C. 3796(a)(1)–(6), and (5) that no limitations in 42 U.S.C. 3796a, *e.g.,* the decedent's voluntary intoxication or gross negligence, bar recovery. Under 42 U.S.C. 3796(b), an individual seeking PSOB Program disability benefits must establish many of the same facts: (1) That the claimant was a public safety

officer as defined in 42 U.S.C. 3796b, (2) that the officer is permanently and totally disabled, (3) that such disability was the direct and proximate result of an injury, (4) that the officer's injury was sustained in the line of duty, and (5) that no limitations in 42 U.S.C. 3796a bar recovery. Under 42 U.S.C. 3796d–1, the spouse or child of a public safety officer determined to have been killed or permanently and totally disabled as the direct and proximate result of an injury sustained in the line of duty is eligible under 42 U.S.C. 3796d–1 to receive financial assistance for purposes of pursuing a program of higher education provided that the claimant is attending or has successfully completed a qualified education program.

The agency last published comprehensive regulations for the PSOB Program in December 2008. *See* 73 FR 76520 (Dec. 17, 2008). Since that time, the Dale Long Act was enacted, which made several significant amendments to the PSOB Act. Recently, in a separate notice of proposed rulemaking (NPRM) published in the **Federal Register** on on July 15, 2016, 81 FR 46019, the agency proposed regulations that would, among other things, implement the Dale Long Act's provisions offsetting certain payments, and ensure that the regulations reflect updated statutory language regarding the presumption in 42 U.S.C. 3796(k) covering certain heart attacks, strokes, and vascular ruptures. The present NPRM addresses other provisions in the Dale Long Act that the agency believes would benefit from rulemaking.

In addition to the Dale Long Act necessitating regulatory revisions, the agency has identified the need to revise its regulations to reflect current interpretations and practice. Since the last comprehensive regulatory revision in 2008, OJP has determined over 2,582 PSOB claims.[4] In so doing, it has identified ambiguities and gaps in existing regulations, as well as opportunities to simplify and improve the program's administration, while maintaining program integrity.

IV. Section-by-Section Analysis

Section 32.2 Computation of Time; Filing

Section 32.2 provides general definitions and guidance as to when something is ''filed'' with the PSOB Office or other PSOB determining officials. Other regulations, *e.g.,* 28 CFR 32.12(a), establish time frames for when a particular type of claim must be filed and provide that the BJA Director may waive the time requirements for good cause shown. Neither the PSOB Act nor its implementing regulations, however, defines what constitutes ''good cause.'' To establish uniform and transparent criteria for consistently evaluating what constitutes good cause, the proposed rule would add a new paragraph (e) describing the circumstances that may constitute good cause and warrant a waiver permitting an individual to file out of time. Under proposed § 32.2(e), circumstances beyond the individual's control such as lengthy illness or physical or mental incapacity, detrimental reliance on erroneous information provided by the public safety officer's agency, public agency determination of the officer's (or survivor's) eligibility or entitlement to death or disability benefits after the time for filing has passed, or other unavoidable circumstances showing that an individual could not have reasonably known about the time limits for filing may establish good cause. Examples of evidence establishing ''good cause' would include a statement or affidavit from the individual seeking the extension or other person with knowledge of the particular basis for the extension. The proposed rule would limit the scope of the aforementioned exceptions by providing that, consistent with current practice, a lack of knowledge about the PSOB Program is not a valid basis for establishing good cause.

In addition, in preparation for going to a ''paperless'' claims processing system, proposed § 32.2(h) would permit the BJA Director, after publishing a Notice in the **Federal Register** consistent with 5 U.S.C. 552(a)(1)(C), and providing reasonable notice through the PSOB Program Web site, to require that all claims and supporting documents be filed in electronic form.

Section 32.3 Definitions

Section 32.3 provides definitions applicable to all three PSOB Program components, death, disability, and education. OJP proposes to amend the existing definitions in § 32.3 as follows:

- *Agent:* Under 42 U.S.C. 3796c, the agency is authorized to promulgate ''regulations governing the recognition of agents or other persons representing claimants.'' The agency has exercised its regulatory authority to establish in current § 32.7 provisions governing the circumstances under which representatives may charge fees for representative services in a claim for benefits under the PSOB Act. However, the current rules do not define the categories of individuals authorized to provide representative services in PSOB claims and the agency believes that such definitions are necessary for the implementation of proposed rules providing the categories of individuals that may charge fees for representative services. The proposed rule would define ''agent'' as an individual who represents persons seeking PSOB Program benefits and is not an attorney.
- *Attorney:* Pursuant to the authority granted by 42 U.S.C. 3796c(a) providing that the agency may promulgate regulations for purposes of recognizing the agents or other persons representing claimants under the PSOB Act, the proposed rule would define the term ''attorney'' as a member in good standing of a State bar. The agency believes that membership in good standing in a State bar is a reliable indicator that such a person would be capable of providing competent and ethical representation in a claim before the agency. This rule is intended to work in conjunction with proposed § 32.7, which would limit the ability to seek fees for representative services to attorneys as defined in this provision.
- *Authorized commuting:* the proposed rule would clarify that a public safety officer's return travel from responding to a fire, rescue, or police emergency is considered to be in the line of duty.
- *Child of a public safety officer:* From the time of the enactment of the PSOB Act in 1976,[5] until January 1, 2013, an individual's status as a child was determined based on the individual's status at the time of the public safety officer's death. Effective January 2, 2013, for all claims pending before BJA on that date, or filed or accruing thereafter, an individual's status as a child is determined at the time of the public safety officer's fatal (or catastrophic, for disability claims), injury.'' The revised rule implements the statutory change by removing provisions inconsistent with the amendment such as those that refer to a ''child [] adopted by [the officer] after the injury date'' and retaining the requirement that an officer's parental rights must be intact as of the officer's injury date to establish that an individual was ''a child of a public safety officer.''
- *Department or agency:* The PSOB Act, for most purposes, defines a public safety officer as an individual serving a public agency in an official capacity as a law enforcement officer, firefighter, or chaplain. 42 U.S.C. 3796b(9)(A). As defined in 42 U.S.C. 3796b(8), the term

[4] Claims determined at the PSOB Office, Hearing Officer, and BJA Director levels between December 17, 2008 and February 1, 2016.

[5] Public Law 94–430, 90 Stat. 1346, 1347 (1976).

public agency generally refers to a unit of government at the federal, state, or local level, and includes subordinate entities of such governments such as a ''department'' or ''agency'' as well as an ''instrumentality'' of any of the aforementioned entities. Nothing in the statutory definition of ''public agency'' or the regulatory definitions of ''instrumentality'' or ''department or agency'' in 28 CFR 32.3 expressly addresses or covers those entities created by interstate compact, many of which perform public safety activity pursuant to the terms of the compact (*e.g.,* the Washington Metropolitan Area Transit Authority or the Port Authority of New York and New Jersey). Because OJP has consistently interpreted the terms ''public agency'' and ''department or agency'' to include such entities, it proposes to add a new provision in 28 CFR 32.3 (defining *Department or agency)* to make this interpretation clear. Under the proposed rule, the definition of ''department or agency'' would include an entity created by interstate compact between two or more States or between a State(s) and the District of Columbia with the consent of the United States Congress.

• *Determination:* Consistent with the proposed removal of current § 32.27, which provides claimants with the option to seek reconsideration of an adverse disability determination, the proposed rule would eliminate from the definition of ''determination'' reference to such a motion.

• *Divorce:* Under the current regulation, a spouse or purported spouse of an individual may be found to be ''divorced'' for purposes of the PSOB Program if, after the marriage or purported marriage, the spouse or purported spouse holds himself out as being divorced from, or otherwise not married to the individual, holds himself out as being married to another individual, or is a party to a marriage ceremony with another individual. The agency's experience with such non-judicial divorce, particularly with long-estranged parties, is that evidence of such acts is inherently unreliable. To make more reliable agency findings of divorce and simplify the administration of the program, the proposed rule would eliminate as a basis for finding ''divorce'' all dissolutions of marriage other than ordered by a court.

• *Employee:* The proposed rule would clarify, pursuant to the statutory limitation in 42 U.S.C. 3796a(5), that the term does not include any active-duty member of the armed forces.

• *Firefighter:* Absent from the language of the PSOB Act is any mention of whether public safety officer candidates or trainees qualify as public safety officers. In a recent report, the House Judiciary Committee noted that ''certain provisions of the [PSOB Act] have the effect of excluding from the program some classes or subclasses of safety officers and of trainees who might better be included under certain circumstances,'' including police academy and firefighter trainees.[6]

Under current regulations, a firefighter trainee, even if participating in a fire suppression exercise of the trainee's public agency that is mandatory for his or her certification or employment as a firefighter by his or her public agency, generally does not qualify as a ''public safety officer'' for purposes of the PSOB Act. This is because the regulatory definition of ''firefighter'' requires that a firefighter possess, among other things, the legal authority and responsibility to engage in the suppression of fire outside of the training environment to be considered a ''public safety officer.'' As a result, such trainees are ineligible except where a trainee has the legal authority and responsibility to act without limitation at the time of the injury.[7]

As demonstrated by the claims for death benefits submitted on behalf of trainees, the hazards faced while participating in training mandatory to serve a public agency as a firefighter (*e.g.,* the suppression of fire), are similar to that encountered in serving the public. Accordingly, OJP believes that a limited expansion of the current rule to include trainees is warranted.

The proposed rule expands the definition of ''firefighter'' to cover an individual who participates in an official training program of the officer's public agency involving the suppression of fire or hazardous-material response that is mandatory for the individual's employment or certification as a firefighter with a particular public agency. The proposed rule would permit payment on behalf of any individual who died or to any who was permanently and totally disabled as the direct and proximate result of an injury sustained while participating in such training.

• *Gross negligence:* Under 42 U.S.C. 3796a(3), the agency is prohibited from paying benefits when, at the time of the officer's fatal or catastrophic injury, the officer is performing his or her duties in a grossly negligent manner. Under the current definition in 28 CFR 32.3, ''gross negligence'' is established when the officer's performance of duty indicates an extraordinary departure from the appropriate degree of care, *e.g.,* a heedless, wanton, or reckless action, and occurs in the face of significant hazards, where serious injury or damage is likely to follow, or where great danger is readily apparent. The agency's experience is that the current rule is difficult to apply in part due to the multiple terms defining the degree of deviation from the standard of care required to establish such negligence as well as the breadth of circumstances under which such a deviation would establish such negligence.

The proposed rule streamlines the definition by using a single term, ''reckless,'' to describe the deviation from the appropriate standard of care, and by using a single set of conditions, ''under circumstances where it is highly likely that serious harm will follow,'' to describe the conditions under which such misconduct would implicate the statutory bar to payment in 42 U.S.C. 3796a(3). The proposed rule also provides that the standard for measuring a public safety officer's conduct is that of a similarly situated public safety officer. The proposed rule is intended to simplify the agency's application of this statutory bar to payment and limit its application to those circumstances in which it is apparent that the officer's gross negligence was a substantial contributing factor in the officer's injury.

• *Injury:* To establish an ''injury'' under current 28 CFR 32.3, a public safety officer must have sustained a traumatic physical wound or traumatized physical condition of the body that is the direct and proximate result of an external force or other factor listed in the definition, including, among other things, chemicals, bacteria, or climatic conditions.

The current rule expressly excludes from coverage as an injury ''occupational disease'' or ''any condition of the body caused or occasioned by stress or strain,'' both of which are defined further in 28 CFR 32.3. Under current regulations, conditions caused by stress or strain and thus excluded from coverage as an injury generally include those caused by physical exertion; chronic, cumulative, and progressive conditions; cardiovascular disease; and heart attacks, strokes, and vascular ruptures.

The agency's experience is that the current regulatory requirement that an

[6] H.R. Rpt. 112–548 at 8–9 (June 25, 2012).

[7] As a result of the current definition of ''firefighter,'' a trainee firefighter who is killed or permanently disabled while participating in an official training program of his or her public agency, that is mandatory for the trainee's certification or employment as a firefighter with that particular public agency, is ineligible for benefits under the PSOB Act by virtue of not qualifying as a ''public safety officer.''

injury must in all cases be the result of an external force or factor, taken together with the current ''stress or strain'' exclusion, excludes from coverage under the PSOB Act all physical conditions caused by exertion. As a result of the current definitions, an officer's death or disability from an acute and immediate physical condition such as exertional heatstroke or rhabdomyolysis [8] would not be eligible for benefits. While retaining the longstanding interpretation that an injury under the PSOB Act is a traumatic physical wound or traumatized physical condition of the body directly and proximately caused by external forces or factors, the proposed rule would provide, consistent with BJA's current interpretation, that injury also includes acute and immediate musculoskeletal strain or muscle damage, and heatstroke, each of which may be established as an acute condition, and without an external force or factor.

In addition, the agency's experience in determining claims suggests that the definition of injury should be revised to make clear current agency interpretations that may not be obvious or intuitive to claimants and other stakeholders. The current definition of injury does not reflect the agency's interpretation that an increase in the severity of an officer's pre-existing physical wound or condition—regardless of the cause of the pre-existing wound or condition—is an injury under the PSOB Act so long as the increase in severity is itself the direct and proximate result of a line of duty injury. The proposed rule would provide that such aggravation of pre-existing conditions would constitute an injury. In stating that certain aggravation of a pre-existing injury may constitute an injury for purposes of the PSOB Program, the proposed rule clarifies that a pre-existing injury is not automatically excluded from consideration as the substantial factor in an officer's death or permanent and total disability.

Based on the claims it has received, the agency believes that the regulatory definition of ''injury'' together with the separate definition of stress or strain, have proven very challenging for claimants to understand and apply, particularly to fatal heart attacks, strokes, and vascular ruptures. The agency believes that this is in part due to the absence from the current definitions the agency's longstanding interpretation that heart attacks and strokes, absent an external force or factor shown to have directly and proximately caused such condition, are not injuries. The agency's interpretation dates back to the first PSOB regulations published in 1977, 42 FR 23252, 23260 (May 6, 1977), and has been upheld in a series of court decisions.[9]

Heart attacks, strokes, and vascular ruptures are eligible for death benefits under the presumption created by the Hometown Heroes Survivors' Benefits Act of 2003 (Pub. L. 108–182) (Hometown Heroes Act) and amended by the Dale Long Public Safety Officers' Benefits Improvement Act of 2012 (Pub. L. 112–239). Together, these amendments have established a rebuttable presumption that a heart attack, stroke, or vascular rupture satisfying the requirements of 42 U.S.C. 3796(k) constitutes a personal injury sustained in the line of duty. Generally speaking, the presumption is established in cases where a public safety officer sustains heart attack, stroke, or vascular rupture while engaging in a situation involving ''nonroutine stressful or strenuous physical [line of duty] . . . activity'' or participating in a training exercise ''involving nonroutine stressful or strenuous physical activity'' (or within 24 hours of such engagement or participation) and the heart attack, stroke, or vascular rupture is the direct and proximate cause of the officer's death. Though not directly related to the definition of injury under § 32.3, in an NPRM published in the **Federal Register** on July 15, 2016, 81 FR 46019, the agency proposed regulations that would define the circumstances under which the presumption is rebutted in amended 42 U.S.C. 3796(k).

To make the agency's interpretation clear, the proposed rule would eliminate the separate definition of stress or strain and would incorporate those conditions excluded by that definition directly into the definition of injury. In so doing, the proposed rule would identify specific types of conditions excluded from the definition of injury including: ''any chronic, cumulative, or progressive condition of the body,'' and ''cardiovascular disease.'' To clarify for claimants and the general public that, under 42 U.S.C. 3796(k), certain heart attacks, strokes, and vascular ruptures may be presumed to be a personal injury, the proposed rule would so state.

Similarly, the current definition of injury does not, by itself, clearly reflect the agency's longstanding interpretation that mental health conditions including post-traumatic stress disorder (PTSD) or anxiety do not constitute an injury, and therefore, the basis of a disability, under the PSOB Act. By way of background, the Law Enforcement Assistance Administration (LEAA) defined the term ''traumatic injury'' in 1977 as excluding ''stress and strain.'' Referring to the legislative history of the PSOB Act, and, in particular, the definition of ''personal injury'' in the House Judiciary Committee Reports, the LEAA stated that ''[d]eaths caused by traumatic injuries do not therefore include deaths directly attributable to exertion or stress encountered in the performance of duty.'' [10] Further supporting LEAA's original interpretation, a 2001 case in the United States Court of Appeals for the Federal Circuit found permissible BJA's regulatory definition ''exclud[ing] from the definition of 'traumatic injury' stress and strain.'' [11] In explaining its conclusion, the court stated that ''the legislative history [of the PSOB Act] points away from an intent on the part of Congress to have the statutory term 'personal injury' include mental strain.'' [12] More recently, in a House Report describing, among other things, amendments to the statute authorizing payment of disability benefits, 42 U.S.C. 3796(b), the Committee on the Judiciary stated that ''a disability benefit is payable only when the Department determines that a public safety officer has sustained a line of duty injury whose direct *physical consequences* permanently prevent the performance of any gainful work.[13]

To better communicate the agency's longstanding interpretation regarding the ineligibility of mental health conditions for PSOB Program benefits, the revised definition of injury would expressly provide that mental health

[8] ''Rhabdomyolysis is the breakdown of muscle tissue that leads to the release of muscle fiber contents into the blood. These substances are harmful to the kidney and often cause kidney damage.'' It may be caused by, among other things, ''severe exertion, such as marathon running or calisthenics.'' National Institutes of Health (MedlinePlus), *Rhabdomyolysis, https://www.nlm.nih.gov/medlineplus/ency/article/000473.htm* (accessed Feb. 11, 2016).

[9] *See e.g., Juneau* v. *Dept. of Justice,* 583 F.3d 777, 782–83 (Fed. Cir. 2009) (holding that an officer's heart attack following a foot chase of shoplifting suspects did not warrant payment of PSOB death benefits as the officer's traumatic condition, *i.e.,* a heart attack, was not caused by an injury as defined in PSOB regulations); *see also Smykowski* v. *United States,* 647 F.2d 1103, 1106 (Ct. Cl. 1981) (concluding that an officer's physical struggle with a suspect immediately preceding a fatal heart attack, although different from stress or strain and cognizable itself as a traumatic event, was not an injury under the PSOB Act.)

[10] 42 FR 23252, 23260, May 6, 1977.

[11] *Yanco* v. *United States* 258 F.3d 1356, 1363 (Fed. Cir. 2001).

[12] *Id.* at 1364.

[13] H.R. Rep. No. 112–548 at 13 (2012) (emphasis added).

conditions are excluded from consideration as an ''injury.''

• *Injury date:* Under current regulations defining ''injury date,'' such date generally means the time of the line of duty injury that directly and proximately resulted in the death or permanent and total disability of the public safety officer. Current regulations do not define when an injury occurs for purposes of 42 U.S.C. 3796(k) for purposes other than ''determining beneficiaries under the Act.'' As the ''injury date'' in a claim based on 42 U.S.C. 3796(k) is relevant for other purposes (*e.g.,* determining voluntary intoxication), the proposed rule would define injury date in such a claim. The proposed rule would provide that, for all purposes relating to 42 U.S.C. 3796(k), injury date means the time of the officer's qualifying engagement or participation referred to in the Act at 42 U.S.C. 3796(k)(1)).

• *Involvement:* Under current regulations, a law enforcement officer trainee, even while participating in an official training program that is mandatory for his or her certification or employment as a law enforcement officer (*e.g.,* firearms training), is generally not a ''public safety officer'' for purposes of the PSOB Act. This is because the regulatory definition of ''involvement'' requires that a law enforcement officer possess, among other things, the unrestricted ''legal authority and -responsibility'' to arrest or apprehend . . . persons for violations of criminal law to qualify as a ''public safety officer.'' As a result, such trainees are ineligible except in the unusual circumstances in which a trainee has the legal authority and responsibility to act as a law enforcement officer without limitation at the time of the injury.[14]

As demonstrated by the claims for death benefits submitted on behalf of trainees, the hazards faced while participating in training mandatory to be serve a public agency as a law enforcement officer (*e.g.,* firearms training, unarmed self-defense, or physical training) are similar to what may be encountered in serving the public. Accordingly, a limited expansion of the current rule to include such circumstances is warranted.

The proposed rule expands the definition of ''involvement'' to cover as a ''law enforcement officer'' any individual who participates in an official training program of the individual's public agency that is mandatory for that individual's employment or certification in certain law enforcement positions such as a police officer, corrections officer, probation officer, or equivalent. The proposed rule would permit payment on behalf of any individual who died or to any who was permanently and totally disabled as the direct and proximate result of an injury sustained while participating in such mandatory training.

• *Line of duty activity or action:* The proposed rule would provide that certain activities or actions of a law enforcement officer or firefighter, performed under emergency circumstances and necessary to save or protect human life, in any jurisdiction, would be deemed to be line of duty activity or action for purposes of the PSOB Act.

Under 42 U.S.C. 3796(a) and (b), the agency pays death or disability benefits when it determines that a public safety officer has died or become permanently and totally disabled as ''the direct and proximate result of a personal injury sustained in the line of duty.'' Under current regulations, a public safety officer's action or activity and resulting injury is ''in the line of duty'' only if it is an action or activity that the officer is legally authorized or obligated to perform as a public safety officer and the officer's public agency recognizes it as such.[15] Where an officer acts outside his or jurisdiction, even if acting in an emergency to save human life, such actions are generally outside the legal authority of the officer's public agency and, as a result, excluded from PSOB Act coverage as not ''in the line of duty.''

As guardians of the public, public safety officers are trained to and called upon to engage in extraordinary acts of self-sacrifice and bravery to save the lives of others. However, these acts may not always occur within an officer's jurisdiction. The regulations which require that an officer's public agency affirm, or at least, not deny, that a public safety officer had the legal authority and responsibility to perform such actions, as currently written, do not take into account the extraordinary situations which require an urgent and immediate response and do not afford a public safety officer an opportunity to seek approval or authorization to act.

Within the context of the PSOB Program, BJA recognizes that public safety officers, by virtue of their training, expertise, and experience, are often compelled to act where human life is endangered. Moreover, a public safety officer's training and experience make them uniquely qualified to intervene to save human life. Accordingly, BJA believes that the actions of public safety officers, *i.e.,* firefighters and law enforcement officers, in these extraordinary and limited circumstances should be covered by the PSOB Program.

As the PSOB Act does not define ''line of duty'' and expressly delegated to the agency in 42 U.S.C. 3796(c) the authority to promulgate implementing regulations, the agency may interpret the term ''line of duty'' in regulations so long as the interpretation is not arbitrary, capricious, or contrary to law.[16] The agency's proposed regulatory interpretation recognizes, consistent with the language of 42 U.S.C. 3796(a) and (b), that ''[t]he word 'duty' connotes a legal or moral obligation'' and that ''[i]n reference to public safety officers, 'duty' refers to the obligation to protect the public in their capacity as firefighters or police officers.'' [17] The proposed rule recognizes the connection between an injury sustained by an officer in the course of performing a lifesaving act, even an officer who may be off-duty and outside of his or her jurisdiction, and the officer's duty as a public safety officer to protect the public. Moreover, the proposed rule is consistent with existing provisions that deem an officer's injury to be in the line of duty even in circumstances when the officer may have been off duty and without regard to the officer's location—when ''such injury resulted from the injured party's status as a public safety officer.'' [18] Other provisions of federal law similarly recognize public safety officers' special role by granting rights beyond those enjoyed by the public at

[14] As a result of the current definition of ''involvement,'' a necessary element of the definition of ''law enforcement officer,'' a trainee police officer who is killed or permanently disabled while participating in an official training program of his or her public agency, that is mandatory for the trainee's certification or employment as a police officer with that particular public agency, is ineligible for benefits under the PSOB Act by virtue of not qualifying as a ''public safety officer.''

[15] See 28 CFR 32.3 (defining *Line of duty activity or action*).

[16] See *Hawkins* v. *United States,* 469 F.3d 993, 1004 (Fed. Cir. 2006) (providing that, as Congress did not define line of duty in the PSOB Act, ''the BJA's regulatory interpretation of 'line of duty' . . . must be upheld unless it is ''arbitrary, capricious, or manifestly contrary to the statute'') (other citation omitted). *Cf. Davis* v. *United States,* 50 Fed.Cl. 192, 200 (2001) (''Congress has spoken on the issue of 'line of duty' and its scope. A public safety officer is killed in the 'line of duty' when his or her death results from the performance of any duty required by law or terms of employment or as a consequence of his or her identity as a safety officer.'').

[17] *Davis* v. *United States,* 50 Fed.Cl. 192, 207 (2001).

[18] *See* 28 CFR 32.3 (defining *Line of duty injury*).

large [19] and recognizing that local public safety officers often serve the public in areas other than the officer's immediate jurisdiction.[20] Finally, in recognizing and covering the risks faced by public safety officers in carrying out their obligation to protect the public, the limited expansion in the proposed rule is also consistent with one of the purposes of the PSOB Act, to recruit and retain public safety officers.

The proposed rule would add to the definition of ''line of duty action or activity'' a narrow exception that would deem the extraordinary acts of a firefighter or law enforcement officer to save a human life as ''in the line of duty.'' To maintain the integrity and limited nature of the exception, such acts would be limited to those circumstances in which (1) the officer's actions constituted public safety activity, (2) the officer's actions were performed in the course of responding to an emergency situation requiring prompt actions to save human life, (3) the officer did not create the emergency situation to which he or she responded, (4) the human life the officer attempted to save or saved was other than that of the officer, and (5) the officer's acts were not contrary to the law of the jurisdiction in which performed.

Providing a narrowly drawn exception to the definition of line of duty is consistent with the purpose of the PSOB Act to extend coverage to firefighters and law enforcement officers who sacrifice their own their lives to save the life of others, or who are catastrophically injured while doing do. The proposed rule will further prevent the anomaly of such a public safety officer being recognized or honored posthumously for extraordinary acts of heroism through BJA programs such as the Public Safety Officer Medal of Valor [21] while at the same time being denied, or having their family denied, PSOB benefits because of narrowly drawn eligibility criteria do not take into account these extraordinary situations.

As provided in sec. 1086 of Public Law 112–239, the Dale Long Act amended the PSOB Act by adding a new provision defining as a public safety officer those members of a rescue squad or ambulance crew who, as authorized, are engaging in rescue activity or providing emergency medical services.[22] Notably, the amendment removed the requirement that an individual member be a ''public employee'' and expanded membership to ''officially recognized or designated employee or volunteer member[s]'' of public agencies as well as those employee or volunteer members of certain ''nonprofit entit[ies] serving the public.''

Under the proposed rule, the ''line of duty activity or action'' definition would reflect the Dale Long Act's expansion of PSOB Program coverage to employee or volunteer members of ambulance crews and rescue squads operated by certain nonprofit entities serving the public. The proposed rule would also implement the reduced scope of PSOB Program coverage in 42 U.S.C. 3796b(9)(D) for all employee and volunteer members of public agency and nonprofit entity ambulance squads and rescue crews based on statutory language limiting public safety officer status to those circumstances in which a member of an ambulance crew or rescue squad is actually engaging in rescue activity or providing emergency medical services.[23]

• *Line of duty injury:* Under current regulations, an injury is sustained in the line of duty if it was suffered during performance of a ''line of duty activity or a line of duty action'' or ''authorized commuting.'' [24] In such circumstances, it is the nature of the officer's actions that determines whether an injury is ''in the line of duty'' and therefore eligible for benefits. Existing PSOB regulations provide an exception to this general principle in that an injury is deemed to be in the line of duty if clear and convincing evidence demonstrates that the injury resulted from a public safety officer's status as a public safety officer. Under the current rule, it is the actions and motivation of the assailant that determine whether an injury is in the line of duty and eligible for benefits; consequently, every injury inflicted upon an off-duty public safety officer is not automatically considered to be in the line of duty. Rather, it must be shown that the motivation for injuring the officer was the officer's status as a public safety officer as opposed to a personal dispute or other event unrelated to the officer's status as a public safety officer.

The agency's experience is that this provision, although appropriately narrow, has proved particularly burdensome for claimants in those claims in which both the officer and the assailant are deceased and there is little or no evidence as to the motivation for injuring the officer. Adding to a claimant's challenges in establishing a line of duty injury in such claims, the current regulation also requires that such injury must be established by clear and convincing evidence rather than the standard of proof of ''more likely than not'' applicable to nearly all other determinations in the PSOB Program. The agency believes that two minor changes to the current regulation would enable claimants to establish eligibility in such claims and maintain the necessarily limited nature of the provision.

The proposed rule would change from ''convincing'' to ''more likely than not'' the standard of proof for establishing that an officer was injured due to the officer's status as a public safety officer. In doing so, the proposed rule would address those situations in which the only evidence of the assailant's intent to injure the officer is circumstantial. As an assailant's intent to injure an officer on account of the officer's status is often intertwined with or manifested in an intent to retaliate against an officer for actions taken in the line of duty by the officer injured or other public safety officers, the proposed rule would also clarify that injury sustained by a public safety officer in retaliation for line of duty actions or activities is a valid basis for establishing line of duty injury as a result of an officer's status.

• *Official capacity:* In addition to the requirement in 42 U.S.C. 3796b(9)(A) and implementing regulations that an individual must possess the qualifications applicable for the particular category of officer to establish public safety officer status, the evidence must also establish that the individual law enforcement officer and firefighter was serving a ''public agency in an official capacity'' at the time of injury. Public agency is defined in 42 U.S.C. 3796b(8) and generally refers to a unit of government at the federal, state, or

[19] *See, e.g.,* Law Enforcement Officers Safety Act of 2004, Public Law 108–277, 118 Stat. 865, *codified at* 18 U.S.C. 926B, 926C (granting ''qualified law enforcement officers'' the right to carry concealed weapons across state lines, notwithstanding provisions of state law prohibiting or limiting concealed weapons).

[20] *See, e.g.,* 5 U.S.C. 8191 (authorizing federal workers' compensation benefits to local law enforcement officers injured while pursuing or apprehending persons sought for crimes against the United States or material witnesses for federal prosecutions).

[21] Public Law 107–12, as amended, established the Public Safety Officer Medal of Valor, which is awarded by the President, in the name of Congress, to public safety officers for ''extraordinary valor above and beyond the call of duty.''

[22] 42 U.S.C. 3796b(9)(D).

[23] As the statutory language of the 2013 amendment limits the scope of coverage to circumstances in which the rescue squad or ambulance crew member is engaging in rescue activity or the provision of emergency medical services ''as authorized or licensed by law and by the applicable agency or entity,'' OJP is unable to establish in regulations an exception for actions taken to save human life outside the member's jurisdiction.

[24] 28 CFR 32.3 (defining *Line of duty injury*).

local level, subordinate entitles of such governments including a ''department'' or ''agency,'' or an instrumentality of any of the aforementioned entities ''Official capacity'' is not defined in the PSOB Act; however, the agency has exercised its regulatory authority to define it in 28 CFR 32.3 as based on two criteria. First, an individual must be officially acknowledged by the agency to be functionally within or part of the agency; an individual's status as a contractor, by itself, does not establish that an individual is functionally within a public agency. Second, the public agency must accept legal responsibility for the acts and omissions of the individual.

Under these existing definitions, an otherwise qualified firefighter or law enforcement officer who is recognized by his or her agency as functionally within or part of the agency, but acts in emergency circumstances to save human life outside his or her agency's jurisdiction or where he or she is otherwise not obligated to act, will generally not be found to be serving a public agency in an official capacity. This is because the firefighter's or law enforcement officer's acts and omissions in such circumstances will generally not be recognized by his or her own public agency as legally those of the agency.

As discussed in the analysis of the proposed revision to the ''line of duty'' regulation, it is not uncommon for public safety officers to respond to emergencies regardless of whether the emergency is in their jurisdiction. The PSOB regulations which require that a public agency affirm, or at least, not deny, that a public safety officer's acts or omissions while acting outside the officer's jurisdiction were legally those of the public agency, as currently written, do not take into account these extraordinary situations which require an urgent and immediate response and do not afford a public agency the opportunity to determine whether it will affirm, or at least not deny legal responsibility for an officer's acts or omissions while so acting.

Within the context of the PSOB Program, BJA recognizes that public safety officers, by virtue of their training, expertise, and experience, are often compelled to act where human life is endangered. Moreover, a public safety officer's training and experience make them uniquely qualified to intervene to save human life. Accordingly, BJA believes that the actions of public safety officers, *i.e.,* firefighters and law enforcement officers, in these extraordinary and limited circumstances should be covered by the PSOB Program.

As the PSOB Act did not define ''official capacity'' as to address whether an officer's off-duty actions could satisfy such requirement and expressly delegated to the agency in 42 U.S.C. 3796(c) the authority to promulgate implementing regulations, the agency may interpret the term ''official capacity'' in regulations so long as the interpretation is not arbitrary, capricious, or contrary to law.[25] Moreover, the proposed rule is consistent with existing provisions that deem an officer's injury to be in the line of duty without regard as to whether the officer was functioning in an official capacity at the time of his or her injury—when such injury resulted from the injured party's status as a public safety officer.[26]

As mentioned with regard to the proposed changes to ''line of duty,'' other provisions of federal law similarly recognize public safety officers' special role by granting rights beyond those enjoyed by the public at large [27] and recognizing that local public safety officers often serve the public outside the officer's immediate jurisdiction.[28] The proposed rule is consistent with the recognition afforded by those provisions. Finally, in recognizing and covering the risks faced by public safety officers in carrying out their obligation to protect the public, the limited expansion in the proposed rule is also consistent with one of the purposes of the PSOB Act: To recruit and retain public safety officers.

The proposed rule would add to the definition of ''official capacity'' a narrow exception that would deem the extraordinary acts of a firefighter or law enforcement officer to save a human life as ''serving a public agency in an official capacity.'' To maintain the integrity and limited nature of the exception, such acts would be limited to those determined to be ''line of duty activity or action'' under the proposed exception to that definition. This proposed change is intended to work in conjunction with the proposed change regarding line of duty.

- *Officially recognized or designated public employee member of a squad or crew:* As provided in sec. 1086 of Public Law 112–239, the proposed rule would revise the existing definition to cover members of ambulance squads and rescue crews who are employed by or volunteer for certain nonprofit entities serving the public.
- *On-site hazard management:* As currently defined in 28 CFR 32.3, the term ''fire suppression'' includes ''on-site hazard evaluation'' but the latter term is not defined and does not include the more comprehensive task, ''on-site hazard management.'' To account for this necessary component of firefighter work, the proposed rule would define on-site hazard management as including actions taken to provide scene security or direct traffic in support of a fire, rescue, or law enforcement emergency.
- *Parent-child relationship:* As defined in 28 CFR 32.3, the terms ''adopted child'' and ''stepchild'' require a PSOB determining official to determine whether a public safety officer had a ''parent-child relationship'' with a child. The current definition of parent-child relationship, *i.e.,* a relationship between a public safety officer and another individual where the officer acts as a parent, requires that the relationship be shown by convincing evidence. This higher standard of proof has delayed the processing of claims involving claimants seeking benefits on behalf of (or as) the stepchild or adopted child of a deceased officer. In nearly all such claims, additional evidence sought to meet the higher standard has confirmed the initial assessment of the determining official.

As the higher standard proof has been shown to add little certainty in what is inherently a subjective determination about the existence of a relationship that is known best by the persons directly involved in it, the agency proposes to revise it. The proposed rule would revise the definition parent-child relationship by changing the standard of proof from ''convincing evidence'' to the standard of ''more likely than not'' applicable in nearly all other PSOB Program determinations.

- *PSOB Counsel:* In 2013, the Attorney General directed that the PSOB claims process be streamlined through the consolidation of legal and other claims functions within BJA. Apart from a final rule revising the definition of ''PSOB Office'' that was published in the **Federal Register** in 2013, 78 FR 29233 (May 20, 2013), the agency has published no regulations identifying the entity or individual providing legal

[25] *See Groff* v. *United States,* 493 F.3d 1343, 1353 (Fed. Cir. 2007) (''Congress did not further define what it means to serve 'in an official capacity,' leaving the statute silent as to whether contract pilots fall within its ambit.'').

[26] *See* 28 CFR 32.3 (defining *Line of duty injury*).

[27] *See, e.g.,* Law Enforcement Officers Safety Act of 2004, Public Law 108–277, 118 Stat. 865, *codified at* 18 U.S.C. 926B, 926C (granting ''qualified law enforcement officers'' the right to carry concealed weapons across state lines, notwithstanding provisions of state law prohibiting or limiting concealed weapons).

[28] *See, e.g.,* 5 U.S.C. 8191 (granting federal workers' compensation benefits to local law enforcement officers injured while pursuing or apprehending persons sought for crimes against the United States or material witnesses for federal prosecutions).

review within BJA. In order to make more transparent the legal review process associated with PSOB claims, the proposed rule would identify PSOB Counsel as the legal staff in BJA responsible for performing legal review of claims for PSOB Program benefits and providing PSOB determining officials with legal advice in PSOB Program matters.

• *Public employee member of a squad or crew:* The agency proposes to remove this definition as a recent amendment to 42 U.S.C. 3796b(7) in sec. 1086 of Public Law 112–239 removed the ''public employee'' requirement from the definition of ''member of a rescue squad or ambulance crew.''

• *Stress or strain:* As discussed in the proposed revision of the definition of ''injury,'' the agency's experience is that the public has found the definition of stress or strain very difficult to understand and apply. For the reasons provided, the proposed rule would eliminate this definition in favor of incorporating the specific conditions that are excluded into the definition of injury. In so doing, the proposed rule would make clear those conditions that are excluded from the definition of injury, streamline the processing of claims, and help to reduce the number of claims filed that, as a matter of law, cannot be paid due to a lack of injury.

• *Suppression of fire:* As currently defined, the term refers to the work and activities connected with extinguishing or containing a fire, beginning with its discovery, and includes extinguishment, physical prevention, or containment of fire, including on-site hazard evaluation. ''On-site hazard evaluation'' is logically part of a larger task, ''on-site hazard management.'' The current definition does not take into account the individual members of fire departments that are deployed to provide on-site hazard management activities including traffic incident management at emergency scenes. These individuals, often referred to as ''fire police,'' are officially designated members of a fire department, receive formal training, and perform operational duties that, in the absence of fire police, would be required to be performed by another member of the department.

When an officially designated member has the legal authority and responsibility to qualify as a firefighter or law enforcement officer as defined in 28 CFR 32.3, and is otherwise serving a public agency in an official capacity, the individual qualifies as a public safety officer. However, in the majority of claims involving personnel whose specialized duties are limited to traffic incident management and other on-site hazard management tasks, the individual lacks the legal authority and responsibility to either engage in the suppression of fire (as currently defined), or arrest persons alleged to have violated the criminal laws, which precludes the individual from qualifying as a public safety officer as a firefighter or law enforcement officer.

The agency's experience is that, apart from engaging in actual fire suppression, personnel providing on-site hazard management are at risk for many of the same hazards encountered at the scene of a fire as do personnel who engage directly in the suppression of fire as firefighters. Fire police and similar fire department personnel are exposed to the hazards of the emergency response, the hazardous materials and toxins released into the air at the scene of the fire, as well as the hazards posed by their traffic control duties that kill or disable firefighters.[29] The proposed rule would expand the type of activities covered as fire suppression to include on-site hazard management, which would be addressed separately in a new definition in 28 CFR 32.3 and would include duties such as providing scene security and directing traffic in response to a fire emergency.

• *Voluntary intoxication at the time of the officer's fatal or catastrophic injury:* Under 42 U.S.C. 3796a(2), the agency is prohibited from paying benefits ''if the public safety officer was voluntarily intoxicated at the time of his fatal or catastrophic injury.'' Under the current regulation implementing 42 U.S.C. 3796a(2), a public safety officer is considered to be voluntarily intoxicated when a drug test establishes in the body of a public safety officer, the presence, in any amount, of a drug listed in the Schedules of Controlled Substances. *See e.g.,* 21 U.S.C. 812; 21 CFR, part 1308. In the overwhelming majority of claims, the officer is found to have been taking a prescribed drug consistent with such prescription and not intoxicated at the time of fatal or catastrophic injury. However, BJA and claimants expend significant resources in determining that this limitation is not implicated, which delays the processing of otherwise valid claims. To enable BJA to focus its inquiry on those drugs used as intoxicants and those that generally produce intoxication, the proposed rule would makes several substantive changes to the existing rule pertaining to how voluntary intoxication is determined with regards to drugs.

The proposed rule would, among other things, revise existing language to provide that voluntary intoxication is not automatically established when the presence of drugs in the body of the public safety officer is generally within prescribed limits and the public safety officer was not acting in an intoxicated manner immediately prior to the injury. To account for circumstances under which there is no witness available to attest as to whether an officer was acting in an intoxicated manner immediately before a fatal injury, the proposed rule would clarify, consistent with BJA's current interpretation, that voluntary intoxication is not implicated when convincing evidence establishes that the drug would not produce intoxication in the amount present in the officer's body.

• *Volunteer fire department:* Under 42 U.S.C. 3796b(9)(A), to be eligible for benefits as a public safety officer, a firefighter must be serving ''a public agency in an official capacity.'' Under the current definition of ''official capacity'' in 28 CFR 32.3, an otherwise qualified volunteer firefighter who is an officially recognized or designated member of a legally established volunteer fire department (VFD) cannot be considered to be serving a public agency in an official capacity and therefore cannot be a public safety officer, unless a public agency recognizes (or, at a minimum, does not deny) that the volunteer firefighter's acts and omissions are legally those of the public agency.

BJA's experience is that in most PSOB claims involving volunteer firefighters, the ''public agency'' and ''official capacity'' requirements for the individual volunteer firefighter are satisfied when the VFD establishes that it is an ''instrumentality'' of a public agency under 28 CFR 32.3 (defining *Instrumentality*) and that, as such, the public agency is legally responsible for the acts and omissions of its members. In a relatively recent trend, the agency has received claims in which a VFD does not fully qualify as an instrumentality despite providing fire protection to a public agency as a noncommercial, non-profit corporation. In nearly all claims in which a VFD does not qualify as an instrumentality, it is because the public agency denies legal responsibility for the acts and omissions of the VFD. Such denial is often manifested in a contract or similar agreement for services under which the public agency expressly states that it is not responsible for the acts or omissions

[29] Between 1996 and 2010, 253 firefighters were killed in vehicle collisions responding to and returning from incidents; 70 more were killed after being struck by vehicles at the scene of emergencies. U.S. Fire Administration, *Traffic Incident Management Systems,* FA–330/March 2012, 4–5, *https://www.usfa.fema.gov/downloads/pdf/publications/fa_330.pdf* (accessed Feb. 26, 2016).

of the VFD. Under such contracts, the public agency may require the VFD to obtain its own insurance (even as the public agency provides the VFD with funding for operations) and indemnify and hold harmless the public agency for its acts and omissions or those of its members. Such contracts may also refer to the volunteer firefighter members of such VFDs as ''independent contractors'' of the public agency despite the fact that the volunteer firefighters are officially recognized members of the VFD, itself a non-commercial, nonprofit corporation.

Since the enactment of the PSOB Act in 1976 and before the agency defined in regulations the terms ''official capacity'' and ''instrumentality,'' qualified members of legally organized VFDs have generally been considered to be public safety officers. To preserve this eligibility and address the trend of shifting liability, the proposed rule provides that a VFD qualifies as an instrumentality as defined in 28 CFR part 32 if it is legally established as a public entity or nonprofit entity serving the public, and it is legally established solely for the purpose of providing fire protection and related services on a noncommercial basis to or on behalf of a public agency or agencies. The proposed rule also provides that to qualify as an instrumentality under this provision, a VFD must provide fire protection to members of the public without preference or subscription fees. The proposed rule would preserve the existing PSOB Act coverage of volunteer firefighters serving the public in noncommercial, nonprofit VFDs and leave undisturbed the agency's longstanding interpretation that, as a general rule, commercial entities cannot establish status as a public agency or as an instrumentality of a public agency.

Section 32.5 Evidence

Under current § 32.5(a), claimants have ''the burden of persuasion as to all material issues of fact, and by the standard of proof of 'more likely than not.' '' The proposed rule would retain this standard of proof, and simplify the current description of claimants' burden by providing that claimants are responsible for establishing all elements of eligibility for the benefit they seek.

The proposed rule would replace the standard for evidentiary submissions in current § 32.5(c), Federal Rules of Evidence 301, 401, 402, 602–604, 701–704, 901–903, and 1001–1007, with a general standard for admissibility similar to that used in other federal benefit programs. *See e.g.,* 20 CFR 10.115 (providing that the evidence submitted in a claim for Office of Workers' Compensation benefits ''must be reliable, probative and substantial''). Although the Federal Rules of Evidence provide a precise set of rules for evaluating evidentiary submissions in litigation, BJA believes that a less formal and legalistic set of standards is better suited for an administrative, non-adversarial claims process in which most claimants are unrepresented. The proposed rule provides that a claimant's evidence must be worthy of belief (credible), tending to prove an issue (probative), and actually existing (substantial). The proposed rule would also provide that, when deemed necessary by a PSOB determining official, a claimant must produce original documents or other copies verified as true and exact by a custodian of such records.

Under current 28 CFR 32.5(i), BJA considers a public safety officer's response to a call to provide emergency service ''prima facie evidence'' that the activity was ''nonroutine'' for purposes of applying the presumption in 42 U.S.C. 3696(k). The agency's experience, which is substantiated by research showing that a public safety officer's sympathetic nervous system is activated with his or her receipt of an alarm, is that a public safety officer's response to an emergency call to perform public safety activity, which generally begins when an officer receives such call, also constitutes evidence of the response's physically stressful character. Accordingly, the proposed rule provides that a public safety officer's response to a call for emergency service shall also constitute prima facie evidence that the response was physically stressful for purposes of 42 U.S.C. 3796(k).

As stated, generally, the evidence of record in a claim must establish material issues of fact to the standard of proof of ''more likely than not.'' However, the unique circumstances of public safety work results in PSOB claims in which many of the incidents or injuries that are the basis of the claim may be without numerous witnesses or extensive documentation. To address the evidentiary challenges posed by the hazards and risks of public safety activity and the unpredictable nature of such work, the agency proposes a limited exception to this standard of proof by adding add a new § 32.5(k) that would address situations in which the proof on either side of an issue is equal. The proposed rule would provide that where the determining official determines the record evidence to be equivalent regarding a fact material to whether or not the circumstances of the death or injury of the officer warrant coverage as a death or permanent and total disability incurred in the line of duty under the Act, the determining official shall resolve the matter in favor of the claimant. The proposed rule makes clear that the absence of evidence in support of a particular fact does not establish that the evidence is equivalent and that the provision is not a substitute for actual evidence establishing or disproving a particular fact.

The proposed rule would also replace the prerequisite certification regulations at 28 CFR 32.15 and 32.25 with a single provision at § 32.5(l) authorizing PSOB determining officials to require from a claimant any proof necessary to establish facts of eligibility essential for death, disability, or education claims under the PSOB Act including proof of birth, death, disability, earnings, education, employment, and injury. Under the current rule, without a waiver from the BJA Director for good cause shown, BJA may not approve any death or disability claim unless the public safety officer's agency produces a certification as defined in § 32.3 and specific types of supporting documentation. For example, even in a claim for PSOB death benefits in which the public agency has paid death benefits to the public safety officer's survivors, BJA may not pay benefits without a certification (or, as appropriate a waiver for good cause shown) from the public safety officer's agency that the officer died as ''a direct and proximate result of a line of duty injury'', or that the public safety officer's survivors have received ''the maximum death benefits legally payable by the agency'' to similarly situated public safety officers.

BJA's experience is that the prerequisite certification regulations impose an extremely high level of precision on the claims process, often require the public safety officer's agency to make legal and medical conclusions they are not qualified to make, and produce delays in adjudication. The better course, and one keeping in line with other government claims programs would be to allow claimants and agencies to provide documents establishing eligibility from a variety of sources including but, not limited to, death certificates, autopsies, toxicology reports, coroner's reports, police reports, investigative reports, workers compensation determinations, State-law line of duty death determinations, insurance policies, newspaper and media reports, and statements from the officer's public agency. Taken together, such documents are more than adequate to establish the relevant facts and circumstances of a public safety officer's injury and the eligibility of beneficiary.

In replacing the prerequisite certification and waiver requirements with a process tailored to the facts of individual claims, the proposed rule would reduce administrative burden and improve the efficiency of the process by reducing delays for unnecessary documents and or waivers.

In a recent report on the PSOB Program, the OIG recommended that BJA implement ''an abandonment policy that gives claimants adequate opportunity to provide needed documentation to support their claims and ensures that the PSOB Office does not use its limited resources conducting outreach on claims, especially those which claimants do not intend to pursue.'' [30] To aid in implementing the OIG's finding, OJP proposes to define in a new § 32.5(m), the circumstances under which a claim is considered to be abandoned.

The proposed rule would consolidate most abandonment provisions in a single provision. Under the proposed rule, when a claimant or agency who does not furnish evidence necessary to a determination within one year of BJA's request, or a claimant fails to pursue in a timely fashion a determination on his or her claim, following appropriate notice BJA will consider the claim abandoned and take no further action on the claim unless it received a complete claim, including the specific information requested, within 180 days from notice of abandonment. Consistent with current practice, the claim would be considered as though never filed, and abandonment would not toll the time periods remaining for filing. In providing claimants with a one-year period to respond to requests for evidence, as well as a ''grace period'' in which claimants may reopen an abandoned claim, the proposed rule provides adequate time for claimants to provide documents supporting their claims while permitting BJA to dedicate its resources to those claims that can be decided on the evidence of record.

Section 32.7—Fees for Representative Services

Under 42 U.S.C. 3796c, the agency is authorized to promulgate ''regulations governing the recognition of agents or other persons representing claimants.'' The agency has exercised its regulatory authority to establish in current § 32.7 provisions governing the circumstances under which representatives may charge fees for representative services in a claim for benefits under the PSOB Act. Claimants for representative services provided in connection with a claim for PSOB Act benefits may not charge fees for representative services based on a stipulated, percentage, or contingency fee recovered and may not charge fees in excess of the amount permitted under the Equal Access to Justice Act, currently $125 per hour. All petitions seeking authorization to charge fees, whether contested by the PSOB claimant-beneficiary or not, are subject to a review for reasonableness based on the factors in § 32.7(c)(1)–(8). Additionally, the current rules do not address who may provide representation in PSOB claims, nor do they address whether non-attorney representatives may charge fees for representation.

The agency proposes to revise § 32.7 to limit paid representation to attorneys and support staff under their direct supervision, keep fees at a reasonable level consistent with the purpose of the program, and improve the processing of claims involving attorney representatives. The intent in so doing is to enable claimants to more easily obtain qualified representation in claims for PSOB death or disability benefits.

In conjunction with a proposed definition of the term ''attorney'' as a member in good standing of a State bar, the proposed rule would limit authorization to charge fees for representative services to such attorneys. The agency views limiting paid representation to attorneys as a means of ensuring that individuals providing paid representation in PSOB claims are capable of providing competent representation, are obligated to provide representation according to code of professional ethics, and are subject to oversight and compliance by an independent licensing body. As non-attorney representatives are not subject to similar testing, ethical requirements, and independent monitoring, the agency proposes to continue to permit them to provide representation but prohibit such individuals from charging claimants fees for representative services.

The proposed rule would permit fees for representative services to be based on a fixed fee, hourly rate, a percentage of benefits recovered, or a combination of such bases. To enable BJA to maintain its oversight role regarding fees, the proposed rule would require that claimants provide to the PSOB Office before seeking authorization to charge fees a copy of any fee agreement for representative services under the Act. To keep fees reasonable, the proposed rule would prohibit fees for representative services in excess of 12 percent of the total PSOB death or disability payment available to a claimant regardless of how the fee agreement is structured.[31] To expedite the review of fee petitions, the proposed rule would also establish a presumption of reasonableness for representative's fees not exceeding 8 percent of the total PSOB death or disability payment available to a claimant in a claim resolved at the PSOB Office level, and establish a presumption of reasonableness for representative's fees not exceeding 10 percent of the total PSOB death or disability payment available to a claimant in a claim resolved at the Hearing Officer or BJA Director level. These presumptions of reasonableness would be rebuttable if an examination of the factors in § 32.7(c) established that the fee is unreasonable.

Section 32.9 Complete Application

One of the recommendations of OJP's independent BPI review of the PSOB Program was that, to improve the efficiency of claims processing, BJA should require a minimum set of supporting information before assigning a claim number and routing the claim for review to reduce the time incomplete claims remain unresolved and to focus BJA resources on those claimants who need assistance in submitting an application for benefits.[32] Consistent with other government claims programs, the BPI review recommended that the PSOB Office shift its focus from a one-on-one outreach model to an approach that returns the responsibilities to the claimant and agency to gather, organize, and submit all required prior to filing a PSOB claim, and being assigned a claim number. Related to the minimum required documents concept, for BJA to establish and implement meaningful timeliness standards for its processing of claims, claims must necessarily be complete and ripe for determination before the ''clock'' starts on calculating the days required by BJA to process a claim to completion.

To improve the efficiency of claims processing pursuant to the BPI recommendation, the agency proposes to add a new § 32.9 defining what

[30] U.S. Dept. of Justice, Office of the Inspector General, *Audit of the Office of Justice Programs' Processing of Public Safety Officers' Benefit Programs Claims*, Audit Division 15–21 at 11 (July 7, 2015).

[31] By way of example, in a claim for benefits based on an officer's death that occurred in FY2014, the total benefit payable under 42 U.S.C. 3796(a) is $333,604.68. In a claim involving a surviving spouse and two children, an attorney representing the two children would be prohibited from charging fees in excess of $20,016.28, which represents 12% of the children's combined ½ share of benefits, $166,892.34.

[32] In a sample of claims reviewed, the BPI review found that an average of 148 days was spent on outreach in death and disability claims.

constitutes a ''complete application'' for benefits under the PSOB Act and implementing regulations prescribing BJA's obligations when it receives such an application. BJA's current practice when it receives an application for benefits that lacks the basic required documents to render a determination is to assign it a claim number, process it as a claim from the moment a claim form is received, and conduct biweekly outreach efforts to obtain from the applicant and the officer's public agency information required to establish eligibility for benefits. BJA's experience is that it allocates significant resources to repeatedly prompting applicants for benefits and public agencies as to what basic required documents they must submit to establish eligibility when BJA's resources could be reallocated to processing otherwise complete applications.

Under the proposed rule, following publication of a Notice in the **Federal Register** consistent with 5 U.S.C. 552(a)(1)(C), the PSOB Office would maintain and publish on the PSOB Program Web site a list of basic required documents that claimants would be required to file with applications for PSOB Program death, disability, and education benefits. These documents would represent the *absolute minimum* documentation BJA would accept before treating an application as a claim, devoting resources to processing it. This documentation, once submitted, would constitute a ''complete application.'' By precluding incomplete applications from being considered as claims in the first instance, the proposed rule would support the OIG and BPI recommendations and BJA's efforts to effectively allocate its resources and avoid issuing merits-based determinations denying benefits based on obviously incomplete applications, which would simply shift initial evidentiary development to determinations by Hearing Officers and the BJA Director.

The proposed rule provides that when BJA receives an application for benefits without the basic required documents (as indicated on the Web site), BJA will notify the applicant in writing of the evidence and information necessary to complete the application, and advise the applicant that BJA will not process the incomplete application as a claim for benefits until the remainder of the documents are received. For purposes of determining whether a claim was timely filed under proposed 28 CFR 32.12 and 32.22, an applicant's submission of either a claim form or report form, *i.e.*, a Report of Public Safety Officer's Death, Claim for Death Benefits, or Report of Public Safety Officers' Permanent And Total Disability, even though not constituting a complete application, would be sufficient to satisfy the requirement that a claim must be filed within three years of the officer's death or injury. To prevent applicants from being prejudiced based on an inability to provide necessary information, the proposed rule would provide that an application will not be considered incomplete if an applicant's inability to file basic required documents was the result of a public agency's refusal or inability to provide the information identified in this section if the applicant provides to the PSOB Office written justification for his or her inability to provide the information and the justification demonstrates that such inability to file evidence is not due to any fault of the applicant.

Section 32.10 PSOB Counsel

Nothing in the PSOB Act or implementing regulations prescribes the relationship between PSOB Counsel and PSOB determining officials. To make transparent the role of PSOB Counsel and the scope of Counsel's review in the PSOB claims process, proposed § 32.10 would require that PSOB determining officials seek legal advice from PSOB Counsel before determining a claim. However, the proposed rule would limit the scope of such advice to the interpretation of law under the PSOB Act and implementing regulations and, unless directed otherwise by the Assistant Attorney General for the Office of Justice Programs, PSOB Counsel would be precluded from reviewing findings of fact made by PSOB determining officials.

Section 32.12 Time for Filing a Claim

Under current § 32.12, unless the time for filing is extended by the BJA Director for good cause shown, a claimant (applicant under proposed § 32.9) must file a claim for PSOB Program death benefits before the later of three years from the date of the public safety officer's death, or one year after a final determination of survivors benefits or statement from the public agency that it was not legally authorized to pay survivors benefits on behalf of such an officer. Consistent with proposed § 32.5(l), and to simplify administration of the program, the proposed rule would eliminate provisions associated with the one-year requirement as well as all provisions referring to prerequisite certification and provide that no application shall be considered if it is filed with the PSOB Office more than three years after the public safety officer's death.

Section 32.13 Definitions

Section 32.13 provides definitions applicable to claims for PSOB Program death benefits. OJP proposes to add new definitions or revise existing definitions in § 32.13 as follows:

• *Beneficiary of a life insurance policy of a public safety officer:* Where it has been established that public safety officer died as the direct and proximate result of a personal injury sustained in the line of duty injury, and there is no surviving spouse, surviving child, or surviving individual designated by the officer to receive the PSOB Program death benefit, under 42 U.S.C. 3796(a)(4)(B), BJA will pay the surviving individual(s) designated by the public safety officer to receive benefits under the officer's most recently executed life insurance policy on file at the time of death with the public safety agency.

Under regulations in 28 CFR 32.13 defining ''beneficiary of a life insurance policy of a public safety officer,'' BJA may consider as revoked a life insurance beneficiary designation which lists a former spouse who, following the designation, was divorced from the public safety officer, unless it is demonstrated that the officer had no intentions of revoking the designation for his or her former spouse.

Similar to the regulation regarding former spouses, the proposed rule would add a new paragraph (3) permitting BJA to consider as revoked a designation in a life insurance policy of a beneficiary who dies after the public safety officer but before a determination can be made in favor of a living contingent beneficiary. In the circumstances described, the proposed rule would enable BJA to honor the public safety officer's designation of a contingent beneficiary rather than disregarding it in favor of the next category of eligible beneficiaries, surviving parents.

• *Engagement in a situation involving law enforcement, fire suppression, rescue, hazardous material response, emergency medical services, prison security, disaster relief, or other emergency response activity:* For a fatal heart attack, stroke, or vascular rupture to qualify for the statutory presumption of death resulting from a line of duty injury in 42 U.S.C. 3796(k), a public safety officer must, among other things, engage in a situation involving specific line-of-duty actions or participate in a training exercise as defined in 28 CFR

32.13.[33] A public safety officer engages in qualifying activity when he or she is actually engaging in law enforcement, suppressing fire, or performing one of the other types of activity currently defined in 28 CFR 32.13.

The agency's experience is that the ''engagement'' activities listed in the law, in some cases, necessarily require other activities to take place prior to a public safety engagement. For example, a firefighter may need to clear the snow from the driveway of a fire station, or change a flat tire on a fire truck before the public agency can engage in fire suppression. Although ''engagement in a situation involving . . . fire suppression'' generally begins with the department's or agency's request for a particular officer to perform this type of activity, under the current rules, it generally cannot be said to include the clearing of the station's driveway or the changing of a tire unless such action is performed in the course of the actual engagement.

The proposed rule would expand the current regulatory definition to cover only those line of duty actions or activities that, if not performed, would directly preclude the public agency from providing fire suppression, rescue, hazardous material response, emergency medical services, prison security, disaster relief, or other emergency response activity. Thus, the proposed definition would cover as part of an engagement under 42 U.S.C. 3796(k) a public safety officer's changing of a flat tire on a fire truck necessary for the public agency to engage in fire suppression.

• *Nonroutine strenuous physical activity:* To be eligible for the presumption in 42 U.S.C. 3796(k), a public safety officer must, among other things, either participate in a training exercise or in a situation involving nonroutine stressful or strenuous physical activity. The agency has defined ''nonroutine stressful or strenuous physical activity'' in regulations as two distinct terms: ''nonroutine stressful physical activity'' and ''nonroutine strenuous physical activity.''

Generally speaking, nonroutine strenuous physical activity is defined in 28 CFR 32.13 as line of duty activity that (1) is not excluded as clerical, administrative, or non-manual in nature, (2) is not routinely performed, and (3) requires ''an unusually-high level of physical exertion.'' Whether a public safety officer's activity constitutes an ''unusually high-level of physical exertion'' has often proven challenging for claimants to demonstrate and the agency to evaluate.[34]

To make clear what constitutes ''strenuous,'' and to facilitate more consistent decision making, the agency proposes to replace the term ''unusually-high'' with the term ''vigorous.'' The use of vigorous as a descriptor is appropriate as it is used by the Centers for Disease Control (CDC) to characterize physical activity that exceeds a moderate level of intensity.[35] Relevant to a standard that must be applied to public safety officers, the CDC's examples take into consideration an individual's age and weight. The proposed rule would not expand the type of physical activity considered to be strenuous, but rather would make claims processing more efficient by providing the public and the agency with a recognized standard that is more easily understood and applied.

• *Nonroutine stressful physical activity:* To be eligible for the presumption in 42 U.S.C. 3796(k), a public safety officer's participation in a training exercise or engagement in a situation involving law enforcement, etc., must also involve either nonroutine stressful physical activity or nonroutine strenuous physical activity. Generally speaking, nonroutine stressful physical activity is defined in current 28 CFR 32.13 as line of duty activity that (1) is not excluded as clerical, administrative, or non-manual in nature, (2) is not routinely performed, and (3) is not capable of being performed without minimal physical exertion. The ''stressful'' component of an officer's nonroutine stressful physical activity is evaluated differently according to whether the officer was (1) engaged in a situation involving law enforcement, fire suppression, rescue, hazardous material response, emergency medical services, prison security, disaster relief, or other emergency response activity, or (2) was participating in a training exercise.

Under current 28 CFR 32.13, an officer's engagement in a situation is considered ''stressful'' if, when viewed objectively, the circumstances of the engagement expose, or appear to expose, the officer to ''significant'' perils or harms not encountered by the public in the ordinary course and, as a result, cause the officer to suffer an ''unusually high'' degree of distress manifested by fear, apprehension, anxiety, or unease. Similarly, under the same regulation, an officer's participation in a training exercise is considered ''stressful'' if, when viewed objectively, the circumstances replicate situations that expose the officer to significant perils or harms, and, as a result, cause the officer to suffer an ''unusually-high'' degree of distress manifested by fear, apprehension, anxiety, or unease.

Similar to the agency's experience with implementing the term ''nonroutine strenuous physical activity,'' whether a public safety officer's activity exposes the officer to ''*significant*'' dangers or produces an ''*unusually-high*'' degree of distress has often proven challenging for claimants to demonstrate and the agency to evaluate. Although it is clear that a traffic stop, arrest of a suspect, response to a motor vehicle accident, or response to a structure fire each expose an officer to significant threats not ordinarily encountered by a member of the public when viewed objectively, produce in the officer some degree of distress, *i.e.*, ''fear or anxiety,'' it is difficult for BJA, the public agency, or the claimant to establish whether these circumstances expose the officer a significant peril or an ''unusually-high level'' of distress, *i.e.*, ''fear or anxiety.''

To make clear what constitutes ''stressful'' activity and to facilitate more consistent decision making, the agency proposes to eliminate in the regulatory definition the term ''significant,'' and to replace the term ''unusually-high'' with ''unusual.'' The elimination of these qualifiers will maintain the integrity of the statutory requirement that the activity be ''stressful'' while aligning the text of the regulation with circumstances faced by public safety officers and the agency's interpretation of such circumstances. The proposed rule would not expand the type of physical activity considered to be stressful, but rather would make claims processing more efficient by providing the public and the agency with a standard that is more easily understood and applied.

[33] The activities in which a public safety officer must engage to obtain the benefit of the presumption, *e.g.*, law enforcement, are defined in 28 CFR 32.3.

[34] *See* Department of Justice, Office of the Inspector General, *The Office of Justice Programs' Implementation of the Hometown Heroes Survivors Benefits Act of 2003*, I–2008–005 i (March 2008) (explaining that OIG conducted its review ''in response to concerns expressed by several members of Congress . . . that OJP's narrow interpretation of terms found in the Act—in particular the phrases ''nonroutine stressful or strenuous physical activity'' and ''competent medical evidence to the contrary''—might be resulting in a high rate of claims denials'').

[35] *See e.g.*, Centers for Disease Control, *General Physical Activities Defined by Level of Intensity, http://www.cdc.gov/nccdphp/dnpa/physical/pdf/PA_Intensity_table_2_1.pdf* (accessed Feb. 11, 2016).

Section 32.14 PSOB Office Determination

Consistent with proposed § 32.5(m), which consolidates all abandonment provisions into a single paragraph, the proposed rule would remove paragraph (b), which prescribes abandonment provisions for death claims.

Section 32.15 Prerequisite Certification

Consistent with proposed § 32.5(l), which replaces §§ 32.15 and 32.25, the proposed rule would remove § 32.15 which prescribes prerequisite certification requirements for death claims.

Section 32.16 Payment

Under current § 32.16(a), BJA may not pay more than one person on the basis of being a public safety officer's parent as a mother, or on that basis as a father. In cases where more than one parent qualifies as the officer's father, or as the officer's mother, the regulation currently limits BJA's payment to the ''one with whom the officer considered himself, as of the injury date, to have the closest relationship.'' The regulation also provides that a biological or legally adoptive parent whose parental rights have not been terminated is rebuttably presumed to have had the closest relationship with the officer.

BJA's experience is that there may exist circumstances in which more than two persons share with the public safety officer a close personal relationship as a parent. The proposed rule would retain the presumption that a biological or legally adoptive parent whose parental rights have not been terminated is presumed to be a ''parent,'' but permit BJA to pay in equal shares additional persons as the parent of a public safety officer when evidence demonstrates that there exists such a relationship as defined in 28 CFR 32.13.

Current regulations do not make clear the agency's interpretation regarding the payment of benefits to a surviving individual in a category of beneficiaries with more than one beneficiary. For example, in an approved PSOB claim in which the surviving parents are the appropriate beneficiaries under 42 U.S.C. 3796(a)(5), and one of the parents has not filed a claim for benefits but there is no evidence that the non-filing parent is deceased, agency practice is to hold the share payable to the surviving parent in the event that the non-filing parent may file a claim, or, if he or she failed to file a claim in the time prescribed, a request for an extension of time to file. To make clear the agency's interpretation and to provide for the timely payment of benefits to individuals determined to be eligible for benefits, BJA proposes to add a new § 32.6(d) that would address such situations. The proposed rule would consider deceased and therefore ineligible, any person, who, being 18 years of age, or older at the date of the public safety officer's injury, and not incapable of self-support as defined in 42 U.S.C. 3796b(3)(C), failed to file an application for benefits within the time prescribed for such filing. Thus, if one of two surviving parents failed to file a written claim, the agency would hold the non-filing parent's share until the time for filing had expired. After such time, the agency would pay the remaining one-half share to the filing parent. The proposed rule is intended to prevent an adult beneficiary's failure to file a claim for benefits from hindering BJA's ability to fairly and timely distribute program benefits amongst a public safety officer's eligible beneficiaries.

Section 32.22 Time for Filing a Claim

Under current § 32.22, unless the time for filing is extended by the BJA Director for good cause shown, a claimant must file a claim for PSOB Program disability benefits before the later of three years from the date of the public safety officer's injury, or one year after a final determination of disability benefits by the public agency or statement from the public agency that it was not legally authorized to pay disability benefits on behalf of such officer. Consistent with proposed § 32.5(l), and to simplify administration of the program, the proposed rule would eliminate provisions associated with the one-year requirement as well as all provisions referring to prerequisite certification, and provide that no application shall be considered if it is filed with the PSOB Office more than three years after the public safety officer's injury.

Section 32.23 Definitions

Section 32.23 provides definitions applicable to claims for PSOB disability benefits. OJP proposes to revise existing definitions in § 32.23 as follows:

- *Gainful work:* The proposed rule would redefine the term ''gainful work'' to provide a framework for PSOB determining officials to analyze whether any type or amount of work performed for pay disqualifies a claimant for PSOB Program disability benefits who has been found by medical professionals to be permanently and significantly disabled from a line of duty injury.

To establish eligibility for the payment of disability benefits under the PSOB Act, it is not enough that a claimant is unable to perform the duties of a public safety officer as the result of a line of duty injury.[36] Rather, the claimant must be permanently unable to perform any ''gainful work'' as the result of a line of duty injury.[37] ''Gainful work'' as currently defined in 28 CFR 32.23 generally refers to either full- or part-time activity for which an individual is paid or would ordinarily be paid Under current PSOB regulations, the agency determines whether a claimant is unable to perform any gainful work based upon a medical, and in some cases, vocational assessment, of the claimant's residual functional capacity, *i.e.,* what the claimant is capable of doing despite the disabling conditions he or she incurred in the line of duty.[38]

As a part of its assessment of disability, the agency also reviews a claimant's tax records to determine whether a claimant has received wages in return for work since the date of injury, or, as appropriate, since the date the officer was found disabled by his or her public agency or separated from his or her public agency by reason of disability. The agency has generally interpreted current regulations defining ''gainful work'' as precluding a finding of total disability when a claimant has, after his or her disability retirement or separation, and contemporaneous with the filing of an application for disability benefits, received any wages in return for work, regardless of the amount of wages received or the type of work for which the wages were paid.

In the overwhelming majority of cases, the current regulations defining ''gainful work'' work well. However, in some complex cases, a claimant found by both medical and vocational professionals to be totally and permanently disabled has nevertheless performed activity that either is actually compensated, (*e.g.,* a claimant with significant orthopedic and cognitive disabilities received $100 honorarium for serving on an organization's governance board), or is commonly compensated, (*e.g.,* a claimant with cognitive impairment resulting from a severe brain injury volunteers intermittently at a hospital by providing directions at an information desk). Despite each claimant having been found to be ''incapable of performing

[36] Under 42 U.S.C. 3796(b), the agency pays disability benefits when it ''determines that a public safety officer has become [both] permanently and totally disabled as the direct and proximate result of a personal injury sustained in the line of duty.''

[37] *See* 42 U.S.C. 3796b(1) (defining ''catastrophic injury'').

[38] 28 CFR 32.23 (defining *Residual functional capacity*).

any gainful work'' as demonstrated by objective medical examination and tests, under the current regulatory definition of ''gainful work,'' the claimant's performance of work that ''actually is compensated or commonly is compensated'' would generally disqualify them from disability benefits.

In such circumstances, the current definition's emphasis on whether work is actually or commonly paid as the single measure of what constitutes ''gainful'' work, without regard to the nature and quantity of work actually performed or the amount of payment received, does not provide an equitable framework for the PSOB determining official to determine whether the claimant is in fact totally disabled. The agency believes that evidence that a claimant received $150 for intermittent work activity that was offered and performed for therapeutic reasons, sheltered work, or was otherwise performed outside the scope of competitive employment, should not, *by itself,* preclude a finding of total disability under the PSOB Act.

As a result, the agency proposes to revise the definition of gainful work to provide that any such work activity must be both substantial and gainful. The proposed rule would define substantial work activity on the basis of whether the activities performed involved significant mental or physical activities and would provide examples of work activity that is and is not considered substantial. The proposed rule would define gainful work activity similarly to the current definition of gainful work by characterizing work activity as gainful if it is actually or commonly compensated, *i.e.,* performed for pay, but exclude from compensation reimbursement for incidental expenses such as parking or de minimis compensation.

The revised definition will enable the agency to fairly determine whether a claimant who has been determined, pursuant to a medical assessment, to be permanently and totally disabled but nonetheless performs some sort of paid work activity, should be awarded disability benefits.

• *Permanently disabled:* Under 28 CFR 32.23, permanent disability is shown when a medical assessment establishes ''to a degree of medical certainty,'' *i.e.,* by clear and convincing evidence, that a claimant's condition will progressively deteriorate or remain constant over his or her expected lifetime, or has reached maximum medical improvement. The higher standard of proof associated with ''medical certainty'' imposed by the current regulation but not required by law often requires the agency to conduct additional evidentiary development, particularly in claims with conflicting medical opinions. The agency's experience in applying the higher standard of proof is that it does not necessarily provide additional certainty as the determining official, as in other claims, makes determinations of eligibility by weighing the evidence, assessing its probative value, and determining which evidence is entitled to more weight and or credibility. As a result, the agency believes applying the standard of proof ''to a degree of medical probability'' would lessen the burden on claimants and the agency to establish permanent disability, would reduce delays in processing disability claims, and would not impact the integrity of the PSOB Program in any way. As a result, the agency proposes to revise the regulation to change the standard of proof required to establish a permanent level of disability from ''medical certainty'' to ''medical probability.''

• *Totally disabled:* Under current regulations in 28 CFR 32.23, total disability is shown when a medical assessment establishes ''to a degree of medical certainty,'' *i.e.,* by clear and convincing evidence, that a claimant's residual functional capacity (that which a medical and vocational assessment demonstrates that the claimant can do despite his or her disability) is such that he or she cannot perform any gainful work. For the reasons discussed in the proposed revision to the definition of ''permanent disabled,'' the agency proposes to revise the regulation to change the standard of proof required to establish such level of disability from ''medical certainty'' to ''medical probability.''

Section 32.24 PSOB Office Determination

Consistent with proposed § 32.5(o), which consolidates all abandonment provisions into a single paragraph, the proposed rule would remove paragraph (b), which prescribes abandonment provisions for disability claims. The proposed rule would also remove references to reconsideration of negative disability findings.

Section 32.25 Prerequisite Certification

Consistent with proposed § 32.5(l), which replaces §§ 32.15 and 32.25, the proposed rule would remove § 32.25, which prescribes prerequisite certification requirements for disability claims.

§ 32.27 Motion for Reconsideration of Negative Disability Finding

Under current § 32.27, a claimant whose claim is denied on the basis that the evidence has not established that the disability is total and permanent may move for reconsideration, under § 32.28, of the specific finding as to the total and permanent character of the claimed disability in lieu of requesting a Hearing Officer determination with respect to the same. Although providing an alternative to a Hearing Officer determination, the process is cumbersome, confusing to claimants, and since fiscal year 2011, fewer than 10 claimants have sought to take advantage of this provision. Due to its lack of use, BJA proposes to remove this rule, but would continue its application for those claims currently in the reconsideration process. For the reasons discussed, BJA also proposes to remove § 32.28 and provisions in § 32.29 referring to such motions.

§ 32.33 Definitions

Section 32.33 provides definitions applicable to PSOB education benefits. OJP proposes to add new definitions or revise existing definitions in § 32.33 as follows:

• *Child of an eligible public safety officer:* The proposed rule would clarify that an individual found to be an eligible beneficiary under 42 U.S.C. 3796(a)(6) (*i.e.,* a person who would be eligible for death benefits as a child but for his age), is not a child of an eligible public safety officer under subpart D, and thus not eligible for educational assistance under the provisions of 42 U.S.C. 3796d–1 through 42 U.S.C. 3796d–7.

• *Dependent:* The proposed rule would eliminate this definition, as the Dale Long Act (sec. 1086 of Pub. L. 112–239) removed the term from the PSOB Act.

• *Educational expenses:* The proposed rule would revise this definition to provide that such expenses refers to out-of-pocket expenses incurred by a claimant or claimant's family. The proposed rule is intended to provide that PSOB education benefits are to reimburse claimants for those expenses actually incurred for tuition, fees, and that other expenses and are not available when an educational institution has waived or otherwise discounted tuition, fees, or the cost of other expenses for the claimant. The proposed rule provides that in such circumstances, BJA would calculate reimbursement based on the actual costs incurred, not the amount of tuition or

fees charged before a waiver or other discount is applied.

• *Eligible dependent:* The proposed rule would eliminate this definition as the Dale Long Act (sec. 1086 of Pub. L. 112–239) removed the term from the PSOB Act.

• *Tax Year:* The proposed rule would remove this definition as the Dale Long Act (sec. 1086 of Pub. L. 112–239) removed the term from the PSOB Act.

Section 32.34 PSOB Office Determination

Consistent with proposed § 32.5(o), which consolidates all abandonment provisions into a single paragraph, the proposed rule would remove paragraph (b), which prescribes abandonment provisions for disability claims. Consistent with revisions to the definitions in § 32.33, the proposed rule would also remove references to ''threshold claims.''

Section 32.41 Scope of Subpart

The proposed rule would remove all references to § 32.27 consistent with the proposal to remove §§ 32.27, 32.28, and 32.29.

Section 32.42 Time for Filing Requests for Determination

The proposed rule would remove all references to § 32.27 consistent with the proposal to remove §§ 32.27, 32.28, and 32.29.

Section 32.44 Hearing Officer Determination

The proposed rule would, consistent with proposed § 32.10, require that Hearing Officers seek legal advice from PSOB Counsel before determining a claim. Consistent with proposed § 32.5(o), which consolidates all abandonment provisions into a single paragraph, the proposed rule would remove paragraph (c), which prescribes abandonment provisions for Hearing Officer determinations.

Section 32.45 Hearings

The proposed rule would clarify that, at a hearing, Hearing Officers are the only individual permitted to examine or question a claimant, other than a claimant's own representative, if any. The purpose of the proposed this rule is to preserve the non-adversarial nature of the Hearing Officer determination and to make clear that a hearing is not for purposes of providing claimants with the opportunity to engage in trial-type discovery as to other claimants.

Section 32.54 Director Determination

Consistent with proposed § 32.5(o), which consolidates all abandonment provisions into a single paragraph, the proposed rule would remove paragraph (b), which prescribes abandonment provisions for Director determinations.

V. Regulatory Requirements

Executive Order 12866 and 13563—Regulatory Planning and Review

This proposed rule has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review,'' section 1(b), Principles of Regulation, and in accordance with Executive Order 13563, ''Improving Regulation and Regulatory Review,'' section 1(b), General Principles of Regulation. Although not an economically significant rulemaking under Executive Orders 12866 and 13563, the Office of Justice Programs has determined that this proposed rule is a ''significant regulatory action'' under section 3(f) of the Executive Order, and accordingly this rule has been reviewed by the Office of Management and Budget (OMB).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). As explained below, the agency has assessed the costs and benefits of this proposed rule as required by Executive Order 12866 and has determined that the benefits of the proposed rule justify the costs.

A. Provisions That Define When an Individual Is a Firefighter

Based on the number of claims received in the past involving similar situations and the circumstances of such claims, OJP estimates that the revised provisions could increase approvals by approximately 1 claim per year. If all such claims were paid at the current rate, the annual PSOB Program death and disability benefit cost would be increased by $339,881. Based on amounts appropriated in FY2016 for PSOB Program death benefits (''such sums as necessary''—estimated at $71,323,000) and disability and education benefits ($16,300,000), the agency knows that it could pay the death claims from its current appropriations, and estimates that it could pay the disability claims from its current appropriations.

B. Provisions That Define When an Organization or Entity Is a Volunteer Fire Department

Under existing law and regulations, BJA currently determines that *certain* volunteer fire departments qualify as public agencies, and, as a result, that qualified firefighters serving such agencies qualify as public safety officers. In addition, the proposed definition of ''volunteer fire department'' does not expand the number or type of organizations that qualify as a public agency under the law but rather only codifies the agency's interpretation of the status of such organizations as a public agency based on existing provisions of law and regulations. As such, OJP estimates that there are no additional death or disability benefit costs associated with this provision.

C. Provisions Pertaining to the Filing of an Application for Benefits, That Define When an Individual Is a Public Safety Officer, When an Officer Has Sustained a Line of Duty Injury, an Officer Is Permanently and Total Disabled When Payment of Benefits Is Prohibited, When Individuals Are Ineligible for Payment, and Related Matters

Based on the number of claims received in the past involving similar situations and the circumstances of such claims, OJP estimates that the revised provisions, taken together, could increase approvals by approximately 9 claims per year. If all 9 claims were paid at the current rate, the annual PSOB Program death and disability benefit cost would be increased by $3,058,929. Based on amounts appropriated in FY2016 for PSOB Program death benefits (''such sums as necessary''—estimated at $71,323,000) and disability and education benefits ($16,300,000), the agency knows that it could pay the death claims from its current appropriations, and estimates that it could pay the disability claims from its current appropriations.

D. Provisions Pertaining to the Admissibility, Sufficiency, Evaluation, and Disclosure of Evidence Submitted in PSOB Claims, and Related Matters

The primary benefit of the proposed rules is that the revised requirements would reduce the burden on claimants to establish eligibility for benefits and provide a corresponding reduction in the agency's processing burden in gathering and evaluating such evidence. The agency estimates that this across-the-board reduction in burden for both claimants and the agency will translate into reduced processing time for claims,

more timely determinations, and improved delivery of benefits. In terms of benefit costs, the agency estimates that there will not be a significant increase in claims approved as compared to the previous regulatory criteria. Accordingly, the proposed rule does not significantly increase benefit costs.

E. Provisions Concerning the Fees That May Be Charged for Representation in PSOB Claims

The primary benefit of the proposed rule is that it makes it easier for individuals seeking benefits to obtain qualified representation. In eliminating restrictions on the types of fee agreements permitted in representation for PSOB claims, eliminating the maximum hourly rate for representative's fees in favor of a percentage-based maximum limit, and establishing a presumption of reasonableness for fees below certain amounts, the agency believes that the proposed rules would encourage more attorneys to provide representation in PSOB claims. A secondary benefit of the proposed rules is that, in eliminating automatic review of all petitions for fees, the proposed rule will reduce agency burden and permit the agency to reallocate these resources to processing claims. These provisions have no impact on benefit costs.

F. Provisions Establishing When an Application for Benefits Is Complete and Will Be Accepted for Processing as a Claim

The primary benefit of the proposed rule defining a ''complete application'' is that it will (1) provide clarity to applicants for benefits as to precisely what documents and information are required for the agency to begin processing the application as a claim, and (2) enable the agency to allocate its resources to those applications that are sufficiently complete to warrant a determination on the merits. A secondary benefit of the proposed rule is that, as the agency transitions further to an entirely paperless processing system, the proposed rule would facilitate processing by releasing for processing, with few exceptions, only complete applications. These provisions have no impact on benefit costs.

G. Provisions Establishing the Scope of Administrative Legal Review of PSOB Claims

The primary benefit of the proposed rule is that it makes transparent the role of PSOB Counsel in the processing of claims. These provisions have no impact on benefit costs, and no impact on administrative or personnel costs.

H. Provisions Pertaining to Educational Assistance and Other Matters Necessary To Implement the Proposed Rule

The primary benefit of the proposed rule is that it makes clear how educational expenses are calculated in the processing of such claims and implements recent amendments to the Act. These provisions have no impact on benefit costs.

I. Personnel and Training Costs for Agency Staff

As PSOB claims and applications under the provisions of the proposed rule would be processed by existing staff, the agency would not incur additional personnel costs in processing these claims. OJP acknowledges that there would be some costs associated with training current staff; however, OJP estimates that such costs would be nominal as such training is ordinarily conducted in-house by existing legal and program staff and is scheduled and conducted to minimize disruptions to claims processing.

This proposed rule would impose no costs on state, local, or tribal governments, or on the private sector.

Executive Order 13132—Federalism

This proposed rule would not have substantial direct effects on the States, on the relationship between the federal government and the States, or on distribution of power and responsibilities among the various levels of government. The PSOB program statutes provide benefits to individuals and do not impose any special or unique requirements on States or localities. Therefore, in accordance with Executive Order No. 13132, it is determined that this proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12988—Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) & (b)(2) of Executive Order No. 12988. Pursuant to section 3(b)(1)(I) of the Executive Order, nothing in this proposed rule or any previous rule (or in any administrative policy, directive, ruling, notice, guideline, guidance, or writing) directly relating to the Program that is the subject of this rule is intended to create any legal or procedural rights enforceable against the United States, except as the same may be contained within part 32 of title 28 of the Code of Federal Regulations.

Regulatory Flexibility Act

This proposed rule would not have a significant economic impact on a substantial number of small entities for the following reasons: This proposed rule addresses federal agency procedures; furthermore, this proposed rule would make amendments to clarify existing regulations and agency practice concerning public safety officers' death, disability, and education benefits and would do nothing to increase the financial burden on any small entities. Therefore, an analysis of the impact of this proposed rule on such entities is not required under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Paperwork Reduction Act of 1995

This proposed rule would impose or modify reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). The PRA requires certain actions before an agency can adopt or revise a collection of information, including publishing a summary of the collection of information and a brief description of the need for and proposed use of the information. 44 U.S.C. 3507.

The proposed rule includes paperwork requirements in three collections of information previously approved by OMB for the PSOB Program. OJP published in the **Federal Register** on January 11, 2016, a 60-day notice of ''Agency Information Collection Activities'' for each of the following forms: *Claim for Death Benefits* (OMB Number 1121–0024), *Report of Public Safety Officer's Death* (OMB Number 1121–0025), and *Public Safety Officers' Disability Benefits* (OMB Number 1121–0166). In calculating the burden associated with these forms/collections, OJP reviewed its previous burden estimates and updated these to reflect the time required for claimants to gather the many different documents necessary to establish eligibility for these benefits, *e.g.,* birth certificates, marriage certificates, divorce decrees (where applicable), public agency determinations as to death or disability benefits, medical records, etc. Information about the proposed collections is as follows:

Claim for Death Benefits—Overview of Information Collection

1. *Type of Information Collection:* Reinstatement with change of a previously approved collection.

2. *The Title of the Form/Collection:* Claim for Death Benefits.

3. *The agency form number, if any, and the applicable component of the*

Department sponsoring the collection: Bureau of Justice Assistance, Office of Justice Programs, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Eligible survivors of fallen public safety officers.

Abstract: BJA's Public Safety Officers' Benefits (PSOB) Office will use these Claim Form information to confirm the eligibility of applicants to receive Public Safety Officers' Death Benefits. Eligibility is dependent on several factors, including public safety officer status, an injury sustained in the line of duty, and the claimant status in the beneficiary hierarchy according to the PSOB Act. In addition, information to help the PSOB Office identify an individual is collected, such as Social Security numbers, telephone numbers, and email addresses. Changes to the claim form have been made in an effort to streamline the application process and eliminate requests for information that are either irrelevant or already being collected by other means.

OJP estimates that no more than 350 respondents will apply each year. Each application takes approximately 120 minutes to complete. OJP estimates that the total public burden (in hours) associated with the collection can be calculated as follows: Total Annual Reporting Burden: 350 × 120 minutes per application = 42,000 minutes/by 60 minutes per hour = 700 hours.

Public Safety Officer's Death—Overview of Information Collection

1. *Type of Information Collection:* Reinstatement with change of a previously approved collection.

2. *The Title of the Form/Collection:* Report of Public Safety Officer's Death.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Bureau of Justice Assistance, Office of Justice Programs, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Public safety agencies experiencing the death of a public safety officer according to the PSOB Act.

Abstract: BJA's Public Safety Officers' Benefits (PSOB) Office will use these Report of Public Safety Officer's Death Form information to confirm the eligibility of applicants to receive Public Safety Officers' Death Benefits. Eligibility is dependent on several factors, including public safety officer status, an injury sustained in the line of duty, and the claimant status in the beneficiary hierarchy according to these Act. In addition, information to help the PSOB Office identify an individual is collected, such as Social Security numbers, telephone numbers, and email addresses. Changes to the report form have been made in an effort to streamline the application process and eliminate requests for information that are either irrelevant or already being collected by other means.

OJP estimates that no more than 350 respondents will apply each year. Each application takes approximately 240 minutes to complete. OJP estimates that the total public burden (in hours) associated with the collection can be calculated as follows: Total Annual Reporting Burden: 350 × 240 minutes per application = 84,000 minutes/by 60 minutes per hour = 1,400 hours.

Public Safety Officers' Disability Benefits—Overview of Information Collection

1. *Type of Information Collection:* Reinstatement with change of a previously approved collection.

2. *The Title of the Form/Collection:* Public Safety Officer's Disability Benefits.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Bureau of Justice Assistance, Office of Justice Programs, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Public safety officers who were permanently and totally disabled in the line of duty.

Abstract: BJA's Public Safety Officers' Benefits (PSOB) Office will use the PSOB Disability Application information to confirm the eligibility of applicants to receive Public Safety Officers' Disability Benefits. Eligibility is dependent on several factors, including public safety officer status, injury sustained in the line of duty, and the total and permanent nature of the line of duty injury. In addition, information to help the PSOB Office identify individuals is collected, such as Social Security numbers, telephone numbers, and email addresses. Changes to the application form have been made in an effort to streamline the application process and eliminate requests for information that are either irrelevant or already being collected by other means.

OJP estimates that no more than 100 respondents will apply each year. Each application takes approximately 300 minutes to complete. OJP estimates that the total public burden (in hours) associated with the collection can be calculated as follows: Total Annual Reporting Burden: 100 × 300 minutes per application = 30,000 minutes/by 60 minutes per hour = 500 hours.

Unfunded Mandates Reform Act of 1995

This proposed rule would not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. The PSOB program is a federal benefits program that provides benefits directly to qualifying individuals. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

List of Subjects in 28 CFR Part 32

Administrative practice and procedure, Claims, Disability benefits, Education, Emergency medical services, Firefighters, Law enforcement officers, Reporting and recordkeeping requirements, Rescue squad.

Accordingly, for the reasons set forth in the preamble, part 32 of chapter I of title 28 of the Code of Federal Regulations is proposed to be amended as follows:

PART 32—PUBLIC SAFETY OFFICERS' DEATH, DISABILITY, AND EDUCATIONAL ASSISTANCE BENEFITS CLAIMS

■ 1. The authority citation for 28 CFR part 32 continues to read as follows:

Authority: 42 U.S.C. ch. 46, subch. XII; 42 U.S.C. 3782(a), 3787, 3788, 3791(a), 3793(a)(4) & (b), 3795a, 3796c–1, 3796c–2; sec. 1601, title XI, Pub. L. 90–351, 82 Stat. 239; secs. 4 through 6, Pub. L. 94–430, 90 Stat. 1348; secs. 1 and 2, Pub. L. 107–37, 115 Stat. 219.

■ 2. Amend § 32.2 by redesignating paragraphs (e) and (f) as paragraphs (f) and (g), respectively, and adding new paragraphs (e) and (h) to read as follows:

§ 32.2 Computation of time; filing.

* * * * *

(e) In determining whether an application, claim, or other document will be considered if filed after the time prescribed for such filing has passed, good cause for such filing (excluding a lack of knowledge about the PSOB Program) may be found if the individual acted with reasonable diligence after any circumstance contributing to the delay was removed, and the delay was attributable to—

(1) Circumstances beyond the individual's control such as not having reached the age of majority, extended illness, or mental or physical incapacity;

(2) Incorrect information provided by the public agency in which the public safety officer served, or another public

agency, related to the filing of a PSOB claim that the individual relied upon to his detriment;

(3) A determination of the officer's (or survivor's) eligibility or entitlement to death or disability benefits by the officer's public agency or other public agency, made after the time for filing has passed; or

(4) Other unavoidable circumstances demonstrating that the individual could not be reasonably expected to know about the time limits for filing an application or claim.

* * * * *

(h) The Director may, after publishing a Notice in the **Federal Register** consistent with 5 U.S.C. 552(a)(1)(C), and providing reasonable notice through the PSOB Program Web site, require all applications, claims, and supporting materials to be filed in electronic or other form as the Director shall prescribe.

* * * * *

■ 3. Amend § 32.3 as follows:

■ a. Add the definitions of *''Agent''* and *''Attorney''.*

■ b. In the definition of ''*Authorized commuting''* add '', including reasonable return travel'' after ''within his line of duty''.

■ c. Revise the definition of ''*Child of a public safety officer''.*

■ d. Remove the definition of *''Consequences of an injury that permanently prevent an individual from performing any gainful work''.*

■ e. Revise the definitions of ''*Department or agency''*, ''*Determination''*, ''*Divorce''*, ''*Employee''*, ''*Firefighter''*, ''*Gross negligence''*, ''*Injury''*, *''Injury date''*, ''*Involvement''*, ''*Line of duty activity or action''*, and ''*Line of duty injury''.*

■ f. Add the definition of *''Medical probability.''*

■ g. Revise the definitions of *''Official capacity''* and ''*Officially recognized or designated public employee member of a squad or crew''.*

■ h. Add the definition of *''On-site hazard management''.*

■ i. Revise the definition of ''*Parent-child relationship''.*

■ j. Add the definition of *''PSOB Counsel''.*

■ k. Remove the definitions of, and ''*Public employee member of a squad or crew,''* and ''*Stress or strain.''*

■ l. Revise the definitions of ''*Suppression of fire''* and ''*Voluntary intoxication''.*

■ m. Add the definition of *''Volunteer fire department''*

The revisions and additions read as follows:

§ 32.3 Definitions

* * * * *

Agent means an individual who provides representative services to an individual seeking benefits under the Act and is not an attorney as provided in this part.

* * * * *

Attorney means a member in good standing of a State bar.

* * * * *

Child of a public safety officer means an individual—

(1) Who meets the definition provided in the Act, at 42 U.S.C. 3796b(3), and

(2) With respect to whom the public safety officer's parental rights have not been terminated, as of the injury date.

* * * * *

Department or agency—An entity is a department or agency within the meaning of the Act, at 42 U.S.C. 3796b(8), and this part, only if the entity is—

(1) A court;

(2) An agency described in the Act, at 42 U.S.C. 3796b(9)(B) or (C);

(3) An entity created by interstate compact between two or more States or between a State or States and the District of Columbia with the consent (through consenting or enabling legislation, or similar mechanism) by the United States Congress; or

(4) Otherwise a public entity—

(i) That is legally an express part of the internal organizational structure of the relevant government;

(ii) That has no legal existence independent of such government; and

(iii) Whose obligations, acts, omissions, officers, and employees are legally those of such government.

* * * * *

Determination means the approval or denial of a claim, the determination described in the Act, at 42 U.S.C. 3796(c), or any recommendation under § 32.54(c)(3).

* * * * *

Divorce means a legally valid, *i.e.,* court-ordered, dissolution of marriage.

* * * * *

Employee does not include—

(1) Any independent contractor;

(2) Any individual who is not eligible to receive death or disability benefits from the purported employer on the same basis as a regular employee of such employer would; or

(3) Any active duty member of the armed forces.

* * * * *

Firefighter means (1) An individual who—

(i) Is trained in—

(A) Suppression of fire; or

(B) Hazardous-material response; and

(ii) Has the legal authority and responsibility to engage in the suppression of fire, as—

(A) An employee of the public agency he serves, which legally recognizes him to have such (or, at a minimum, does not deny (or has not denied) him to have such); or

(B) An individual otherwise included within the definition provided in the Act, at 42 U.S.C. 3796b(4); or

(2) An individual who is a participant in an official training program of the officer's public agency that is mandatory for that individual's employment or certification as a firefighter and such training program involves the suppression of fire or hazardous-material response.

* * * * *

Gross negligence means a reckless departure from the ordinary care used by similarly situated public safety officers under circumstances where it is highly likely that serious harm will follow.

* * * * *

Injury—(1) Injury means—

(i) A traumatic physical wound or a traumatized condition of the body, or the increase in severity of such an existing wound or condition, directly and proximately caused by—

(A) External force such as bullets or physical blows;

(B) Exposure to external factors such as chemicals, electricity, climatic conditions, infectious disease, radiation, virus, or bacteria;

(C) Heatstroke; or

(D) Acute and immediate musculoskeletal strain or muscle damage such as a disc herniation or rhabdomyolysis,

(ii) But does not include—

(A) Any occupational disease;

(B) Any chronic, cumulative, or progressive condition of the body;

(C) Cardiovascular disease; or

(D) Any mental health condition including post-traumatic stress disorder, depression, or anxiety.

(2) With respect to claims based on a fatal heart attack, stroke, or vascular rupture, injury also means the presumption of personal injury established when the requirements of 42 U.S.C. 3796(k) are satisfied.

* * * * *

Injury date—(1) In general, injury date means the time of the line of duty injury that—

(i) Directly and proximately results in the public safety officer's death, with respect to a claim under—

(A) Subpart B of this part; or

(B) Subpart D of this part, by virtue of his death; or

(ii) Directly (or directly and proximately) results in the public safety officer's total and permanent disability, with respect to a claim under—

(A) Subpart C of this part; or

(B) Subpart D of this part, by virtue of his disability.

(2) With respect to claims under the Act, at 42 U.S.C. 3796(k), injury date means the time of the public safety officer's qualifying engagement or participation referred to in the Act at 42 U.S.C. 3796(k)(1).

* * * * *

Involvement—An individual is involved in crime and juvenile delinquency control or reduction, or enforcement of the criminal laws (including juvenile delinquency), only if the individual is an officer, or in the case of an officer trainee, an employee, of a public agency and, in that capacity, is recognized by such agency, or the relevant government (or, at a minimum, not denied by such agency, or the relevant government) as having—

(1) Legal authority to arrest, apprehend, prosecute, adjudicate, correct or detain (in a prison or other detention or confinement facility), or supervise (as a parole or probation officer), persons who are alleged or found to have violated the criminal laws, or

(2) Legal authority to participate in an official training program of the officer's public agency that is mandatory for that individual's employment or certification as a police officer, corrections officer, probation officer, or their equivalent.

* * * * *

Line of duty activity or action—Activity or an action is performed in the line of duty if it is not described in the Act, at 42 U.S.C. 3796a(1), in the case of a public safety officer who is—

(1) A law enforcement officer or firefighter—

(i) Whose primary function (as applicable) is public safety activity, only if it is activity or an action that he is obligated or authorized by statute, rule, regulation, condition of employment or service, official mutual aid agreement, or other law, to perform (including any social, ceremonial, or athletic functions (or any official training programs of his public agency) to which he is assigned, or for which he is compensated), under the auspices of the public agency he serves, and such agency (or the relevant government) legally recognizes that activity or action to have been so obligated or authorized at the time performed (or, at a minimum, does not deny (or has not denied) it to have been such); or

(ii) Whose primary function is not public safety activity, only if—

(A) It is activity or an action that he is obligated or authorized by statute, rule, regulation, condition of employment or service, official mutual-aid agreement, or other law, to perform, under the auspices of the public agency he serves, and such agency (or the relevant government) legally recognizes that activity or action to have been so obligated or authorized at the time performed (or, at a minimum, does not deny (or has not denied) it to have been such); and

(B) It is performed (as applicable) in the course of public safety activity (including emergency response activity the agency is authorized to perform), or taking part (as a trainer or trainee) in an official training program of his public agency for such activity (including participation as a trainee in an official training program of his public agency that is mandatory for that individual's employment or certification as a firefighter, police officer, corrections officer, probation officer, or equivalent), and such agency (or the relevant government) legally recognizes it to have been such at the time performed (or, at a minimum, does not deny (or has not denied) it to have been such); or

(iii) Only if it constitutes public safety activity, is performed in the course of responding to an emergency situation that the officer did not create through his own actions, requires prompt decisions and action to save another human life, and is not contrary to the law of the jurisdiction in which performed;

(2) A member of a rescue squad or ambulance crew, only if it is activity or an action that he is obligated or authorized by statute, rule, regulation, condition of employment or service, official mutual-aid agreement, or other law, to perform, under the auspices of the public agency or nonprofit entity he serves, it is performed in the course of engaging in rescue activity or providing emergency medical services, and such agency (or the relevant government) or nonprofit entity legally recognizes it to have been such at the time performed (or, at a minimum, does not deny (or has not denied) it to have been such; or

(3) A disaster relief worker, only if, it is disaster relief activity, and the agency he serves (or the relevant government), being described in the Act, at 42 U.S.C. 3796b(9)(B) or (C), legally recognizes it to have been such at the time performed (or, at a minimum, does not deny (or has not denied) it to have been such); or

(4) A chaplain, only if—

(i) It is activity or an action that he is obligated or authorized by statute, rule, regulation, condition of employment or service, official mutual-aid agreement, or other law, to perform, under the auspices of the public agency he serves, and such agency (or the relevant government) legally recognizes it to have been such at the time performed (or, at a minimum, does not deny (or has not denied) it to have been such); and

(ii) It is performed in the course of responding to a fire-, rescue-, or police emergency, and such agency (or the relevant government) legally recognizes it to have been such at the time performed (or, at a minimum, does not deny (or has not denied) it to have been such).

* * * * *

Line of duty injury—An injury is sustained in the line of duty only if—

(1) It is sustained in the course of—

(i) Performance of line of duty activity or a line of duty action; or

(ii) Authorized commuting; or

(2) Such injury resulted from the injured party's status as a public safety officer, or was sustained in retaliation for line of duty actions taken by the officer or other public safety officers.

* * * * *

Medical probability—A fact is indicated to a degree of medical probability, when, pursuant to a medical assessment, the fact is indicated by a preponderance of such evidence as may be available.

* * * * *

Official capacity—An individual serves a public agency in an official capacity only if—

(1) He is officially authorized, -recognized, or -designated (by such agency) as functionally within or -part of it, and

(2) His acts and omissions, while so serving, are legally those of such agency, which legally recognizes them as such (or, at a minimum, does not deny (or has not denied) them to be such); or

(3) His acts and omissions while responding to an emergency for purposes of saving human life constitute a line of duty action or activity as defined in this part.

* * * * *

Officially recognized or designated employee or volunteer member of a rescue squad or ambulance crew means an employee or volunteer member of a rescue squad or ambulance crew who—

(1) Is officially recognized (or officially designated) as such an employee or volunteer member, by the public agency or nonprofit entity serving the public under whose auspices the squad or crew operates, and

(2) Is engaging in rescue activity or in the provision of emergency medical services as authorized or licensed by

law and by the applicable agency or entity.

* * * * *

On-site hazard management means on-site hazard evaluation and providing scene security or directing traffic in response to any fire, rescue, or law enforcement emergency.

* * * * *

Parent-child relationship means a relationship between a public safety officer and another individual, in which the officer has the role of parent (other than biological or legally-adoptive).

* * * * *

PSOB Counsel means the legal staff within BJA that provides programmatic legal advice to PSOB determining officials and performs legal review of PSOB Program claims and related matters.

* * * * *

Suppression of fire means extinguishment, physical prevention, containment of fire, and on-site hazard management.

* * * * *

Voluntary intoxication at the time of death or catastrophic injury means the following, as shown by any commonly accepted tissue, -fluid, or -breath test or by other competent evidence:

(1) With respect to alcohol,

(i) In any claim arising from a public safety officer's death in which the death was simultaneous (or practically simultaneous) with the injury, it means intoxication as defined in the Act, at 42 U.S.C. 3796b(5), unless convincing evidence demonstrates that the officer did not introduce the alcohol into his body intentionally; or

(ii) In any claim in which a public safety officer's death occurred after the injury date, unless convincing evidence demonstrates that the officer did not introduce the alcohol into his body intentionally, it means intoxication—

(A) As defined in the Act, at 42 U.S.C. 3796b(5); and

(B) As of the injury date; or

(2) With respect to drugs or other *s*ubstances, it means intoxication as defined in the Act, at 42 U.S.C. 3796b(5), as evidenced by—

(i) The officer acting in an intoxicated manner as of the injury date, unless convincing evidence demonstrates that the introduction of drugs or other substances was not an intentional act of the officer's; or

(ii) The presence (as of the injury date) in the body of the public safety officer of drugs or substances included on Schedules I–III of the drug control and enforcement laws (see 21 U.S.C. 812(a)), unless convincing evidence demonstrates that—

(A) The introduction of such drug or other substance was not an intentional act of the officer's, or

(B) The drug or other substance would not produce intoxication in the amount present in the public safety officer's body.

* * * * *

Volunteer fire department—a volunteer fire department is an instrumentality within the meaning of the Act at 42 U.S.C. 3796b(8) if—

(1) It is legally established as a nonprofit entity serving the public,

(2) It is legally established and operates solely for the purpose of providing fire protection and related services to or on behalf of a public agency or agencies, and

(3) It provides fire protection and related services to the public without preference or subscription.

■ 4. Amend § 32.5 as follows:

■ a. Revise paragraph (a).

■ b. Remove paragraphs (c) and (d)(3).

■ c. Redesignate paragraph (b) as paragraph (c).

■ d. In paragraph (i) add ''and physically stressful'' after ''non-routine''.

■ e. Add new paragraphs (b), (k), (l), and (m).

The revision and additions read as follows:

§ 32.5 Evidence.

(a) Except as otherwise may be expressly provided in the Act or this part, a claimant is responsible for establishing all issues of fact for the particular benefit sought by the standard of proof of ''more likely than not.''

(b) The evidence that a claimant produces, both circumstantial and direct, must be credible, probative, and substantial, and, when deemed necessary by a PSOB determining official, produced in original format or certified as a true and exact copy of a record by a custodian of such records or other person capable of verifying the authenticity of such records.

* * * * *

(k) In instances where the determining official finds that there is a balance of positive and negative evidence for an issue material to the particular benefit sought, the PSOB determining official will resolve the point in favor of the payment of benefits. Such a finding of equivalence must be based on reason, logic, common sense, and the determining official's experience, and, under no circumstances, may a lack of evidence in support of a particular fact be understood to establish or create such equivalence.

(l) A PSOB determining official may require from a claimant proof of birth, death, disability, earnings, education, employment, expenses, injury, relationship, marriage, or other information deemed necessary to establish eligibility for a benefit under the Act. A PSOB determining official may also require waivers, consents, or authorizations from claimants to obtain directly from third parties tax, medical, employment, or other information that the PSOB determining official deems relevant in determining the claimant's eligibility, and may request an opportunity to review original documents submitted in connection with the claim.

(m) In the absence of reasonable excuse or justification, when evidence necessary to a determination on a claim that has been requested in writing in connection with a complete claim for benefits is not filed with the PSOB Office within one year of the date of such request, or a claimant has otherwise failed to pursue in a timely fashion a determination on his or her claim, the claim will be considered as abandoned, as though never filed. Not less than 33 days prior to the PSOB determining official finding the claim to be abandoned, the PSOB Office shall serve the claimant with notice of intent to deem the claim abandoned. In the event of abandonment, the time periods prescribed for filing an initial application for benefits or other filing deadline are neither tolled nor applicable. A claimant may reopen an abandoned claim within 180 days from the date of abandonment provided claimant files with the PSOB Office a complete claim, including any information previously requested but not provided. After a claim for benefits has been abandoned and a complete claim has not been filed with the PSOB Office in the time prescribed for reopening such claim, no further action on the claim will be taken by the agency.

■ 5. Revise § 32.7 to read as follows:

§ 32.7 Fees for representative services.

(a) Only attorneys, as defined in this part, or an individual working under the direct supervision of an attorney and for whose conduct the attorney is responsible for under applicable Rules of Professional Conduct (*e.g.,* a paralegal), may charge fees for representative services provided in connection with any claim. Fees sought for representative services provided in connection with any claim must be reasonable. Subject to paragraphs (e) and (f) of this section, fees may be based on a fixed fee, hourly rate, a percentage

of benefits recovered, or a combination of such bases. An authorization under paragraph (c) of this section shall be based on consideration of the following factors:

(1) The nature of the services provided by the petitioner;

(2) The complexity of the claim;

(3) The level of skill and competence required to provide the petitioner's services;

(4) The amount of time spent on the claim by the petitioner;

(5) The level of administrative or judicial review to which the claim was pursued and the point at which the petitioner entered the proceedings;

(6) The ordinary, usual, or customary fee charged by other persons (and by the petitioner) for services of a similar nature; and

(b) Before submitting the petition described in paragraph (c) of this section, a person seeking to receive any amount of fees from a claimant for representative services provided in connection with any claim under the Act shall file with the PSOB Office a copy of the fee agreement.

(c) To receive fees for representative services provided in connection with any claim, a representative shall petition the PSOB Office for authorization under this section. Such petition shall include—

(1) An itemized description of the services;

(2) The total amount sought to be received, from any source, as consideration for the services;

(3) An itemized description of any representative or other services provided to (or on behalf of) the claimant in connection with other claims or causes of action, unrelated to the Act, before any public agency or non-public entity (including any insurer), arising from the public safety officer's death, disability, or injury;

(4) The total amount requested, charged, received, or sought to be received, from any source, as consideration for the services described in paragraph (c)(3) of this section;

(5) A statement of whether the petitioner has legal training or is licensed to practice law, and a description of any special qualifications possessed by the petitioner (other than legal training or a license to practice law) that increased the value of his services to (or on behalf of) the claimant;

(6) A certification that the claimant was provided, simultaneously with the filing of the petition, with—

(i) A copy of the petition; and

(ii) A letter advising the claimant that he could file his comments on the petition, if any, with the PSOB Office, within thirty-three days of the date of that letter; and

(7) A copy of the letter described in paragraph (c)(6)(ii) of this section.

(d) Unless, for good cause shown, the Director extends the time for filing, no petition under paragraph (a) of this section shall be considered if the petition is filed with the PSOB Office later than one year after the date of the final agency determination of the claim.

(e) No amount shall be authorized under this section for—

(1) Fees in excess of 12 percent of the total death or disability benefit payment available to a claimant regardless of how the fee agreement is structured; or

(2) Services provided in connection with—

(i) Obtaining or providing evidence or information previously obtained by the PSOB determining official;

(ii) Preparing the petition; or

(iii) Explaining or delivering an approved claim to the claimant.

(f) Fees otherwise qualifying under this section shall be presumed reasonable—

(1) In a claim determined by the PSOB Office that does not exceed 8 percent of the total death or disability benefit payment available to a claimant, or

(2) In a claim determined by the Hearing Officer or Director that does not exceed 10 percent of the total death or disability benefit payment available to a claimant.

(g) The presumptions in paragraph (f) of this section may be rebutted through an examination of the factors in paragraph (a) of this section establishing by clear and convincing evidence that the fee is unreasonable.

(h) Upon its authorizing or not authorizing the payment of any amount under paragraph (a) of this section, the PSOB Office shall serve notice of the same upon the claimant and the petitioner. Such notice shall specify the amount, if any, the petitioner is authorized to charge the claimant and the basis of the authorization.

(i) No agreement for representative services in connection with a claim shall be valid if the agreement provides for any consideration other than under this section. A person's receipt of consideration for such services other than under this section may, among other things, be the subject of referral by BJA to appropriate professional, administrative, disciplinary, or other legal authorities.

■ 6. Add § 32.9 to read as follows:

§ 32.9 Complete applications.

(a) Before an application for benefits under the Act will be processed as a claim, *i.e.,* assigned a claim number by the PSOB Office, determined by the PSOB Office, and reviewed for legal sufficiency, such application must be ''complete'' as provided in this section.

(b) Except as indicated in paragraph (d) of this section, an application for death benefits or disability benefits shall constitute a complete application only if all of the basic required documents identified on the ''PSOB Checklist of Required Documents for Filing a PSOB Death [or Disability, as appropriate] Benefits Claim,'' available at the PSOB Program Web site, are filed with the PSOB Office.

(c) If an applicant files with the PSOB Office an application for benefits that, pursuant to paragraph (b) of this section, is not complete, the PSOB Office will serve the applicant with written notice of the information necessary to complete the application and defer any further processing of the application and consideration as a claim until such Office receives all of the information described in paragraph (b).

(d) An applicant's inability to file evidence as a result of a refusal by a public agency in which the officer served to provide the information identified in this section (or the public agency's demonstrated inability to provide such information) shall not render an application incomplete if the applicant provides to the PSOB Office evidence demonstrating that such inability to file basic required documents is not due to any fault of the applicant.

■ 7. Add § 32.10 to read as follows:

§ 32.10 PSOB Counsel.

(a) Before determining a claim for benefits under the Act, PSOB determining officials shall seek legal advice from PSOB Counsel.

(b) Legal advice provided by PSOB Counsel to PSOB determining officials shall be limited to the interpretation and application of the PSOB Act and implementing regulations and law and regulations referenced in or having direct application to the PSOB Act or its implementing regulations.

(c) Unless otherwise ordered by the Assistant Attorney General for the Office of Justice Programs, the scope of PSOB Counsel's legal advice shall not include the review of findings of fact made by PSOB determining officials.

■ 8. Revise § 32.12 as follows:

§ 32.12 Time for filing claim.

(a) Unless, for good cause shown, as defined in § 32.2(e) of this part, the Director extends the time for filing, no application shall be considered if it is filed with the PSOB Office more than

three years after the public safety officer's death.

(b) An applicant may file with the PSOB Office such supporting documentary, electronic, video, or other nonphysical evidence and legal arguments as he may wish to provide.

■ 9. Amend § 32.13 as follows:

■ a. Revise the definition of ''*Beneficiary of a life insurance policy of a public safety officer*''.

■ b. Remove from the definition of ''*child-parent relationship*'' the phrase '', as shown by convincing evidence''.

■ c. Revise the definition of ''*Engagement in a situation involving law enforcement, fire suppression, rescue, hazardous material response, emergency medical services, prison security, disaster relief, or other emergency response activity*''.

■ d. Remove the definition of ''*Medical probability*''.

■ e. Revise the definitions of ''*Nonroutine strenuous physical activity'' and ''Nonroutine stressful physical activity*''.

The revisions read as follows:

§ 32.13 Definitions.

* * * * *

Beneficiary of a life insurance policy of a public safety officer—An individual (living or deceased on the date of death of the public safety officer) is designated as beneficiary of a life insurance policy of such officer as of such date, only if the designation is, as of such date, legal and valid (as a designation of beneficiary of a life insurance policy) and unrevoked (by such officer or by operation of law) or otherwise unterminated, except that—

(1) Any designation of an individual (including any designation of the biological or adoptive offspring of such individual) made in contemplation of such individual's marriage (or purported marriage) to such officer shall be considered to be revoked by such officer as of such date of death if the marriage (or purported marriage) did not take place, unless preponderant evidence demonstrates that—

(i) It did not take place for reasons other than personal differences between the officer and the individual; or

(ii) No such revocation was intended by the officer;

(2) Any designation of a spouse (or purported spouse) made in contemplation of or during such spouse's (or purported spouse's) marriage (or purported marriage) to such officer (including any designation of the biological or adoptive offspring of such spouse (or purported spouse)) shall be considered to be revoked by such officer as of such date of death if the spouse (or purported spouse) is divorced from such officer after the date of designation and before such date of death, unless preponderant evidence demonstrates that no such revocation was intended by the officer, and.

(3) Any designation of an individual, who was living on the date of the officer's death, but who dies before a determination of PSOB death benefits, shall be considered to be revoked by such officer on the date of the officer's death in favor of the officer's living contingent beneficiary or beneficiaries, if any.

* * * * *

Engagement in a situation involving law enforcement, fire suppression, rescue, hazardous material response, emergency medical services, prison security, disaster relief, or other emergency response activity—A public safety officer is so engaged only when, within his line of duty—

(1) He is in the course of actually—

(i) Engaging in law enforcement;

(ii) Suppressing fire;

(iii) Responding to a hazardous-material emergency;

(iv) Performing rescue activity;

(v) Providing emergency medical services;

(vi) Performing disaster relief activity;

(vii) Otherwise engaging in emergency response activity; or

(viii) Performing a line of duty activity or action, that had it not been performed immediately, would have rendered the public agency unable to perform the activities in paragraphs (1)(i) through (vii) of this section; and

(2) The public agency he serves (or the relevant government) legally recognizes him to have been in such course at the time of such engagement or activity (or, at a minimum, does not deny (or has not denied) him so to have been).

* * * * *

Nonroutine strenuous physical activity means line of duty activity that—

(1) Is not excluded by the Act, at 42 U.S.C. 3796(l);

(2) Is not performed as a matter of routine; and

(3) Entails a vigorous level of physical exertion.

Nonroutine stressful physical activity means line of duty activity that—

(1) Is not excluded by the Act, at 42 U.S.C. 3796(l);

(2) Is not performed as a matter of routine;

(3) Entails non-negligible physical exertion; and

(4) Occurs—

(i) With respect to a situation in which a public safety officer is engaged, under circumstances that objectively and reasonably—

(A) Pose (or appear to pose) dangers, threats, or hazards (or reasonably-foreseeable risks thereof), not faced by similarly-situated members of the public in the ordinary course; and

(B) Provoke, cause, or occasion unusual alarm, fear, or anxiety; or

(ii) With respect to a training exercise in which a public safety officer participates, under circumstances that objectively and reasonably—

(A) Simulate in realistic fashion situations that pose dangers, threats, or hazards; and

(B) Provoke, cause, or occasion unusual alarm, fear, or anxiety.

* * * * *

■ 10. Revise § 32.14 to read as follows:

§ 32.14 PSOB Office determination.

Upon its approving or denying a claim, the PSOB Office shall serve notice of the same upon the claimant (and upon any other claimant who may have filed a claim with respect to the same public safety officer). In the event of a denial, such notice shall—

(a) Specify the factual findings and legal conclusions that support it; and

(b) Provide information as to requesting a Hearing Officer determination.

§ 32.15 [Removed]

■ 11. Remove § 32.15.

§ 32,16 [Redesignated as § 32.15]

■ 12. Redesignate § 32.16 as § 32.15 and revise newly redesignated § 32.15 to read as follows:

§ 32.15 Payment.

(a) For purposes of determining who qualifies as a parent under 42 U.S.C. 3796(a)(5), any biological or legally-adoptive parent whose parental rights have not been terminated as of the injury date shall be presumed rebuttably to be one. If evidence demonstrates that additional individuals also qualify as the parent of a public safety officer, such payment shall be made in equal shares.

(b) Any amount payable with respect to a minor or incompetent shall be paid to his legal guardian, to be expended solely for the benefit of such minor or incompetent.

(c) If more than one individual should qualify for payment—

(1) Under the Act, at 42 U.S.C. 3796(a)(4)(i), payment shall be made to each of them in equal shares, except that, if the designation itself should manifest a different distribution, payment shall be made to each of them in shares in accordance with such distribution; or

(2) Under the Act, at 42 U.S.C. 3796(a)(4)(ii), payment shall be made to each of them in equal shares.

(d) In determining whether an eligible survivor exists under 42 U.S.C. 3796(a)(2), (4), (5), or (6) such that payment must be divided amongst such survivors, the PSOB determining official shall consider any person (other than as defined in 42 U.S.C. 3796b(3)(C)) not to have survived the public safety officer and thus ineligible, who, being 18 years of age or older at the date of the officer's fatal injury, has not filed an application for benefits under 42 U.S.C. 3796(a) within the time prescribed in this part.

§ 32.17 [Redesignated as § 32.16]

■ 13. Redesignate § 32.17 as § 32.16.

■ 14. Revise § 32.22 to read as follows:

§ 32.22 Time for filing claim.

(a) Unless, for good cause shown, as defined in § 32.2(e) of this part, the Director extends the time for filing, no application shall be considered if it is filed with the PSOB Office more than three years after the injury date.

(b) An applicant may file with the PSOB Office such supporting documentary, electronic, video, or other nonphysical evidence and legal arguments as he may wish to provide.

■ 15. Amend 32.23 as follows:

■ a. Revise the definition of ''*Gainful work*''.

■ b. Remove the definition of ''*Medical certainty*''.

■ c. Amend the definition of ''*Permanently disabled*'' and ''*Totally disabled*'' by removing in the introductory sentence ''certainty'' and adding in its place ''probability''.

The revision to read as follows:

§ 32.23 Definitions.

* * * * *

Gainful work means work activity that is both substantial and gainful.

(1) Substantial work activity means work activity that involves doing significant physical or mental activities such as work that requires a claimant to use his or her experience, skills, supervision, or contribute substantially to the operation of a business. Evidence that work activity may not be substantial includes—

(i) Work involving ordinary or simple tasks that a claimant cannot perform without more supervision or assistance than is usually given other people doing similar work,

(ii) Work involving minimal duties that make little or no demands on a claimant and that are of little or no monetary value to an employer;

(iii) Work performed under special conditions take into account a claimant's impairment such as work done in a sheltered workshop; and

(iv) Work offered despite a claimant's impairment because of family relationship, a past association with claimant's employer or other organization to which the claimant was affiliated with, or an employer's or affiliated organization's concern for claimant's welfare.

(2) Gainful work activity means full- or part-time work activity that actually is compensated or is commonly compensated, but compensation does not include reimbursement of incidental expenses such as parking, transportation, and meals, or de minimis compensation.

* * * * *

■ 16. Revise § 32.24 to read as follows:

§ 32.24 PSOB Office determination.

Upon its approving or denying a claim, the PSOB Office shall serve notice of the same upon the claimant. In the event of a denial, such notice shall—

(a) Specify the factual findings and legal conclusions that support it; and

(b) Provide information as to requesting a Hearing Officer determination.

§ 32.25 [Removed]

■ 17. Remove § 32.25.

§ 32.26 [Redesignated as § 32.25]

■ 18. Redesignate § 32.26 as § 32.25.

§§ 32.27 and 32.28 [Removed]

■ 19. Remove §§ 32.27 and 28.

§ 32.29 [Redesignated as § 32.26]

■ 20. Redesignate § 32.29 as § 32.26 and revise newly redesignated § 32.26 to read as follows:

§ 32.26 Request for Hearing Officer determination.

In order to exhaust his administrative remedies, a claimant seeking relief from the denial of his claim shall request a Hearing Officer determination under subpart E of this part. Consistent with § 32.8, any denial that is not the subject of such a request shall constitute the final agency determination.

■ 21. Amend § 32.33 as follows:

■ a. Revise the definition of ''*Child of an eligible public safety officer*''.

■ b. Remove the definition of ''*Dependent*''.

■ c. Revise the definition of ''*Educational expenses*''.

■ d. Remove the definitions of ''*Eligible dependent*'', and ''*Tax year*''.

The revisions read as follows:

§ 32.33 Definitions.

* * * * *

Child of an eligible public safety officer means the child of a public safety officer, which officer is an eligible public safety officer, but does not include any individual described in 42 U.S.C. 3796(a)(6).

* * * * *

Educational expenses means out-of-pocket expenses actually incurred by the claimant or claimant's family and excludes expenses not incurred by reason of a waiver, scholarship, grant, or equivalent reduction for such of the following as may be in furtherance of the educational, professional, or vocational objective of the program of education that forms the basis of a financial claim:

(1) Tuition and fees, as described in 20 U.S.C. 1087*ll*(1) (higher education assistance);

(2) Reasonable expenses for—

(i) Room and board (if incurred for attendance on at least a half-time basis);

(ii) Books;

(iii) Computer equipment;

(iv) Supplies;

(v) Transportation; and

(3) For attendance on at least a three-quarter-time basis, a standard allowance for miscellaneous personal expenses that is the greater of—

(i) The allowance for such expenses, as established by the eligible educational institution for purposes of financial aid; or

(ii) $200.00 per month.

* * * * *

■ 22. Revise § 32.34 to read as follows:

§ 32.34 PSOB Office determination.

In the event of the PSOB Office's denying a claim, the notice it serves upon the claimant shall—

(a) Specify the factual findings and legal conclusions that support the denial; and

(b) Provide information as to requesting a Hearing Officer determination.

■ 23. Revise § 32.41 to read as follows:

§ 32.41 Scope of subpart.

Consistent with § 32.1, this subpart contains provisions applicable to requests for Hearing Officer determination of claims denied under subpart B, C, or D of this part, and of claims remanded (or matters referred) under § 32.54(c).

■ 24. Revise § 32.42 to read as follows:

§ 32.42 Time for filing request for determination.

(a) Unless, for good cause shown, as defined in § 32.2(e) of this part, the Director extends the time for filing, no claim shall be determined if the request therefor is filed with the PSOB Office

later than thirty-three days after the service of notice of the denial (under subpart B, C, or D of this part) of a claim.

(b) A claimant may file with his request for a Hearing Officer determination such supporting documentary, electronic, video, or other non-physical evidence and legal arguments as he may wish to provide.

■ 25. Revise § 32.44 to read as follows:

§ 32.44 Hearing Officer determination.

(a) Before determining a claim, the Hearing Officer shall seek legal advice from PSOB Counsel.

(b) Upon his determining a claim, the Hearing Officer shall file a notice of the same simultaneously with the Director (for his review under subpart F of this part in the event of approval), the PSOB Office, which notice shall specify the factual findings and legal conclusions that support it, and PSOB Counsel.

(c) Upon a Hearing Officer's denying a claim, the PSOB Office shall serve notice of the same upon the claimant (and upon any other claimant who may have filed a claim with respect to the same public safety officer), which notice shall—

(1) Specify the Hearing Officer's factual findings and legal conclusions that support it; and

(2) Provide information as to Director appeals.

■ 26. Amend § 32.45 as follows:

■ a. In paragraph (d)(1) remove ''and'' after ''cumulative evidence:''.

■ b. In paragraph (d)(2), remove the period after ''witnesses'' and add in its place ''; and''.

■ c. Add paragraph (d)(3)

The addition reads as follows:

§ 32.45 Hearings

* * * * *

(d) * * *

(3) Shall be the only individual permitted to examine or question a claimant apart from that claimant's representative, if any.

* * * * *

§ 32.54 [Amended]

■ 27. Amend § 32.54 by removing paragraph (b) and redesignating paragraph (c) as paragraph (b).

Dated: August 2, 2016.

Karol V. Mason,

Assistant Attorney General.

[FR Doc. 2016–18811 Filed 8–19–16; 8:45 am]

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Part IV

Department of Energy

10 CFR Part 430
Energy Conservation Program: Test Procedures for Cooking Products; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE–2012–BT–TP–0013]

RIN 1904–AC71

Energy Conservation Program: Test Procedures for Cooking Products

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

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: On December 3, 2014, the U.S. Department of Energy (DOE) issued a supplemental notice of proposed rulemaking (SNOPR) to revise its test procedures for cooking products. As part of the December 2014 test procedure SNOPR, DOE proposed a change to the test equipment that would allow for measuring the energy efficiency of induction cooking tops. DOE also proposed methods to test non-circular electric surface units, electric surface units with flexible concentric cooking zones, full-surface induction cooking tops, and gas burners with high input rates. In this SNOPR, to address issues raised by interested parties regarding the ability of the previous cooking top proposals to adequately measure energy use during a representative average use cycle, DOE proposes to amend its test procedure for all conventional electric cooking tops to incorporate by reference the relevant selections from European standard EN 60350–2:2013 ''Household electric cooking appliances Part 2: Hobs—Methods for measuring performance'' (EN 60350–2:2013). DOE also revises its proposals for testing non-circular electric surface units, electric surface units with flexible concentric cooking zones, and full-surface induction cooking tops based on EN 60350–2:2013. Furthermore, DOE proposes to extend the test methods in EN 60350–2:2013 to measure the energy consumption of gas cooking tops by correlating test equipment diameter to burner input rate, including input rates that exceed 14,000 British thermal units per hour (Btu/h). DOE also proposes to modify the calculations of conventional cooking top annual energy consumption and integrated annual energy consumption to account for the proposed water-heating test method. DOE proposes to incorporate by reference test structures from American National Standards Institute (ANSI) Z21.1–2016 ''Household cooking gas appliances'' to standardize the installation conditions under which cooking tops are tested. DOE also proposes minor technical clarifications to the gas heating value correction and other grammatical changes to the regulatory text in appendix I that do not alter the substance of the existing test methods. With regard to conventional ovens, DOE proposes to repeal the regulatory provisions establishing the test procedure for conventional ovens under the Energy Policy and Conservation Act (EPCA). DOE has determined that the conventional oven test procedure may not accurately represent consumer use as it favors conventional ovens with low thermal mass and does not capture cooking performance-related benefits due to increased thermal mass of the oven cavity.

DATES: DOE will accept comments, data, and information regarding this SNOPR no later than September 21, 2016. See section V, ''Public Participation,'' for details.

Any comments submitted must identify the SNOPR for Test Procedures for Cooking Products, and provide docket number EE–2012–BT–TP–0013 and/or regulatory information number (RIN) number 1904–AC71. Comments may be submitted using any of the following methods:

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

2. *Email: Induction-Cooking-Prod-2012-TP-0013@ee.doe.gov.* Include the docket number and/or RIN in the subject line of the message. Submit electronic comments in WordPerfect, Microsoft Word, PDF, or ASCII file format, and avoid the use of special characters or any form of encryption.

3. *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC, 20585–0121. Telephone: (202) 586–6636. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW., 6th Floor, Washington, DC, 20024. Telephone: (202) 586–6636. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

For detailed instructions on submitting comments and additional information on the rulemaking process, see section V of this document (Public Participation).

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

A link to the docket Web page can be found at: *https://www.regulations.gov/#!docketDetail;D=EERE-2012-BT-TP-0013.* This Web page will contain a link to the docket for this notice on the *www.regulations.gov* site. The *www.regulations.gov* Web page will contain simple instructions on how to access all documents, including public comments, in the docket. See section VII for information on how to submit comments through regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Ms. Ashley Armstrong, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW., Washington, DC, 20585–0121. Telephone: (202) 586–6590. Email: *ashley.armstrong@ee.doe.gov.*

Ms. Celia Sher, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC, 20585–0121. Telephone: (202) 202–287–6122. Email: *Celia.Sher@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact the Appliance and Equipment Standards Program staff at (202) 586–6636 or by email: *Induction-Cooking-Prod-2012-TP-0013@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE intends to incorporate by reference certain sections of the following industry standards into 10 CFR part 430:

(1) ANSI Standard Z21.1–2016—''Household cooking gas appliances'' (ANSI Z21.1).

- Copies of ANSI Z21.1, can be obtained from ANSI, 25 W 43rd Street, 4th Floor, New York, NY, 10036, or by going to *http://webstore.ansi.org/default.aspx.*

(2) EN 60350–2:2013 ''Household electric cooking appliances Part 2: Hobs—Methods for measuring performance'' (EN 60350–2:2013).

- Copies of EN 60350–2:2013, a European standard approved by the European Committee for Electrotechnical Standardization (CENELEC), can be obtained from the

British Standards Institute (BSI Group), 389 Chiswick High Road, London, W4 4AL, United Kingdom, or by going to *http://shop.bsigroup.com/.*

See section IV.M for a further discussion of these standards.

Table of Contents

I. Authority and Background

Title III of the Energy Policy and Conservation Act of 1975 (42 U.S.C. 6291, *et seq.;* ''EPCA'' or, ''the Act'') sets forth a variety of provisions designed to improve energy efficiency. (All references to EPCA refer to the statute as amended through the Energy Efficiency Improvement Act of 2015, Public Law 114–11 (Apr. 30, 2015).) Part B of title III, which for editorial reasons was redesignated as Part A upon incorporation into the U.S. Code (42 U.S.C. 6291–6309, as codified), establishes the ''Energy Conservation Program for Consumer Products Other Than Automobiles.'' These include cooking products,[1] and specifically conventional cooking tops [2] and conventional ovens,[3] the primary subject of this document. (42 U.S.C. 6292(a)(10))

Under EPCA, the energy conservation program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. The testing requirements consist of test procedures that manufacturers of covered products must use as the basis for (1) certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA, and (2) making representations about the efficiency of those products. Similarly, DOE must use these test procedures to determine whether the products comply with any relevant standards promulgated under EPCA.

[1] DOE's regulations define ''cooking products'' as one of the following classes: Conventional ranges, conventional cooking tops, conventional ovens, microwave ovens, microwave/conventional ranges and other cooking products. (10 CFR 430.2)

[2] Conventional cooking top means a class of kitchen ranges and ovens which is a household cooking appliance consisting of a horizontal surface containing one or more surface units which include either a gas flame or electric resistance heating. (10 CFR 430.2)

[3] Conventional oven means a class of kitchen ranges and ovens which is a household cooking appliance consisting of one or more compartments intended for the cooking or heating of food by means of either a gas flame or electric resistance heating. It does not include portable or countertop ovens which use electric resistance heating for the cooking or heating of food and are designed for an electrical supply of approximately 120 volts.(10 CFR 430.2)

A. General Test Procedure Rulemaking

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA provides in relevant part that any test procedures prescribed or amended under this section shall be reasonably designed to produce test results which measure energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and shall not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

In addition, if DOE determines that a test procedure amendment is warranted, it must publish proposed test procedures and offer the public an opportunity to present oral and written comments on them. (42 U.S.C. 6293(b)(2)) Finally, in any rulemaking to amend a test procedure, DOE must determine to what extent, if any, the proposed test procedure would alter the measured energy efficiency of any covered product as determined under the existing test procedure. (42 U.S.C. 6293(e)(1))

B. Test Procedures for Cooking Products

DOE's test procedures for conventional cooking tops, conventional ovens, and microwave ovens are codified at appendix I to subpart B of 10 CFR part 430 (appendix I).

DOE established the test procedures in a final rule published in the **Federal Register** on May 10, 1978. 43 FR 20108, 20120–28. DOE revised its test procedures for cooking products to more accurately measure their efficiency and energy use, and published the revisions as a final rule in 1997. 62 FR 51976 (Oct. 3, 1997). These test procedure amendments included: (1) A reduction in the annual useful cooking energy; (2) a reduction in the number of self-cleaning oven cycles per year; and (3) incorporation of portions of International Electrotechnical Commission (IEC) Standard 705–1988, ''Methods for measuring the performance of microwave ovens for household and similar purposes,'' and Amendment 2–1993 for the testing of microwave ovens. *Id.* The test procedures for conventional cooking products establish provisions for determining estimated annual operating cost, cooking efficiency (defined as the ratio of cooking energy output to cooking energy input), and energy factor (defined as the ratio of annual useful cooking energy output to total annual energy input). 10 CFR 430.23(i); appendix I. These provisions for conventional cooking products are not

currently used for compliance with any energy conservation standards because the present standards are design requirements; in addition, there is no EnergyGuide [4] labeling program for cooking products.

DOE subsequently conducted a rulemaking to address standby and off mode energy consumption, as well as certain active mode testing provisions, for residential dishwashers, dehumidifiers, and conventional cooking products. DOE published a final rule on October 31, 2012 (77 FR 65942, hereinafter referred to as the October 2012 Final Rule), adopting standby and off mode provisions that satisfy the EPCA requirement that DOE include measures of standby mode and off mode power in its test procedures for residential products, if technically feasible. (42 U.S.C. 6295(gg)(2)(A))

C. The January 2013 TP NOPR

On January 30, 2013, DOE published a notice of proposed rulemaking (NOPR) (78 FR 6232, hereinafter referred to as the January 2013 TP NOPR) proposing amendments to appendix I that would allow for measuring the active mode energy consumption of induction cooking products (*i.e.,* conventional cooking tops equipped with induction heating technology for one or more surface units [5] on the cooking top). DOE proposed to incorporate induction cooking tops by amending the definition of ''conventional cooking top'' to include induction heating technology. Furthermore, DOE proposed to require for all cooking tops the use of test equipment compatible with induction technology. Specifically, DOE proposed to replace the solid aluminum test blocks currently specified in the test procedure for cooking tops with hybrid test blocks comprising two separate pieces: an aluminum body and a stainless steel base. In the January 2013 TP NOPR, DOE also proposed amendments to include a clarification that the test block size be determined using the smallest dimension of the electric surface unit. 78 FR 6232, 6234 (Jan. 30, 2013).

D. The December 2014 TP SNOPR

On December 3, 2014, DOE published an SNOPR (79 FR 71894, hereinafter referred to as the December 2014 TP SNOPR), modifying its proposal from the January 2013 TP NOPR to more accurately measure the energy efficiency of induction cooking tops. DOE proposed to add a layer of thermal grease between the stainless steel base and aluminum body of the hybrid test block to facilitate heat transfer between the two pieces. DOE also proposed additional test equipment for electric surface units with large diameters (both induction and electric resistance) and gas cooking top burners with high input rates. 79 FR 71894 (Dec. 3, 2014). In addition, DOE proposed methods to test non-circular electric surface units, electric surface units with flexible concentric cooking zones, and full-surface induction cooking tops. *Id.*

In the December 2014 TP SNOPR, DOE also proposed to incorporate methods for measuring conventional oven volume, clarify that the existing oven test block must be used to test all ovens regardless of input rate, and provide a method to measure the energy consumption and efficiency of conventional ovens equipped with an oven separator. 79 FR 71894 (Dec. 3, 2014). On July 3, 2015, DOE published a final rule addressing the test procedure amendments for conventional ovens only. (80 FR 37954, hereinafter referred to as the July 2015 Final Rule). In this SNOPR, DOE is continuing the rulemaking to consider additional methodology for testing conventional cooking tops. In addition, based on further review of public comments and data provided by manufacturers, DOE is proposing in this SNOPR to repeal the regulatory provisions establishing the test procedures of conventional ovens.

II. Summary of the Supplemental Notice of Proposed Rulemaking

DOE received comments on the energy conservation standards NOPR for conventional ovens (80 FR 33030) published on June 10, 2015 (the June 2015 STD NOPR) highlighting uncertainty about whether the unique features of commercial-style ovens were appropriately accounted for when measuring energy consumption using the existing conventional oven test procedure. After review of these comments, DOE determined that additional investigation is required to establish a representative test procedure for conventional ovens. DOE is proposing to repeal the provisions in the existing cooking products test procedure relating to conventional ovens.

For conventional cooking tops, based on review of the public comments received in response to the December 2014 TP SNOPR, and a series of manufacturer interviews conducted in February and March 2015 to discuss key concerns regarding the hybrid test block method proposed in the December 2014 TP SNOPR, DOE is withdrawing its proposal for testing conventional cooking tops with a hybrid test block. Instead, DOE proposes to modify its test procedure to incorporate by reference the relevant sections of EN 60350–2:2013 ''Household electric cooking appliances Part 2: Hobs—Methods for measuring performance'' [6] (EN 60350–2:2013), which uses a water-heating test method to measure the energy consumption of electric cooking tops. EN 60530–2:2013 specifies heating a water load to a certain temperature at the maximum energy input setting for a single surface unit, and then reducing the energy input to the surface unit to a lower setting for an extended simmering period. The test method specifies the quantity of water to be heated in a standardized test vessel whose size is based on the diameter of the surface unit under test. For each surface unit, the test energy consumption is measured and then divided by the mass of the water load used to test each surface unit to calculate the energy consumed per gram of water. The measurements of energy consumption per gram of water calculated for each surface unit are averaged, then normalized to a single water quantity to determine the total energy consumption of the cooking top. Based on DOE's further review of a report on round robin testing commissioned by the European Committee of Domestic Equipment Manufacturers (CECED) [7] using a draft version of EN 60350–2:2013 conducted in 2011, review of the public comments received in response to the December 2014 TP SNOPR, and a series of manufacturer interviews conducted in February 2015, as well as further evaluation of DOE's own test data, DOE determined that the test methods to measure surface unit energy consumption specified in EN 60350–2:2013 produce repeatable and reproducible test results. DOE also notes that the test vessels specified in EN 60350–2:2013 are compatible with all cooking top technologies. Additionally, the range of test vessel diameters specified in EN 60350–2:2013 covers the full range of surface unit diameters available on the U.S. market. Moreover, incorporating EN 60350–2:2013 by reference has the benefit of harmonization with international testing

[4] For more information on the EnergyGuide labeling program, see: *www.access.gpo.gov/nara/cfr/waisidx_00/16cfr305_00.html.*

[5] The term surface unit refers to burners for gas cooking tops, electric resistance heating elements for electric cooking tops, and inductive heating elements for induction cooking tops.

[6] Hob is the British English term for cooking top.

[7] Italian National Agency for New Technologies, Energy and Sustainable Economic Development—Technical Unit Energy Efficiency (ENEA–UTEE), ''CECED Round Robin Tests for Hobs and Microwave Ovens—Final Report for Hobs,'' July 2011.

methods. Although DOE is proposing to incorporate the EN 60350–2:2013 method to measure the energy consumption of the cooking top, DOE is proposing to modify the water quantity used to normalize the total energy consumption of the cooking top, in order to estimate a representative annual energy consumption for the U.S. market.

In the December 2014 TP SNOPR, DOE proposed test methods for non-circular electric cooking top surface units and full-surface induction cooking tops with ''cook anywhere'' functionality. 79 FR 71894, 71905 (Dec. 3, 2014). In this SNOPR, DOE proposes, instead, to adopt the test methods and specifications for non-circular surface units and full-surface induction cooking tops included in EN 60350–2:2013. However, for surface units with flexible concentric sizes (*i.e.,* units with multiple zones of the same shape but varying shortest dimensions), DOE continues to propose that the surface unit be tested at each unique size setting. DOE also further clarifies in this SNOPR that for all cooking tops, specialty surface units such as bridge zones, warming plates, grills, and griddles are not covered by the proposed appendix I.

Only electric cooking tops are covered by the methods specified in EN 60350–2:2013. DOE is proposing to extend the water-heating test method to gas cooking tops by correlating the burner input rate and test vessel diameters specified in EN 30–2–1:1998 *Domestic cooking appliances burning gas—Part 2–1: Rational use of energy—General* (EN 30–2–1) to the test vessel diameters and water loads already included in EN 60350–2:2013. The range of gas burner input rates covered by EN 30–2–1 includes burners exceeding 14,000 British thermal units per hour (Btu/h), and thus provides a method to test gas burners with high input rates.

Although EN 60350–2:2013 includes a method to determine the normalized per-cycle energy consumption of the cooking top, it does not include a method to determine total annual energy consumption. DOE is proposing in this SNOPR to include a calculation of the annual energy consumption and integrated annual energy consumption of conventional cooking tops using the cooking frequency determined in the 2009 DOE Energy Information Administration (EIA) Residential Energy Consumption Survey (RECS).[8] The EIA RECS collects energy-related data for occupied primary housing units in the United States. DOE also reviewed recent field energy use survey data presented in the 2010 California Residential Appliance Saturation Study (CA RASS) [9] and the Florida Solar Energy Center (FSEC) [10] to determine whether the proposed test method and cooking frequency based on RECS data produce an annual energy consumption representative of consumer use. Based on this CA RASS and FSEC field use data, and based on testing of a sample of products, DOE determined that the estimated annual active mode cooking top energy consumption using the proposed test method and cooking frequency based on RECS data does not adequately represent consumer use. As a result, DOE is proposing to normalize the cooking frequency to account for differences between the duration of a cooking event represented in the RECS data and DOE's proposed test load for measuring the energy consumption of the cooking top. DOE is proposing to use the resulting normalized number of cooking cycles per year multiplied by the normalized per-cycle energy consumption and the number of days in a year (365) to calculate annual active mode cooking energy consumption for the cooking top.

DOE also proposes to define the term ''combined cooking product'' as a cooking product that combines a conventional cooking product with other appliance functionality, which may or may not include another cooking product. Examples of such ''combined cooking products'' include conventional ranges, microwave/conventional cooking tops, microwave/conventional ovens, and microwave/conventional ranges. In this SNOPR, DOE is proposing to clarify that the active mode test procedures in appendix I apply to the conventional cooking top component of a combined cooking product. However, the combined low-power of these products can only be measured for the combined product and not the individual components. Thus, DOE is proposing a method to apportion the combined low-power mode energy consumption measured for the combined cooking product to the individual cooking top component of the combined cooking product using the ratio of component cooking hours per year to the total cooking hours per year of the combined cooking product.

DOE is also aware that the installation test conditions currently specified in appendix I are not clearly defined. Thus, DOE is proposing to incorporate by reference test structures from the ANSI standard Z21.1–2016—''Household cooking gas appliances'' (ANSI Z21.1) to standardize the conditions under which cooking tops are tested.

DOE also notes that section 2.9.4 of the existing test procedure in appendix I does not clearly state what temperature and pressure conditions should be used to correct the gas heating value. DOE is proposing to clarify that the measurement of the heating value of natural gas or propane specified in section 2.9.4 in appendix I be corrected to standard pressure and temperature conditions in accordance with the U.S. Bureau of Standards, circular C417, 1938.

Finally, DOE is proposing minor technical grammatical corrections to certain sections of appendix I that serve as clarifications and do not change the substance of the test method.

III. Discussion

A. Products Covered by This Test Procedure Rulemaking

As discussed in section I.A, DOE has the authority to amend test procedures for covered products. 42 U.S.C. 6292(a)(10) of EPCA covers kitchen ranges and ovens. In a final rule issued on September 8, 1998 (63 FR 48038), DOE amended its regulations to substitute the term ''kitchen ranges and ovens'' with ''cooking products''. DOE regulations currently define ''cooking products'' as consumer products that are used as the major household cooking appliances. They are designed to cook or heat different types of food by one or more of the following sources of heat: gas, electricity, or microwave energy. Each product may consist of a horizontal cooking top containing one or more surface units and/or one or more heating compartments. They must be one of the following classes: conventional ranges, conventional cooking tops, conventional ovens, microwave ovens, microwave/conventional ranges and other cooking products.[11] (10 CFR 430.2)

[8] Available online at: *http://www.eia.gov/consumption/residential/data/2009/.*

[9] California Energy Commission. 2009 California Residential Appliance Saturation Study, October 2010. Prepared for the California Energy Commission by KEMA, Inc. Contract No. 200–2010–004. <*http://www.energy.ca.gov/2010publications/CEC-200-2010-004/CEC-200-2010-004-V2.PDF*>.

[10] FSEC 2010. Updated Miscellaneous Electricity Loads and Appliance Energy Usage Profiles for Use in Home Energy Ratings, the Building America Benchmark and Related Calculations. Published as FSEC–CR–1837–10, Florida Solar Energy Center, Cocoa, FL.

[11] As discussed in the January 2013 TP NOPR and December 2014 TP SNOPR, DOE proposed to amend the definition of ''conventional cooking top'' to include products that feature electric inductive heating surface units. 78 FR 6232, 6234–6235 (Jan.

Continued

In this SNOPR, DOE is addressing test procedures for conventional cooking tops and is proposing to repeal the test procedures for conventional ovens In addition, because DOE regulations currently continue to use the term ''kitchen ranges and ovens'' and other terms to describe the product that is the subject of this rulemaking, DOE proposes in this SNOPR to consistently refer to the product as ''cooking products'' in DOE's regulations codified at 10 CFR parts 429 and 430.

DOE notes that certain residential household cooking appliances combine a conventional cooking product component with other appliance functionality, which may or may not perform a cooking-related function. Examples of such ''combined cooking products'' include a conventional range, which combines a conventional cooking top and one or more conventional ovens; a microwave/conventional cooking top, which combines a microwave oven and a conventional cooking top; a microwave/conventional oven, which combines a microwave oven and a conventional oven; and a microwave/conventional range, which combines a microwave oven and a conventional oven in separate compartments and a conventional cooking top. Because combined cooking products may consist of multiple classes of cooking products, any potential conventional cooking top or oven energy conservation standard would apply to the individual components of the combined cooking product. Thus, the cooking top test procedures proposed in this SNOPR also apply to the individual conventional cooking top portion of a combined cooking product. Because combined cooking products are a kind of cooking product that combines a conventional cooking product with other appliance functionality and not a distinct product class, DOE is proposing to remove the definitions of the various kinds of combined cooking products that are currently included in 10 CFR 430.2, and then add a definition of ''combined cooking product'' to appendix I, as this definition would be related to the test of combined cooking products and is not a unique product class itself. DOE also notes that the definitions of conventional cooking top, conventional oven, microwave oven, and other cooking products refer to these products as classes of cooking products. Because these are more general product categories and not specific product classes, DOE is proposing to amend the definitions of conventional cooking top, conventional oven, microwave oven, and other cooking products in 10 CFR 430.2 to reflect this clarification.

In its product testing conducted in support of the December 2014 TP SNOPR, DOE observed that for combined cooking products, the annual combined low-power mode energy consumption can only be measured for the combined cooking product and not the individual components. In order to calculate the integrated annual energy consumption of the conventional cooking top component separately, DOE is proposing in this SNOPR to allocate a portion of the combined low-power mode energy consumption measured for the combined cooking product to the conventional cooking top component using the estimated annual cooking hours for the given components comprising the combined cooking product. Similarly for microwave ovens, in order to calculate the annual combined low-power mode energy consumption for the microwave oven component separately, DOE is proposing to allocate a portion of the combined low-power mode energy consumption measured for the combined cooking product to the microwave oven component, based on the estimated annual cooking hours for the given components comprising the combined cooking product. Section III.H provides a complete discussion of the derivation of integrated annual energy consumption for the individual components of a combined cooking product.

Gas Cooking Products With High Input Rates

In the December 2014 TP SNOPR, DOE proposed to amend the conventional cooking top test procedure in appendix I to measure the energy use of gas surface units with high input rates and noted that the current definition for ''conventional cooking top'' in 10 CFR 430.2 already covers conventional gas cooking products with higher input rates (including commercial-style gas cooking products), as these products are household cooking appliances with surface units or compartments intended for the cooking or heating of food by means of a gas flame. DOE considers a cooking top burner with a high input rate to be a burner rated greater than 14,000 Btu/h. 79 FR 71894, 71897 (Dec. 3, 2014).

Sub-Zero Group, Inc. (Sub-Zero) commented that cooking with larger cooking vessels and high performance burners requires increased grate-to-burner spacing to maximize air flow and improve burner combustion, which in turn impacts efficiency as measured by the test procedure. According to Sub-Zero, a ''one size fits all'' test procedure is inequitable and would place gas cooking tops with higher input rates at a market disadvantage. (Sub-Zero, TP No. 20 at p. 3) [12] Sub-Zero also commented that the proposed test procedure does not accurately measure the performance and efficiency of the larger, higher-output components and leads to misleading results. (Sub-Zero, TP No. 20 at pp. 2–3) Sub-Zero believes that due to the lack of data, test procedure complexities, and the limited potential for energy savings, DOE should exempt high-performance products (*i.e.,* commercial-style cooking tops) from standards until adequate further analysis is conducted such that these products can be accurately and fairly evaluated. (Sub-Zero, TP No. 20 at p. 3)

As discussed further in the following sections, and specifically in section III.F of this notice, DOE is proposing that the energy consumption of conventional gas cooking tops be measured using a range of test vessel diameters and water loads that are selected based on input rate of the burner, including those with burners having input rates greater than 14,000 Btu/h (including commercial-style gas cooking tops). The current definition for ''conventional cooking top'' in 10 CFR 430.2 already covers conventional gas cooking products with higher input rates, as these products are household cooking appliances with surface units or compartments intended for the cooking or heating of food by means of a gas flame.

B. Repeal of the Conventional Oven Test Procedure

The existing test procedure to measure the active mode annual energy consumption of conventional ovens in appendix I involves setting the oven controls to achieve an average internal cavity temperature that is 325 degrees Fahrenheit (°F) ± 5 °F higher than the room ambient air temperature and measuring the amount of energy required to raise the temperature of an aluminum block test load from room temperature to 234 °F above its initial temperature. The measured energy

30, 2013); 79 FR 71894, 71897 (Dec. 3, 2014). As DOE did not receive any additional comments on this proposal, DOE is maintaining these proposed modifications in this SNOPR.

[12] A notation in the form ''Sub-Zero, TP No. 20 at p. 3'' identifies a written comment (1) made by Sub-Zero on the Test Procedure for cooking products; (2) recorded in document number 20 that is filed in the docket of this cooking products test procedures rulemaking (Docket No. EERE–2012–BT–TP–0013) and available for review at *www.regulations.gov;* and (3) which appears on page 3 of document number 20.

consumption includes the energy input during the time the load is being heated plus the energy consumed during fan-only mode. In the July 2015 TP Final Rule, DOE did not modify the active mode test method but proposed to incorporate methods for measuring conventional oven volume according to an Association of Home Appliance Manufacturers (AHAM) procedure,[13] to clarify that the existing oven test block must be used to test all ovens regardless of input rate, and to measure the energy consumption and efficiency of conventional ovens equipped with an oven separator. 80 FR 37954.

As part of the concurrent energy conservation standards rulemaking analysis, DOE received comments regarding the representativeness of the active mode oven test procedure in appendix I for commercial-style cooking products. Sub-Zero commented that ''high performance'' (*i.e.,* commercial-style) ovens include the following design features that enhance cooking performance (professional quality baking, broiling, roasting, slow bake, proofing, and other functions) but negatively impact efficiency and are not accounted for in the existing test procedure:

- Heavier gauge materials which extend product life and enhance product quality, cooking functionality and durability;
- Configurations that allow for up to six-rack baking capability with full extension, heavy-gauge oven racks to support large loads and provide enhanced safety and ergonomic benefit;
- Full oven-height dual convection blowers to optimize cooking air flow;
- Hidden bake elements that enhance customer safety, cleanability and heat distribution for better cooking performance;
- Controls and software to maximize the long-term reliability of oven cavity porcelain when employing a hidden bake element; and
- Cooling fans for the electronic printed circuit boards that provide precise oven control and touch-screen user interface for cooking modes and other features. (Sub-Zero, STD No. 25 at pp. 3, 5–6) [14]

BSH also noted that commercial-style ovens include unique design features as identified by Sub-Zero, and listed the following additional design features associated with commercial-style products:

- Soft-close hinges to handle constant loading and unloading of the oven to eliminate the noise of slamming doors;
- A variety of modes and options not typically found in residential-style products (*e.g.,* rapid steam generator, additional convection heating element, high power combination modes such as convection broil and steam convection);
- Powerful heating elements to maintain set temperatures during sessions of loading and unloading food (*e.g.,* caterers and entertainers at large house parties); and
- Very large usable baking space, *e.g.,* two ovens in a 60-inch range that operate independently to provide more versatility in cooking with each cavity capable of cooking one to three racks of food. In addition, commercial-style ovens can accommodate commercial baking pans that are more than twice the size of standard residential baking pans. (BSH, STD No. 41 at p. 2)

BSH and Miele also commented that DOE should consider whether a different test procedure is needed that adequately measures commercial-style products' energy use and accounts for the enhanced cooking performance. (BSH, STD No. 41 at p. 3; Miele, STD No. 42 at pp. 1–2) Miele commented that the DOE test procedure does not adequately reflect the energy use of commercial-style products because it does not account for the effects of door openings and the energy required for thermal recovery. Miele noted that the added mass of commercial-style ovens provides the advantage of requiring less energy and time to recover from a door opening, which alters the quality of foods being cooked. (Miele, STD No. 42 at pp. 1–2)

Based on DOE's review of these comments and additional data provided by manufacturers, DOE determined that commercial-style ovens typically incorporate design features (*e.g.,* heavier-gauge cavity construction, high input rate burners, extension racks) that result in inherently lower efficiencies than for residential-style ovens with comparable cavity sizes, due to the greater thermal mass of the cavity and racks when measured using the test procedure adopted in the July 2015 TP Final Rule. Furthermore, DOE concludes that certain additional factors that are not currently addressed in the test procedure, such as the impact of door openings on thermal recovery, could, if included in the test procedure, alter the efficiencies of commercial-style ovens relative to the efficiencies of residential-style ovens. For these reasons, DOE is proposing to repeal the provisions in appendix I for measuring conventional oven integrated annual energy consumption (IAEC). In addition, because DOE is proposing to repeal the provisions for measuring conventional oven IAEC, DOE is also proposing to remove the reference to AHAM OV–1–2011 ''Procedures for the Determination and Expression of the Volume of Household Microwave and Conventional Ovens'' contained in 10 CFR 430.3.

C. Hybrid Test Block Method

DOE received a number of comments from interested parties on the cooking top active mode test procedure proposed in the December 2014 TP SNOPR. In February and March of 2015, DOE also conducted a series of interviews with manufacturers representing the majority of the U.S. market to discuss key issues with the proposed cooking top test procedure. The concerns of interviewed manufacturers were similar to those expressed in the written comments on the proposal, but were collected from a larger group of manufacturers. Overall, interested parties' major concerns with the hybrid test block method, as proposed, included the thermal grease specification, the fabrication of the hybrid test block, the proposed test block diameters, and the representativeness, repeatability, and reproducibility of the hybrid test block method. Given the feedback from interested parties, and for the reasons discussed in the following sections, DOE is no longer proposing to amend appendix I to require hybrid test blocks and is instead proposing to incorporate by reference the relevant sections of the water-heating test method for measuring the energy consumption of cooking tops in EN 60350–2:2013.

1. Thermal Grease

In the December 2014 TP SNOPR, DOE proposed that a layer of thermal grease should be applied evenly between the contacting surfaces of the stainless steel base and the aluminum body of the hybrid test block for all test block sizes. The amount of thermal grease applied to the test block depended on the test block diameter. DOE also proposed a minimum thermal conductivity for the grease and that the layer of thermal grease be periodically reapplied, as DOE observed that the grease would dry out after several tests. 79 FR 71894, 71906–71908 (Dec. 3, 2014).

[13] The test standard published by the AHAM titled, ''Procedures for the Determination and Expression of the Volume of Household Microwave and Conventional Ovens,'' Standard OV–1–2011.

[14] A notation in the form ''Sub-Zero, STD No. 25 at p. 3'' identifies a written comment (1) made by Sub-Zero on the Energy Conservation Standards for conventional ovens; (2) recorded in document number 25 that is filed in the docket of the cooking product energy conservation standards rulemaking (Docket No. EERE–2014–BT–STD–0005) and available for review at *www.regulations.gov;* and (3) which appears on page 3 of document number 25.

General Electric Appliances (GE) commented in response to the December 2014 TP SNOPR that it was not able to replicate the DOE test results using the proposed test methods. (GE, TP No. 17 at p. 2) Specifically, GE observed during its testing that the aluminum body slid off the stainless steel base, the thermal grease dried out, and the amount of grease between the blocks changed from one test to another. *Id.* During individual manufacturer interviews, multiple manufacturers also confirmed the block-sliding phenomenon and the issues with dried out grease. Additionally, AHAM, BSH Home Appliances Corporation (BSH), and GE noted that DOE did not specify an operating temperature range nor application thickness for the thermal grease, and also noted that the thermal conductivity and viscosity of the grease might change over time or after repeated use at high temperatures. (BSH, TP No. 16 at p. 11; GE, TP No. 17 at p. 2; AHAM, TP No. 18 at p. 3)

After further investigation into the properties of the thermal grease used during the testing conducted to support the December 2014 TP SNOPR, DOE agrees that further specifications would be necessary to ensure that the hybrid test block method is sufficiently repeatable and reproducible. DOE became aware, through discussions with a thermal grease supplier, that thermal grease formulations are not required to be rated according to a test standard. Additionally, although such a test standard exists, the grease supplier commented that the rating method is for a specific set of conditions and materials, and may not be reflective of all applications. Thus, different thermal greases with the same published characteristics may perform differently when used with the hybrid test blocks. DOE's research also suggests that effective thermal conductivity depends on how the thermal grease fills the microscopic crevices of the test block surface, meaning that the effective thermal conductivity of the grease could change from test block to test block depending on how the metal was machined. Some thermal greases also have temperature- and time-dependent stabilization periods which are not explicitly defined by the grease supplier, leading to further opportunities for variation in performance with each application. Depending on the allowable operating temperature range, some thermal greases may dry out more quickly than others, suggesting that simply specifying a maximum number of runs for a given application of grease is not sufficient. Moreover, DOE does not believe it is practical to specify and measure the thickness for the layer of applied grease. The required amount and thickness would vary both with the material properties of the grease as well as the technique used to apply the grease to the test block surface.

AHAM also commented that the hybrid test block, as proposed, is not yet appropriate for testing induction technologies because of the variability in the temperature gradient between its steel base and aluminum body with respect to different heating elements, which in turn affects the efficiency result. (AHAM, TP No. 18 at p. 3) BSH commented that by basing its analysis exclusively on only nine different appliances in the December 2014 TP SNOPR, DOE did not completely consider the diversity of induction technology. (BSH, TP No. 16 at p. 1) DOE notes that it initially proposed to add a layer of thermal grease to the hybrid test block to facilitate heat transfer between the base and body of the hybrid test block, specifically when used with induction cooking technology. If heat does not transfer from the stainless steel base to the aluminum body at a fast enough rate, the sensors and control algorithms designed to limit the surface temperature of the surface unit may turn off or limit power to the surface unit to prevent it from overheating and damaging the cooking top. Although adding thermal grease to the hybrid test block helped to minimize this issue for the cooking tops in DOE's test sample, during recent interviews, a few manufacturers noted that they use a lower temperature threshold and different control strategies to prevent overheating in induction heating elements. As a result, these manufacturers stated that they were unable to complete a test of an induction surface unit without the unit overheating.

For the reasons described in this preamble, DOE has determined that thermal grease cannot be specified without significant further study or further modification in the construction of the hybrid test block.

2. Test Block Diameter and Composition

In addition to the two existing test block diameters specified in appendix I for the testing of conventional cooking tops, DOE proposed in the December 2014 TP SNOPR an additional test block diameter for electric surface units having a smallest dimension of 10 inches or greater and for gas surface units with input rates greater than or equal to 14,000 Btu/h. 79 FR 71894, 71904 (Dec. 3, 2014). DOE based its assessment on a review of the electric surface unit diameters and pan sizes available on the market, as well as investigative testing of the carbon monoxide emissions and measured efficiencies of various test block sizes on gas cooking tops with high-input rate burners. DOE tentatively concluded that, by adding only one larger additional test block diameter, the test procedure would appropriately capture cooking tops designed to be used with large cookware, without increasing the test burden for manufacturers. *Id.*

During manufacturer interviews, most manufacturers highlighted the need for DOE to specify larger test block sizes to test electric surface units having 12-inch and 13-inch diameters and gas surface units with high input rates. In written comments, BSH, GE, and AHAM asserted that the proposed test block sizes do not adequately reflect the surface unit sizes currently available on the market, given that some electric surface units exceed 11 inches in diameter. (BSH, TP No. 16 at p. 5; GE, TP No. 17 at p. 2; AHAM, TP No. 18 at p. 2) Sub-Zero also noted that there are a variety of large cooking zones on electric cooktops, induction cooktops, and gas burner systems that the proposed test block diameters would not adequately evaluate. Sub-Zero stated that these products would be disadvantaged if the test equipment does not match the size of the surface unit. (Sub-Zero, TP No. 20 at p. 3) Sub-Zero further stated that for gas burners, caps can be as large as 4 inches in diameter and when combined with gas burner designs that project the flame horizontally in order to evenly distribute heat to a cooking utensil with a large footprint, rather than focusing an intense flame towards the center, the surface contact of the burner will be greatly minimized if used with a small-diameter test block. (Sub-Zero, TP No. 20 at p. 3)

DOE notes that most user instruction manuals for conventional cooking tops, regardless of heating technology type, specify that pot or pan size should match the size of the surface unit. After reviewing public comments and information received during manufacturer interviews, and further review of the surface unit diameters available on the market, DOE acknowledges that it should consider additional test equipment diameters for the testing of conventional cooking tops. The test equipment should be reasonably matched to the diameter of the surface unit or the gas burner input rate. In section III.D of this notice, DOE describes the range of test vessel

diameters and water loads it is proposing to incorporate by reference from EN 60350–2:2013 as part of this SNOPR.

During the interviews conducted in February and March of 2015, multiple manufacturers commented that they had difficulty obtaining the proposed hybrid test block materials in the diameter and thickness proposed in the December 2014 TP SNOPR. GE also commented in response to the December 2014 TP SNOPR that the components of the proposed hybrid test block, especially for the stainless steel base, had not been proven to be easily procured in the required diameter and to the flatness tolerances specified by DOE, nor had the durability of this thickness been assessed. (GE, TP No. 17 at p. 2) Although DOE did not have difficulty procuring the proposed hybrid test block materials in the diameters and flatness tolerances specified, manufacturer comments regarding the difficulties of producing the test block factored into DOE's decision to consider alternative cooking top test methods discussed in the following sections.

Energy Innovations commented that the DOE test procedure test results as presented in the December 2014 TP SNOPR represent the heat transfer efficiency from the cooking top to the cooking utensil, rather than the cooking efficiency, and appear to be reasonable for determining the energy efficiency of cooking in a covered utensil without significant losses due to escaped steam. (Energy Innovations, TP No. 15 at pp. 9–10) Energy Innovations commented that much energy is wasted in generating steam, and thus the actual cooking efficiency is much lower than the heat transfer efficiency. (Energy Innovations, TP No. 15 at p. 9) Energy Innovations also commented that cooking with a covered utensil prevents steam from escaping the utensil and greatly reduces the amount of energy required to maintain a boiling state of the contents. (Energy Innovations, TP No. 15 at p. 5) However, Energy Innovations presented survey data in which 81 percent of respondents reported not using covered utensils most of the time, and 28 percent reported conducting most of their cooking without the cover at all. (Energy Innovations, TP No. 15 at p. 8) For this reason, Energy Innovations commented that DOE should develop a multiplicative factor representative of how consumers actually use cooking utensils to convert heat transfer efficiency to an estimate of the real-world energy efficiency. (Energy Innovations, TP No. 15 at pp. 9–10)

As discussed in section III.D of this notice, DOE is proposing in this SNOPR to incorporate by reference the water-heating test methods provided in EN 60350–2:2013. The proposed test method requires the use of test vessels with lids with holes to allow for evaporation of water to simulate the energy uptake of a food load during the simmering phase of the test. DOE welcomes comment on whether the proposed test method accurately reflects real-world use.

D. Water-Heating Test Method

The test method to measure the energy consumption of electric cooking tops provided in EN 60350–2:2013 is similar to the existing DOE test procedure for conventional cooking tops specified in appendix I in that it consists of two phases. The first phase of the EN 60350–2 test requires heating a test load to a calculated ''turndown temperature'' at the maximum energy input setting. During the second phase of the test, the energy input rate is reduced to a setting that will maintain the water temperature above 194 °F (a simmering temperature) but as close to 194 °F as possible without additional adjustment of the low-power setting. The test ends 20 minutes after the temperature first increases above 194 °F.

To determine the turndown temperature, EN 60350–2:2013 requires an initial test to determine the number of degrees that the temperature continues to rise after turning the unit off from the maximum energy input setting. For the test load, EN 60350–2:2013 specifies a quantity of water to be heated in a standardized test vessel. The test vessel consists of a thin-walled stainless steel cylinder attached to a flat, stainless steel 430 base plate. The test method also specifies an aluminum lid with vent holes and a small center hole to fix the thermocouple in the center of the pot. There are eight standardized cooking vessel diameters ranging from 4.7 inches to 13 inches, one of which is selected to test a given surface unit based on the diameter of the surface unit. The amount of water also varies with test vessel diameter. Table III.1 lists the full range of test vessel diameters, water loads, and the corresponding surface unit diameters as specified in EN 60350–2:2013 for electric cooking tops. EN 60350–2:2013 also classifies the specified test vessels into categories representing different cookware types.

TABLE III.1—EN 60350–2:2013 TEST VESSEL DIAMETER AND WATER LOAD

Test vessel diameter inches (mm)	Mass of the water load lbs (kg)	Corresponding surface unit diameter inches (mm)	Standard cookware category
4.72 (120)	1.43 (0.65)	3.93 ≤ x < 5.12 (100 ≤ x < 130)	A
5.91 (150)	2.27 (1.03)	5.12 ≤ x < 6.30 (130 ≤ x < 160)	
7.09 (180)	3.31 (1.50)	6.30 ≤ x < 7.48 (160 ≤ x < 190)	B
8.27 (210)	4.52 (2.05)	7.48 ≤ x < 8.66 (190 ≤ x < 220)	C
9.45 (240)	5.95 (2.70)	8.66 ≤ x < 9.84 (220 ≤ x < 250)	
10.63 (270)	7.54 (3.42)	9.84 ≤ x < 11.02 (250 ≤ x < 280)	D
11.81 (300)	9.35 (4.24)	11.02 ≤ x < 12.20 (280 ≤ x < 310)	
12.99 (330)	11.33 (5.14)	12.20 ≤ x < 12.99 (310 ≤ x ≤ 330)	

The number of test vessels needed to assess the energy consumption of the cooking top is based on the number of controls that can be independently but simultaneously operated on the cooking top. By assessing the number of independent controls and not just the marked surface units, the test procedure accounts for cooking tops with cooking zones that do not have limitative markings. Each independently controlled surface unit or area of a ''cooking zone'' is tested individually. The temperature of the water and the total input energy consumption is measured throughout the test. Total cooking top energy consumption is determined as the average of the energy consumed during each independent test divided by the mass of the water load used for the test. This average energy consumption in Watt-hours (Wh) is then normalized to a standard water load size (1,000 grams (g)) to determine the average per-cycle energy consumption of the cooking top. Normalizing to a single load size ensures that

manufacturers are not penalized for offering a variety of surface unit diameters to consumers.

For cooking tops with standard circular electric surface units, the test vessel with a diameter that best matches the surface unit diameter is selected. Different surface units on the cooking top could be tested with the same test vessel diameter. However, if the number of independent controls/surface units for the cooking top exceeds two, the selected test vessels must come from at least two cookware categories. This means that one or more of the surface units on the cooking top will be tested with the next best-fitting test vessel in another cookware category. By adding this requirement, EN 603050–2:2013 accounts for the variety of cookware that would be used on the cooking top and prevents the test procedure from penalizing cooking tops that have a range of surface unit sizes with a range of surface unit input rates.

For cooking tops without defined surface units, such as cooking tops with full-surface induction cooking zones, EN 60350–2:2013 specifies a method to select the appropriate test position for each test vessel based on a pattern starting from the geometric center of the cooking zone. Instead of requiring that test vessels be selected based on best fit, the test vessel diameters are explicitly defined, and vary with the number of controls, to capture how different cookware types may be used on the unmarked cooking surface.

1. Representativeness of the Water-Heating Test Method

To support its analysis in the January 2013 TP NOPR, DOE conducted water-heating tests using test loads and test methods derived from a draft amendment to the IEC Standard 60350–2 Edition 1.0 ''Household electric cooking appliances—Part 2: Hobs—Method for measuring performance'' (IEC 60350–2).[15] 78 FR 6232, 6239–6240 (Jan. 30, 2013). In the January 2013 TP NOPR, DOE acknowledged that water provides a heating medium that is more representative of actual consumer use because many foods cooked on a cooking top have a relatively high liquid content. However, DOE noted that a water heating test method could introduce additional sources of variability not present for metal block heating. *Id.*

In support of the December 2014 TP SNOPR, DOE performed further investigative testing using a modified version of the IEC 60350–2 water-heating test method. When compared to the hybrid test block method, DOE found the water-heating test method to be less repeatable and continued to propose the use of the hybrid test block. 79 FR 71894, 71900–71903 (Dec. 3, 2014).

In response to DOE's proposal to use the hybrid test block method as opposed to a water-heating test method, BSH commented that the proposed hybrid test block method did not include certain specifications necessary for test procedure reproducibility, such as test load sizing and positioning, and recommended that DOE consider the specifications in IEC Standard 60350–2. (BSH, No. 16 at p. 1) Additionally, interviewed manufacturers that produce and sell products in Europe uniformly supported the use of a water-heating test method and harmonization with IEC Standard 60350–2 for measuring the energy consumption of electric cooking tops. These manufacturers cited the benefits of adopting a test method similar to the IEC water-heating method as including: (1) Compatibility with all electric cooking top types, (2) additional test vessel diameters to account for the variety of surface unit sizes on the market, and (3) the test load's ability to represent a real-world cooking top load.

Pacific Gas and Electric Company (PG&E), Southern California Gas Company (SCGC), San Diego Gas and Electric (SDG&E), and Southern California Edison (SCE) (collectively, the California investor-owned utilities (IOUs)) also recommended that DOE require a water-heating test method to measure the cooking efficiency of conventional cooking tops. Specifically, the California IOUs requested that DOE align the cooking product test methods with existing industry test procedures, such as American Society for Testing and Materials (ASTM) standard F1521–12, ''Standard Test Methods for Performance of Range Tops'', and IEC Standard 60350–2. (California IOUs, TP No. 19 at p. 1) The California IOUs commented that aligning test procedures with existing industry test procedures will reduce the burden of new test materials and procedures on laboratories and manufacturers. (California IOUs, TP No. 19 at p. 2) According to the California IOUs, the differences in test procedure standard deviation between the hybrid test block and water-heating test method as presented in the December 2014 TP SNOPR did not sufficiently show that the hybrid test block method is more repeatable than a water-heating method. (California IOUs, TP No. 19 at p. 2) Additionally, the California IOUs believe cooking efficiencies derived using a water-heating test method are more representative of the actual cooking performance of cooking tops as opposed to a test procedure using hybrid test blocks, since many foods prepared on cooking tops have relatively high liquid content. (California IOUs, TP No. 19 at p. 1)

As discussed in section III.C of this notice, review of public comments and information received during manufacturer interviews led DOE to determine that the hybrid test block method, as proposed in the December 2014 TP SNOPR, may not be sufficiently repeatable and reproducible. Thus, as suggested by interested parties, DOE performed further evaluation of its own water-heating test data and reviewed additional studies on the repeatability and reproducibility of the water-heating test method to determine whether the water-heating test method specified in EN 60350–2:2013 should be considered.

In the December 2014 TP SNOPR, DOE found that the reproducibility of the water-heating test method, as determined by comparing the surface unit efficiency measured at two different test laboratories, was similar to that of the hybrid test block method. 79 FR 71894, 71901 (Dec. 3, 2014). DOE also evaluated the repeatability of the surface unit efficiency results by assessing the standard deviation of the measured surface unit efficiency for a selected number of tests. The average standard deviation for the proposed hybrid test method across all test surface unit types was 0.67 percent for the 9-inch test block and 1.17 percent for the 6.25-inch block. Conversely, the average standard deviation across all surface unit types for the water-heating method was 1.25 percent for the 9.5-inch test vessel and 2.21 percent for the 5.9-inch test vessel. 79 FR 71894, 71902 (Dec. 3, 2014).

Although the average standard deviations of the measured surface unit efficiency were slightly higher for the water-heating test method, DOE notes that it evaluated a modified version of the procedures in the draft amendment to IEC 60350–2 by using only the two test vessels that had diameters closest to the diameters specified for the existing test blocks in appendix I (6.25 inches and 9 inches). 79 FR 71894, 71900–71903 (Dec. 3, 2014). As part of this testing, DOE also used the ambient test

[15] On April 25, 2014, IEC made available the draft version of IEC Standard 60350–2 Edition 2.0 Committee Draft (IEC 60350–2 CD). DOE notes that the draft amendment to IEC 60350–2 on which testing for the January 2013 NOPR was based includes the same basic test method as the 2014 IEC 60350–2 CD. DOE also notes that the European standard EN 60350–2:2013 is based on the draft amendment to IEC 60350–2. DOE believes that the IEC procedure, once finalized, will retain the same basic test method as currently contained in EN 60350–2:2013.

conditions specified in appendix I to directly compare the repeatability of the water-heating and hybrid test block test methods. 79 FR 71894, 71902 (Dec. 3, 2014). DOE notes that ambient air pressure and temperature could significantly impact the amount of water that evaporates during the test and the temperature at which the water begins to boil. Appendix I allows a relatively large tolerance, ±9 °F, for ambient air temperature that may have contributed to increased test variability observed for the water-heating test method. Conversely, EN 60350–2:2013 specifies an ambient temperature tolerance of ±3.6 °F (2 °C) for the cooking top energy consumption test. EN 60350–2:2013 also specifies an absolute air pressure range of 0.901 to 1.05 atmospheres (atm).

For the testing conducted for the January 2013 TP NOPR and the December 2014 TP SNOPR, DOE also developed its own set of efficiency calculations for purposes of comparison with the hybrid test block method. In comments received during manufacturer interviews, manufacturers stated that it was inappropriate to calculate efficiency with a water-heating method because, despite including a measurement of the mass of the water before and after the test, it is unknown what precise quantity of water is lost to boiling as some water may condense on the underside of the lid and drop back into the test vessel. To address this issue, DOE reviewed the coefficients of variation for the measured surface unit energy consumption presented in the December 2014 TP SNOPR, which DOE originally evaluated only to assess the variability of energy consumption in relation to the cooking top efficiency calculation, and not the variation between the water-heating and hybrid test block test methods. 79 FR 71894, 71902–03 (Dec. 3, 2014). The average coefficient of variation for both the modified water-heating test method and the hybrid test block method was very similar (0.024 versus 0.025).

DOE is aware of round robin testing performed in 2011 by CECED to evaluate the repeatability and reproducibility of a draft version EN 60350–2:2013.[16] Three cooking top technologies were tested: Induction, smooth electric radiant, and electric solid plate, at 12 different test facilities. While solid plate cooking top technology is not available on the U.S. market, DOE anticipates that the results obtained for this technology type are most similar to those obtained for electric coil cooking tops because the electric resistance heating element is in direct contact with the cooking vessel. The test facilities conducting the round robin testing were divided into two groups, one group of manufacturer test labs and another group of independent test labs. Only a single surface unit, approximately 7 inches in diameter (180 mm), was measured for each cooking top.

DOE reviewed its test results from the December 2014 TP SNOPR and compared these to the measured surface unit energy consumption standard deviations observed during the 2011 CECED Round Robin Testing. Table III.2 presents repeatability results from the 2011 CECED Round Robin Testing for the average measured surface unit efficiency for each cooking top technology type. Table III.3 presents repeatability results from the December 2014 TP SNOPR for the average measured surface unit efficiency for selected cooking tops in the DOE test sample.

TABLE III.2—AVERAGE STANDARD DEVIATION OF THE MEASURED ENERGY CONSUMPTION—2011 CECED ROUND ROBIN TEST SAMPLE

	Induction	Radiant	Solid plate	Average
Draft IEC 60350–2 Water-heating Test Method: [a]				
Standard Deviation (*Wh*)	2.27	7.39	3.15	.....
Standard Deviation (*%*)	0.87%	2.69%	1.14%	1.57%

[a] DOE notes that the European standard EN 60350–2:2013 is derived from IEC 60350–2:2011 but includes the draft amendments to IEC 60350–2 specified in in the IEC document TC59X/217/DC. DOE believes that the draft IEC procedure, once finalized, will retain the same basic test method as contained in EN 60350–2:2013.

TABLE III.3—AVERAGE STANDARD DEVIATION OF THE MEASURED ENERGY CONSUMPTION—DOE TEST SAMPLE FROM THE DECEMBER 2014 TP SNOPR

	Induction 1	Induction 2	Radiant	Coil	Average
DOE Hybrid Test Block:					
Standard Deviation (*Wh*)	3.37	8.25	9.88	8.51	.....
Standard Deviation (*%*)	1.20%	2.32%	2.83%	2.98%	2.33%
DOE Modified Water-Heating Method:					
Standard Deviation (*Wh*)	12.31	8.08	5.91	8.93	.....
Standard Deviation (*%*)	3.04%	2.67%	1.28%	2.31%	2.33%

The average standard deviation for surface unit measured energy consumption, as determined by the 2011 CECED Round Robin Testing, is less than 3 percent for all cooking top technology types. Although DOE established in this preamble that the modified water-heating test results are not comparable to the results obtained for the 2011 CECED Round Robin Testing, DOE still notes that the average percent standard deviation for the surface units in the DOE test sample tested according to the modified water-heating test method shown in Table III.3, is higher than for the 2011 CECED Round Robin Testing shown in Table III.2. Additionally, the average percent standard deviation for the surface unit energy consumption measured using the hybrid test block method is equal to that of the modified water-heating test method when averaged for all cooking top technology types.

The 2011 CECED Round Robin Testing also included an evaluation of the reproducibility of test results. The

[16] Italian National Agency for New Technologies, Energy and Sustainable Economic Development—Technical Unit Energy Efficiency (ENEA–UTEE), ''CECED Round Robin Tests for Hobs and Microwave Ovens—Final Report for Hobs,'' July 2011.

report calculated reproducibility as the square root of the sum of the between-laboratory variance and the mean of the within-laboratory variances (taken over all laboratories). When considering all 12 test facilities, the average reproducibility of the measured total energy consumption was below 3 percent for each cooking top technology type, with an average of 2.75 percent.

Based on DOE's review of the test data discussed in this preamble, DOE preliminarily concludes that the EN 60350–2:2013 water-heating method proposed as a part of this SNOPR is sufficiently repeatable and reproducible.

2. Incorporating by Reference EN 60350–2:2013

In this SNOPR, DOE is proposing to incorporate by reference only certain sections of EN 60350–2:2013, as the full test procedure also includes test methods to measure heat distribution and other forms of cooking performance not related to the energy consumption of the cooking top. Specifically, DOE is proposing to incorporate Section 5, ''General conditions for the measurements,'' which outlines the test room and test equipment conditions; Section 6.2, ''Cooking zones per hob,'' which outlines how to determine the number of controls and the dimensions of the cooking zones; and Section 7.1, ''Energy consumption and heating up time,'' which outlines both the test methods and equipment required to measure cooking top energy consumption. However, DOE is proposing to omit Section 7.1.Z5, ''Procedure for measuring the heating up time,'' as it is not required to calculate the overall energy consumption of the cooking top and would increase manufacturer test burden. Additionally, DOE is proposing to omit Section 7.1.Z7, ''Evaluation and calculation,'' as DOE is proposing to normalize the measured cooking top energy consumption to a standard water load size of 2,853 g for both electric and gas cooking tops instead of the 1,000 g currently specified in EN 60350–2:2013, as discussed in section III.G. DOE is also proposing to incorporate by reference Annex ZA through Annex ZD, which provide further requirements for measuring the energy consumption, clarify test vessel construction, and provide examples for how to select the appropriate test vessels. DOE also proposes to include many of the definitions related to the measure of cooking top energy consumption specified in Section 3 of EN 60350–2:2013. However, due to differences in terminology between the United States and Europe, such as the use of the word hob for cooking top, DOE is proposing to explicitly define relevant terms from Section 3 of EN 60350–2:2013 in appendix I.

E. Multi-Ring and Non-Circular Surface Units

In the December 2014 TP SNOPR, DOE specified that for electric cooking tops, test equipment for non-circular surface units should be selected based on the surface unit's shortest dimension. 79 FR 71894, 71896 (Dec. 3, 2014). BSH and AHAM commented that using the smallest dimension of a noncircular electric surface unit is not always appropriate for determining the proper test equipment size because the induction market includes products that have different printings and shapes of cooking zones, and in cases where there is no clearly defined printing diameter, there is no suitable way to define the dimension of a surface unit. (BSH, TP No. 16 at p. 7; AHAM, TP No. 18 p. 2) BSH and AHAM also commented that specifying a position for test equipment on flexible induction units is important. According to these commenters, the positioning of the test equipment can have significant influence on the efficiency result. (BSH, TP No. 16 at p. 7; AHAM, TP No. 18 p. 2) BSH and AHAM further requested that DOE consider adopting the center position description from the draft IEC 60350–2 procedure for full surface induction units in order to make results more repeatable and reproducible. (BSH, TP No. 16 at p. 9; AHAM, TP No. 18 p. 3) GE also asked that DOE clearly define the placement of test equipment, prior to finalizing the SNOPR or any cooking top efficiency standard. (GE, TP No. 17 at p. 2)

As discussed in section III.C.1 of this notice, DOE is proposing to incorporate by reference specific provisions in EN 60350–2:2013. For cooking zones that include a circular and an elliptical or rectangular part, DOE is proposing, as per Section 7.Z1 in EN 60350–02:2013, that only the circular section be tested. Additionally, Section 7.1.Z4 and Annex ZA of EN 60350–2:2013, which would be incorporated by reference, define the center of elliptical and rectangular surface units by their geometric centers and provide the required test positions of test vessels on these kinds of surface units.

In the December 2014 TP SNOPR, DOE specified that for electric cooking tops, surface units with flexible concentric sizes (*i.e.,* units with multiple zones of the same shape but varying shortest dimensions) should be tested at each unique size setting. 79 FR 71894, 71896 (Dec. 3, 2014). Many smooth—electric radiant cooking tops have ''multi-ring'' elements that have multiple concentric heating elements for a single surface unit. When a single ring is energized, this corresponds to the smallest-diameter surface unit available. When two rings are energized, the diameter of the surface unit increases. This continues for as many concentric heating elements as are available for the surface unit. Multiple heating elements give the user flexibility to adjust the surface unit to fit a certain cookware size. Results from DOE testing presented in the December 2014 TP SNOPR showed a significant decrease in efficiency at the smaller-diameter settings as compared to the largest-diameter setting of a multi-ring surface unit. Because of the observed differences in efficiency, DOE proposed that each distinct diameter setting for a multi-ring surface unit be tested as a separate surface unit. For example, if the surface unit has three settings with outer diameters of 12, 9, and 6 inches, each setting would be tested separately with the appropriately sized test equipment, and the results would be factored into the overall energy consumption calculation as if they were individual surface units. 79 FR 71894, 71906 (Dec. 3, 2014).

GE and AHAM commented that DOE should not require measurement of the individual inner zones of multi-ring surface units with flexible concentric sizes, as doing so may lead to results that would not be indicative of actual product performance or be precise enough for standards-setting purposes. (GE, TP No. 17 at p. 2; AHAM, TP No. 18 p. 3) During manufacturer interviews, manufacturers stated that requiring that each setting be tested separately would increase the test burden. Furthermore, manufacturers noted that the ability to match the surface unit diameter to the pan size is an important consumer utility that might be penalized by the proposed test procedure. However, several manufacturers also independently confirmed that using the inner ring of a multi-ring burner is inherently less efficient because some of the generated heat will be lost to the portion of the heating element that is not energized.

According to EN 60350–2:2013, only the energy consumption of the largest diameter of a multi-ring surface unit is measured, unless an additional test vessel category is needed to meet the requirements of the test procedure, in which case one of the smaller-diameter settings of the surface unit that matches the next best-fitting test vessel diameter is tested. However, DOE is proposing to require each setting of the multi-ring

surface unit be tested independently. DOE notes that each setting could be used as an individual surface unit, and thus should factor into the calculated annual energy consumption of the cooking top. Each diameter setting of the multi-ring surface unit would be tested and included as a unique surface unit in the average energy consumption calculation for the cooking top. DOE welcomes consumer usage data demonstrating if and how these surface units are used differently than surface units without an adjustable diameter.

In the December 2014 TP SNOPR, DOE also discussed other non-circular cooking top elements such as bridge zones, warming plates, grills, and griddles that are not intended for use with a typical circular piece of cookware. Appropriate test blocks for these heating elements would depend on the intended function of each surface unit. DOE did not propose to require testing these surface units because the additional equipment necessary for the test method to be representative would place an unreasonable burden on test laboratories and manufacturers. Additionally, DOE stated that it expects use of these types of surface units to be much less frequent than the standard surface units used for circular pots and pans. 79 FR 71894, 71906 (Dec. 3, 2014).

GE commented that DOE should not require measuring the efficiency of warming plates, griddles, grills or other elements for which there is not an appropriately shaped and sized test block. (GE, TP No. 17 at p. 2) BSH and AHAM requested that DOE clarify whether the exclusion of bridge zones includes products with a bridge mode (which connects two surface units together as a single zone), and whether a flexible cooking area is considered a bridge mode. (BSH, TP No. 16 at p. 10; AHAM, TP No. 18 at p. 3) BSH and AHAM requested that roaster extensions also be excluded. (BSH, TP No. 16 at p. 10; AHAM, TP No. 18 at p. 3) After considering these comments, DOE is maintaining its proposal to exclude testing of bridge zones, warming plates, grills, and griddles in determining the energy consumption of a cooking top. DOE is also proposing to exclude roaster extensions from test. Furthermore, DOE is clarifying that it is not proposing to require testing of bridge modes that couple several surface units together for use as a warming plate or for use with a roasting pan, but is proposing to test the individual circular heating elements if they can be used independently of the bridge mode. DOE is also clarifying that a flexible cooking area, *i.e.,* a full-surface induction cooking zone, able to heat multiple items of cookware simultaneously, with independent control options for each piece of cookware, does not constitute a bridge mode.

In the December 2014 TP SNOPR, DOE specified that full-surface induction cooking tops with ''cook anywhere'' functionality should be tested with multiple test equipment diameters in the center of the usable cooking surface. 79 FR 71894 71905 (Dec. 3, 2014). These full-surface induction cooking tops have no clearly defined cooking zones. The location of the cookware is detected when it is placed on the surface, and multiple cookware can be independently controlled and used on the cooking top simultaneously. Annex ZA of EN 60350–2:2013, which DOE is proposing to incorporate by reference as discussed in section III.D of this notice, specifies that for a cooking area without limitative marking, *e.g.,* a full-surface induction zone, the number of controls is defined by the number of cookware items that can be used independently and simultaneously, and the number of controls determines the number of tests.

F. Extending EN 60350–2:2013 to Gas Cooking Tops

DOE notes that the test methods specified in the relevant sections of EN 60350–2:2013 were intended for use with only electric cooking tops. To extend this method to gas cooking tops, DOE reviewed another European water-heating test standard, EN 30–2–1:1998 *Domestic cooking appliances burning gas—Part 2–1: Rational use of energy—General,* which includes test methods specifically for gas cooking tops. EN 30–2–1 is similar to the electric cooking top water-heating test method in that it specifies a series of test vessels and water loads that are dependent on a nominal characteristic of the surface unit. EN 30–2–1 specifies the diameter of the test vessel and the mass of the water load based on the heat input of the gas burner being tested.

The methods of test in EN 60305–2:2013 and EN 30–2–1 differ slightly, so if DOE were to incorporate both by reference, the resulting measured energy consumption of gas and electric cooking tops would not be comparable. For example, EN 30–2–1 specifies an aluminum test vessel, without a lid, instead of a stainless steel vessel. Additionally, the procedure to determine the efficiency of a gas burner in EN 30–2–1 includes a heat-up phase at the maximum burner setting but does not capture energy consumed during a simmering phase. DOE is not aware of data showing that consumers cook food differently with gas cooking tops than with electric cooking tops. For these reasons, DOE is proposing to extend the test methods specified for electric cooking tops in EN 60350–2:2013 to gas cooking tops, but to specify test vessels and water loads based on the correlation between input rate of the burner and test vessel size in EN 30–2–1. Figure III.1 compares the test vessels in EN 30–2–1 to EN 603050–2.

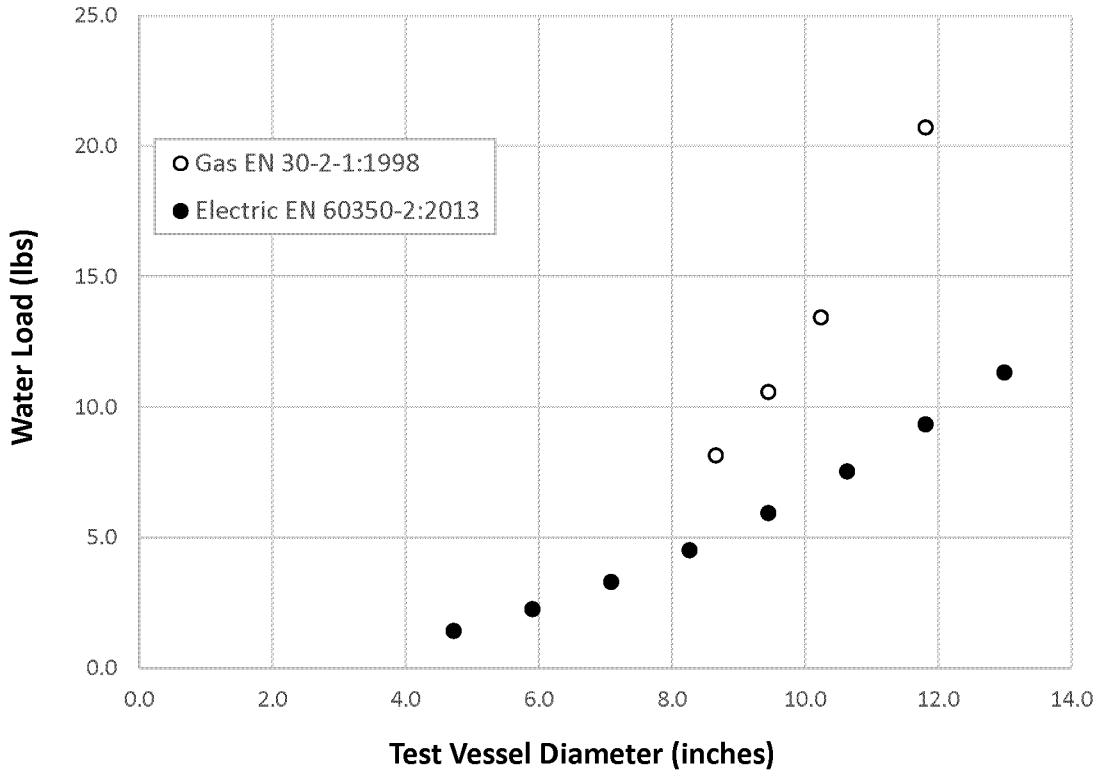

Figure III.1 Test Vessel Water Load versus Diameter as Specified in EN 30-2-1 and EN 60350-2:2013

DOE notes that for comparable test vessel diameters specified in the two test procedures, the water loads vary significantly. However, DOE is not aware of any data suggesting that a representative test load should be significantly different for gas cooking tops than for electric cooking tops. As a result, DOE is proposing to use the test vessel diameters and the corresponding water loads from EN 60350–2:2013 that most closely match the test vessel diameters specified in EN 30–2–1 to test conventional gas cooking tops. Proposing to use the same test vessels and water loads as specified for electric cooking tops, as well as the same general test method, reduces the burden on manufacturers by minimizing the amount of new test equipment required to be purchased. Table III.4 lists DOE's proposal for gas cooking top test vessel diameter and water load by nominal burner input rate.

TABLE III.4—PROPOSED TEST VESSEL DIAMETERS AND WATER LOADS FOR THE TEST OF CONVENTIONAL GAS COOKING TOPS

Nominal gas burner input rate		Test vessel diameter (inches (mm))	Mass of the water load (lbs (kg))
Minimum Btu/h (kW)	Maximum Btu/h (kW)		
3,958 (1.16)	5,596 (1.64)	8.27 (210)	4.52 (2.05)
5,630 (1.65)	6,756 (1.98)	9.45 (240)	5.95 (2.70)
6,790 (1.99)	8,053 (2.36)	10.63 (270)	7.54 (3.42)
8,087 (2.37)	14,331 (4.2)	10.63 (270)	7.54 (3.42)
>14,331 (4.2)	.....	11.81 (300)	11.33 (4.24)

Unlike electric cooking tops, DOE is not proposing to require a minimum number of cookware categories for the test of a gas cooking top. Given that the diameter of the gas flame cannot be adjusted when the burner is at its maximum setting, only the best fitting test vessel, as specified in Table III.4, would be used for the surface unit test. DOE is also proposing to maintain the gas test conditions and measurements currently specified in appendix I for the test of gas cooking tops because gas testing is not addressed in EN 60350–2:2013.

DOE seeks comment on its proposed test vessel diameters and water loads for the test of conventional gas cooking tops. DOE also seeks comment on whether a representative water load for gas cooking tops should differ significantly from those for electric cooking tops. DOE requests input on whether the range of gas burner input rates derived from European standard EN 30–2–1 appropriately captures the burner input rates available on the U.S. market.

G. Annual Energy Consumption

In section 4.2.2 of the existing test procedure in appendix I, the annual energy consumption for electric and gas cooking tops is specified as the ratio of the annual useful cooking energy output to the cooking efficiency measured with a test block. The cooking efficiency is the average of the surface unit efficiencies measured for the cooking top. The annual useful cooking energy output was determined during the initial development of the cooking products test procedure in 1978. It correlated cooking field data to results obtained using the aluminum test block method and the DOE test procedure. In subsequent analyses for cooking products energy conservation standards and updates to the test procedure, the annual useful cooking energy output was scaled to adjust for changes in consumer cooking habits.

In this SNOPR, DOE is proposing to incorporate by reference relevant sections of EN 60350–2:2013, which does not include a method to determine surface unit efficiency and thus, cooking top efficiency. DOE also noted in section III.D.1 of this notice the repeatability and reproducibility issues related to specifying an efficiency metric for the water-heating test method. As a result, DOE is proposing to include a method to calculate both annual energy consumption and integrated annual energy consumption using the average of the test energy consumption measured for each surface unit of the cooking top, normalized to a representative water load size.

Section 7.1.Z7.2 of EN 60350–2:2013 specifies that the energy consumption of the cooking top be normalized to 1,000 g of water. However, DOE notes that 1,000 g of water may not be representative of the average load used with cooking tops found in the U.S. market. According to the table of standardized test vessel diameters and water amounts listed in Table III.1, a load size of 1,000 g approximately corresponds to a test vessel diameter of 6 inches, which, according to the following analysis, is not the most representative test vessel diameter. To determine the representative load size for both electric and gas cooking tops, DOE first reviewed the surface unit diameters and input rates for cooking tops (including those incorporated into combined cooking products) available on the market. As discussed in section III.D, section 7.1.Z2 of EN 60350–2 includes methodology for selecting the test vessel diameter and a corresponding water load for each surface unit based on the number of surface units on the cooking top and the diameter of each surface unit. Using this methodology, DOE determined the test vessel diameters and water load sizes that would be required for the test of each cooking top model. Based on this analysis, DOE determined that the average water load size for both electric and gas cooking top models available on the market was 2,853 g. As a result, DOE is proposing to calculate the normalized cooking top energy consumption for electric products as

$$E_{CTE} = \frac{2853g}{n_{tv}} \times \sum_{tv=1}^{n_{tv}} \frac{E_{tv}}{m_{tv}}$$

and the normalized cooking top energy consumption for gas products as

$$E_{CTG} = \frac{2853g}{n_{tv}} \times \sum_{tv=1}^{n_{tv}} \frac{E_{tv}}{m_{tv}}$$

Where:

E_{CTE} is the energy consumption of an electric cooking top calculated per 2,853 g of water, in Wh;

E_{CTG} is the energy consumption of a gas cooking top calculated per 2,853 g of water, in Wh;

E_{tv} is the energy consumption measured for a given test vessel, tv, in Wh;

m_{tv} is the mass of water in the test vessel, in g; and,

n_{tv} is the number of test vessels used to test the complete cooking top.

To extrapolate the cooking top's normalized test energy consumption to an annual energy consumption, DOE considered cooking top usage data available through EIA RECS, which collects energy-related data for occupied primary housing units in the United States. The 2009 RECS collected data from 12,083 housing units representing almost 113.6 million households. RECS provides values for the frequency of household cooking events by product class as listed in Table III.5.

TABLE III.5—RECS 2009 AVERAGE MEALS PER DAY FOR CONVENTIONAL COOKING TOPS

Cooking top type	RECS average cooking frequency (meals per day)
Electric	1.21
Smooth Electric[a]	1.21
Gas	1.25

[a] Smooth Electric as listed here includes both smooth electric radiant and induction cooking tops.

However, RECS does not provide details about the cooking load (*e.g.,* load size or composition) nor the duration of the cooking event. As a result, DOE is proposing to normalize the number of cooking cycles to account for differences between the duration of a cooking event represented in the RECS data and DOE's proposed test load for measuring the energy consumption of the cooking top to calculate the annual energy consumption.

To evaluate the difference between field energy use and test energy consumption, DOE reviewed recent survey data of residential cooking presented in the 2010 CA RASS and the FSEC, from which DOE determined that the representative average annual energy consumption of conventional electric ranges is 287.5 kWh/year. In appendix 7A of the technical support document (TSD) for the conventional ovens energy conservation standards NOPR (80 FR 33030 (June 10, 2015)), DOE provides a methodology to disaggregate the range energy consumption into two portions—one allocated to the oven and the other portion allocated to the cooking top. This methodology assumes that the annual cooking energy consumption of a cooking top is a fraction of that of a standard oven, and that the ratio of annual useful cooktop energy output to standard oven useful energy output in a range has not changed over time. This methodology also assumes that this ratio for electric cooking products applies to gas cooking products as well. After applying these assumptions, the resulting field energy use estimates of the average annual energy consumption of an electric cooking top and gas cooking top were 114 kWh/yr and 858 kBtu/yr, respectively.

For comparison of the proposed test procedure to the field energy use estimates, DOE conducted testing on a select number of cooking tops, capturing all product classes and a range of cooking top features. DOE estimated the annual energy consumption of a conventional cooking top by multiplying the normalized test energy consumption of the cooking top by the cooking frequency in Table III.5 and the number of days in a year (365). The maximum annual energy consumption for electric cooking tops and gas cooking tops in the DOE test sample were 234.9 kWh/yr and 1,925 kBtu/yr respectively. The significant difference between the annual energy consumption determined using the proposed test procedure and the cooking frequency presented in Table III.5 compared to the field energy consumption data, presented in this preamble, confirms the need to adjust the number of cooking cycles per year used in the annual energy consumption calculation to account for differences between consumer use of the cooking top represented by the EIA RECS data

and the proposed water heating test method.

Using the average ratio between the maximum annual energy consumption measured in the DOE test sample and the estimated field energy use of both gas and electric cooking tops, DOE proposes to apply a normalization factor of 0.47 to the number of cycles per year such that,

$N_{CE} = 441.5 \times 0.47 = 207.5$ cooking cycles per year, the average number of cooking cycles per year normalized for duration of a cooking event estimated for electric cooking tops.

$N_{CG} = 456.3 \times 0.47 = 214.5$ cooking cycles per year, the average number of cooking cycles per year normalized for duration of a cooking event estimated for gas cooking tops.

DOE is proposing to calculate the annual energy consumption of a conventional cooking top by multiplying the normalized test energy consumption of the cooking top by the normalized cooking frequency and the number of days in a year (365). Integrated annual energy consumption for the cooking top would in turn be calculated by adding the annual conventional cooking top combined low-power mode energy consumption.

H. Calculation of Annual Energy Consumption of Combined Cooking Products

As discussed in section III.A, DOE notes that the test procedures proposed in this SNOPR apply to conventional cooking tops, including the individual cooking top component of a combined cooking product. However, DOE also notes that the annual combined low-power mode energy consumption can only be measured for the combined cooking product as a whole and not for the individual components. To determine the integrated annual energy consumption of the conventional cooking top component of a combined cooking product, DOE is proposing to allocate a portion of the combined low-power mode energy consumption for the combined cooking product to the conventional cooking top component based on the ratio of the annual cooking hours for the cooking top to the sum of the annual cooking hours for all components making up the combined cooking product. DOE is also proposing to use the same apportioning method to determine the annual low-power mode energy consumption for the microwave oven component of a combined cooking product.

For conventional cooking tops, DOE determined the annual cooking hours to be 213.1 hours based on the total inactive mode and off mode hours specified in the current version of appendix I, sections 4.2.2.1.2 and 4.2.2.2.2. For conventional ovens, DOE similarly determined the annual cooking hours to be 219.9 based on the total inactive mode and off mode hours specified in the current version of appendix I, section 4.1.2.3 using the annual hours already established for a conventional oven. For microwave ovens, DOE determined the number of annual cooking hours to be 44.9 hours based on consumer usage data presented in the February 4, 2013 NOPR proposing active mode test procedures for microwave ovens. 78 FR 7940, 7950.

Based on this, DOE is proposing to calculate the integrated annual energy consumption for the conventional cooking top component of a combined cooking product as the sum of the annual energy consumption and the portion of the combined cooking product's annual combined low-power mode energy consumption allocated to the cooking top component. Because appendix I currently contains test procedures for microwave ovens that measure only standby mode and off mode test energy consumption, DOE is including an annual combined low-power mode energy consumption calculation for the microwave oven component of a combined cooking product. As discussed in section III.G of this SNOPR, DOE is proposing to repeal the test procedures for conventional ovens. As a result, DOE is not proposing to incorporate methods to calculate the integrated annual energy consumption for the conventional oven component of a combined cooking product.

DOE also proposes to modify the requirements in 10 CFR 430.23 to align with the changes proposed for appendix I, clarifying test procedures for the measurement of energy consumption for combined cooking products.

I. Installation Test Conditions

DOE notes that section 2.1 of appendix I defines installation test conditions for some cooking products but does not explicitly describe the installation test conditions required for conventional cooking tops. The test conditions described for freestanding ''kitchen ranges'' specify that the product be installed with the back directly against, or as near as possible to, a vertical wall which extends at least 1 foot above and on either side of the appliance, and that a drop-in, built-in, or wall-mounted cooking product be installed in an enclosure in accordance with the manufacturer's instructions.

During interviews conducted in February and March 2015, manufacturers commented that the installation conditions described in the existing DOE test procedure are outdated. Specifically, manufacturers explained that certain conventional cooking tops, conventional ovens, and combined cooking products, such as conventional ranges, are designed to be used in a few different installation configurations. They stated that manufacturer installation guides may contain several sets of instructions, and the existing DOE test procedure does not sufficiently define which set should be selected for test. Manufacturers also commented that the installation configuration may impact the measured energy consumption. Because they are already required to test products according to ANSI Z21.1 for safety purposes, manufacturers suggested that DOE consider specifying the same test cabinetry in appendix I to minimize burden and ensure that all products are tested using a standardized cabinetry.

DOE agrees with manufacturers that a standardized test cabinetry should be specified for all cooking product types to ensure that test results are comparable across manufacturers and are repeatable and reproducible. For testing conventional cooking tops and combined components, DOE is proposing in this SNOPR to incorporate by reference the following test structures specified in ANSI Z21.1 sections 5.1 and 5.19:

- Figure 7, ''Test structure for built-in top surface cooking units and open top broiler units;''
- Figure 5, ''Test structure for floor-supported units not having elevated cooking sections;'' and
- Figure 6, ''Test structure for floor-supported units having elevated cooking sections.''

Although ANSI Z21.1 pertains to gas cooking appliances, DOE is proposing to require these test structures for both gas and electric conventional cooking products. ANSI Z21.1 definitions for the various installation configurations also differ slightly from those specified by DOE in the existing appendix I. According to ANSI Z21.1, a ''built-in unit'' is defined as a cooking appliance designed to be recessed into, placed upon, or attached to the construction of a building other than the floor, while a ''floor-supported'' unit is a cooking appliance for installation directly on the floor without requiring supporting cabinetry or structure. However, DOE notes that its definition for ''built-in'' in appendix I also applies to ''slide-in'' products that may be floor supported. In this SNOPR, DOE is proposing to further

clarify its definition of ''built-in'' to mean a product that is enclosed in surrounding cabinetry, walls, or other similar structures on at least three sides, and that can be supported by surrounding cabinetry (*e.g.,* drop-in cooking tops) or the floor (*e.g.,* slide-in conventional ranges). DOE is also proposing to revise its definition for freestanding cooking products to mean a product that is supported by the floor and is not designed to be enclosed by surrounding cabinetry, walls, or other similar structures.

In addition, DOE notes that in general, where the test procedure references manufacturer instructions used to determine the installation conditions for the unit under test, those instructions must be those normally shipped with product, or if only available online, the version of the instructions available online at the time of test. DOE recognizes that some manufacturer instructions may specify that the cooking product may be used in multiple installation conditions (*i.e.,* built-in and freestanding). DOE notes that because built-in products are installed in configurations with more surrounding cabinetry that may limit airflow and venting compared to freestanding products, products capable of built-in installation configurations may require additional features such as exhaust fans or added insulation to meet the same safety requirements (*e.g.,* surface temperature requirements specified in Table 12 of ANSI Z21.1) that impact energy use of the unit. As a result, DOE is proposing that if the manufacturer instructions specify that the cooking product may be used in multiple installation conditions, it should be installed according to the built-in configuration.

J. Technical Clarification to the Correction of the Gas Heating Value

DOE notes that section 2.9.4 in the existing test procedure appendix I specifies that the heating value of natural gas or propane must be corrected for local temperature and pressure conditions, but does not clearly state what conditions should be used for this correction. DOE notes that the test procedure for residential gas clothes dryers in 10 CFR 430 subpart B, appendix D2, specifies that the heating value should be corrected to standard temperature and pressure conditions in accordance with U.S. Bureau of Standards, circular C417, 1938. DOE notes other test procedures (*e.g.,* residential water heaters (10 CFR 430 subpart B, appendix E)) also specify that the temperature and pressure conditions should be corrected to standard temperature and pressure conditions. As a result, DOE is proposing to clarify that the measurement of the heating value of natural gas or propane specified in appendix I be corrected to standard pressure and temperature conditions in accordance with the U.S. Bureau of Standards, circular C417, 1938. This clarification ensures that the same correction methods are used by all operators of the test.

K. Grammatical Changes to Certain Sections of Appendix I

In an effort to clarify the text in certain sections of appendix I, DOE has provided minor grammatical corrections or modifications. DOE also notes that the watt meter requirements specified in 2.9.1.2 in the existing appendix I are no longer used in the test procedure. As a result, DOE is also proposing to remove this section. These minor proposed modifications do not change the substance of the test methods or descriptions provided in these sections.

L. Compliance With Other EPCA Requirements

EPCA requires that any new or amended test procedures for consumer products must be reasonably designed to produce test results which measure energy efficiency, energy use, or estimated annual operating cost of a covered product during a representative average use cycle or period of use, and must not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

DOE tentatively concludes that the amended test procedures proposed herein would produce test results that measure the energy consumption of conventional cooking tops during representative use, and that the test procedures would not be unduly burdensome to conduct.

While the test procedures proposed in this SNOPR differ from the method currently included in appendix I for testing cooking tops, the essential method of test which includes an initial temperature rise of the test load and a simmering phase, is performed in approximately the same amount of time as the existing test procedure in appendix I. The existing test equipment in appendix I would be replaced with the eight test vessels described in section 7.1.Z2 of EN 60350–2:2013. DOE estimates current testing represents a cost of roughly $700 per test for labor, with a one-time investment of $2,000 for test equipment ($1,000 for test blocks and $1,000 for instrumentation). The proposed reusable test vessels would represent an additional one-time expense of $5,000 for the test vessels. Although manufacturers would be required to purchase and construct the test structures described in section III.I of this notice, many manufacturers stated during interviews that because these test structures are already used for gas product compliance testing required in ANSI Z21.1, these structures are already available in-house. DOE also notes that the only additional instrumentation required would be an absolute pressure transducer to measure the ambient air pressure of the test room. DOE estimates the cost of this transducer to be $100 or less for a model compatible with typical existing data collection systems used by the manufacturer. The allowable range of room air pressure specified in EN 60350–2:2013 is wide enough that a pressurized test chamber would not be required. Air pressure at elevations less than 3000 feet above sea level falls within the range. DOE does not believe this additional cost represents an excessive burden for test laboratories or manufacturers given the significant investments necessary to manufacture, test and market consumer appliances. Given the similarities (in terms of the test equipment, test method, the time needed to perform the test, and the calculations necessary to determine IAEC, DOE asserts that the newly proposed amended test procedure for cooking tops would not be unreasonably burdensome to conduct as compared to the existing test procedure in appendix I.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

The Office of Management and Budget (OMB) has determined that test procedure rulemakings do not constitute ''significant regulatory actions'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA) in OMB.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IFRA) for any rule that by law must be proposed for public comment and a final regulatory flexibility analysis for any such rule that an agency adopts as a final rule, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order

13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site: *http://energy.gov/gc/office-general-counsel.*

DOE reviewed this proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. The proposed rule would amend the test method for measuring the energy efficiency of conventional cooking tops, including methods applicable to induction cooking products and gas cooking tops with higher input rates.

The Small Business Administration (SBA) considers a business entity to be a small business, if, together with its affiliates, it employs less than a threshold number of workers or earns less than the average annual receipts specified in 13 CFR part 121. The threshold values set forth in these regulations use size standards and codes established by the North American Industry Classification System (NAICS) that are available at: *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.* The threshold number for NAICS classification code 335221, titled ''Household Cooking Appliance Manufacturing,'' is 750 employees; this classification includes manufacturers of residential conventional cooking products.

Most of the manufacturers supplying conventional cooking products are large multinational corporations. DOE surveyed the AHAM member directory to identify manufacturers of residential conventional cooking tops. DOE then consulted publicly-available data, purchased company reports from vendors such as Dun and Bradstreet, and contacted manufacturers, where needed, to determine if they meet the SBA's definition of a ''small business manufacturing facility'' and have their manufacturing facilities located within the United States. Based on this analysis, DOE estimates that there are nine small businesses that manufacture conventional cooking products covered by the proposed test procedure amendments.

For the reasons stated in the preamble, DOE has tentatively concluded that the proposed rule would not have a significant impact on small manufacturers under the applicable provisions of the Regulatory Flexibility Act. The proposed rule would amend DOE's test procedures for cooking tops by incorporating testing provisions from EN 60350–2:2013 to address active mode energy consumption for all conventional cooking top technology types, including induction surface units and surface units with higher input rates. The amended test procedure would be used to develop and test compliance with any future energy conservation standards for cooking tops that may be established by DOE. The proposed test procedure amendments involve the measurement of active mode energy consumption through the use of a water-heating test method that requires different test equipment than is currently specified for conventional cooking tops. The test equipment consists of a set of eight stainless steel test vessels. DOE estimates the cost for this new equipment to be approximately $5,000–$10,000, depending on the number of sets the manufacturer wishes to procure. Additionally, DOE estimates a cost of approximately $33,450 for an average small manufacturer to test a full product line of induction surface units and surface units with high input rates not currently covered by the existing test procedure in appendix I. This estimate assumes $700 per test, as described in section III.L of this notice, with up to 48 total tests per manufacturer needed, assuming 11 models [17] with either four or six individual surface unit tests per cooking top model. This cost is small (0.21 percent) compared to the average annual revenue of the nine identified small businesses, which DOE estimates to be over $16 million.[18]

For combined cooking products, DOE is proposing to modify the calculation of the IAEC of a combined cooking product by apportioning the combined low-power mode energy consumption measured for the combined cooking product to each individual component making up the combined cooking product. These modifications require the same methodology, test equipment, and test facilities used to measure the combined low-power mode energy consumption of stand-alone cooking products and therefore would not result in any additional facility or testing costs.

The incorporation by reference of the test structures from ANSI Z21.1 to standardize the installation conditions used during the test of conventional cooking tops are not expected to significantly impact small manufacturers under the applicable provisions of the Regulatory Flexibility Act. DOE estimates a cost of $500 for an average small manufacturer to fabricate the test structures for the test of cooking tops and combined cooking products, which is negligible when compared to the average annual revenue of the nine identified small businesses. Additionally, small manufacturers of gas cooking appliances likely already use these test structures to perform safety testing according to ANSI Z21.1.

For these reasons, DOE tentatively concludes and certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking. DOE will transmit the certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the SBA for review under 5 U.S.C. 605(b).

C. Reduction Act of 1995

Manufacturers of conventional cooking products must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for conventional cooking products, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including conventional cooking products. (76 FR 12422 (March 7, 2011). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910–1400. DOE requested OMB approval of an extension of this information collection for three years, specifically including the collection of information proposed in the present rulemaking, and estimated that the annual number of burden hours under this extension is 30 hours per company. In response to DOE's request, OMB approved DOE's information collection requirements covered under OMB control number 1910–1400 through November 30, 2017. 80 FR 5099 (Jan. 30, 2015).

Notwithstanding any other provision of the law, no person is required to

[17] DOE considered different configurations of the same basic model (where surface units were placed in different positions on the cooking top) as unique models.

[18] Estimated average revenue is based on financial information provided for the small businesses in reports provided by Dun and Bradstreet.

respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

In this proposed rule, DOE proposes test procedure amendments that it expects will be used to develop and implement future energy conservation standards for conventional cooking products. DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, this proposed rule would amend the existing test procedures without affecting the amount, quality or distribution of energy usage, and, therefore, would not result in any environmental impacts. Thus, this rulemaking is covered by Categorical Exclusion A5 under 10 CFR part 1021, subpart D, which applies to any rulemaking that interprets or amends an existing rule without changing the environmental effect of that rule. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, the proposed rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *http://energy.gov/gc/office-general-counsel.* DOE examined this proposed rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights'' 53 FR 8859 (March 18, 1988), that this regulation would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's

guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

The proposed regulatory action to amend the test procedure for measuring the energy efficiency of conventional cooking tops is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; FEAA) Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition.

The proposed rule incorporates testing methods contained in certain sections of the following commercial standards: EN 60350–2:2013 ''Household electric cooking appliances Part 2: Hobs—Methods for measuring performance'', and ANSI Z21.1–2016 ''Household cooking gas appliances.'' While the proposed test procedure is not exclusively based on the provisions in these industry standards, many components of the test procedure have been proposed to be adopted without amendment. The Department has evaluated these standards and is unable to conclude whether they fully comply with the requirements of section 32(b) of the FEAA, (*i.e.*, that they were developed in a manner that fully provides for public participation, comment, and review). DOE will consult with the Attorney General and the Chairman of the FTC concerning the impact of these test procedures on competition, prior to prescribing a final rule.

M. Description of Materials Incorporated by Reference

In this SNOPR, DOE proposes to incorporate by reference certain sections of the test standard published by ANSI, titled ''Household cooking gas appliances,'' ANSI Z21.1–2016. ANSI Z21.1 is an industry accepted test procedure that provides a basic standard for safe operation of residential gas cooking appliances. The test procedure proposed in this SNOPR references various sections of ANSI Z21.1 that address test setup and describe the various installation test structures used to test combined cooking products and conventional cooking tops. ANSI Z21.1 is readily available on ANSI's Web site at *http://webstore.ansi.org/default.aspx.*

DOE also proposes to incorporate by reference certain sections of the test standard published by CENELEC, titled ''Household electric cooking appliances Part 2: Hobs—Methods for measuring performance,'' EN 60350–2:2013. EN 60350–2:2013 is an industry accepted European test procedure that measures cooking top energy consumption and performance. DOE has determined that EN 60350–2:2013, with the proposed clarifications discussed in sections III.E, III.F, and III.G, provides test methods for determining the annual energy use metrics and are applicable to all residential conventional cooking tops sold in the United States. The test procedure proposed in this SNOPR references various sections of EN 60350–2:2013 that address test setup, instrumentation, test conduct, and measurement procedure. EN 60350–2:2013 is readily available on the British Standards Institute's Web site at *http://shop.bsigroup.com/.*

V. Public Participation

A. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments using any of the methods described in the **ADDRESSES** section at the beginning of this notice.

Submitting comments via regulations.gov. The *regulations.gov* Web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through *regulations.gov* cannot be claimed as CBI. Comments received through the Web site will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for

up to several weeks. Please keep the comment tracking number that *regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery, or mail. Comments and documents submitted via email, hand delivery, or mail also will be posted to *regulations.gov*. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery, please provide all items on a CD, if feasible. It is not necessary to submit printed copies. No facsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: One copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked non-confidential with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

B. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

1. Repeal of the Conventional Oven Test Procedure

DOE welcomes comment on its proposal to repeal the provisions in appendix I for measuring conventional oven IAEC. (See section III.B of this notice.)

2. Gas Burners With High Input Rates

DOE welcomes comment on what constitutes a representative test load for gas burners with high input rates. DOE is especially interested in consumer usage data demonstrating how consumers might use burners with high input rates differently than those with standard input rates. (See section III.A of this notice.)

3. Hybrid Test Blocks

DOE seeks comment on its decision to no longer propose the use of hybrid test blocks for the test of conventional cooking tops, given the outstanding issues associated with thermal grease and test block construction. (See section III.B of this notice.)

4. Representativeness of the Water-Heating Test Method for Electric Surface Units

DOE seeks comment on its proposal to incorporate by reference certain sections of EN 60350–2:2013 and specifically on whether the proposed test vessels and water loads are representative of actual consumer loads used with electric surface units. (See section III.D.1 of this notice.)

5. Non-Circular and Flexible Electric Surface Units

DOE invites comments on whether the specifications included in EN 60350–2:2013 are appropriate for determining the test vessel size and position for non-circular surface units and full-surface induction zones. DOE also invites comments on its proposal to test surface units with flexible concentric sizes at each unique size setting. DOE also welcomes comments on its proposal to not require testing of certain electric and gas cooking top surface units, such as bridge zones, warming plates, grills and griddles, in determining cooking top efficiency. (See section III.E of this notice.)

6. Representativeness of the Water-Heating Test Method for Gas Surface Units

DOE seeks comment on its proposal to extend the water-heating test method to gas cooking tops by correlating surface unit input rate to test vessel diameter and the mass of the water load. DOE also seeks comment on its proposed test vessel diameters and water loads for the test of conventional gas cooking tops and whether a representative water load for gas cooking tops should differ significantly from that of electric cooking tops. Additionally, DOE seeks input regarding whether the range of gas burner input rates derived from EN 30–2–1 appropriately captures the burner input rates available on the U.S. market. (See section III.F of this notice.)

7. Annual Energy Consumption Calculation

DOE seeks comment on its proposed method and calculation to determine the annual energy consumption and integrated annual energy consumption of conventional cooking tops. (See section III.G of this notice.)

8. Combined Cooking Products

DOE seeks comment on its proposed method and calculation to determine the integrated annual energy consumption for the conventional cooking top component of a combined cooking product and the combined annual low-power mode energy consumption for the microwave oven component of a combined cooking product. (See section III.H of this notice.)

9. Installation Test Conditions

DOE seeks comment on its proposal to incorporate by reference certain test structures from ANSI Z2.1 as required

installation test conditions for use with conventional cooking tops and combined cooking products. DOE seeks comment on its proposal to clarify the definitions for built-in and freestanding cooking products to appropriately reflect how these products are installed in the field. (See section III.I of this notice.)

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this proposed rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Issued in Washington, DC, on August 5, 2016.

Kathleen B. Hogan,

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

For the reasons stated in the preamble, DOE is proposing to amend part 430 of chapter II of title 10, Code of Federal Regulations as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Section 430.2 is amended by:
■ a. Removing the definitions for ''Conventional range,'' ''Microwave/conventional cooking top,'' ''Microwave/conventional oven,'' and ''Microwave/conventional range;'' and
■ b. Revising the definitions for ''Conventional cooking top,'' ''Conventional oven'', ''Cooking products'', ''Microwave oven'', and ''Other cooking products''.

The revisions read as follows:

§ 430.2 Definitions.

* * * * *

Conventional cooking top means a category of cooking products which is a household cooking appliance consisting of a horizontal surface containing one or more surface units that utilize a gas flame, electric resistance heating, or electric inductive heating. This includes any conventional cooking top component of a combined cooking product.

* * * * *

Conventional oven means a category of cooking products which is a household cooking appliance consisting of one or more compartments intended for the cooking or heating of food by means of either a gas flame or electric resistance heating. It does not include portable or countertop ovens which use electric resistance heating for the cooking or heating of food and are designed for an electrical supply of approximately 120 volts. This includes any conventional oven(s) component of a combined cooking product.

Cooking products means consumer products that are used as the major household cooking appliances. They are designed to cook or heat different types of food by one or more of the following sources of heat: Gas, electricity, or microwave energy. Each product may consist of a horizontal cooking top containing one or more surface units and/or one or more heating compartments.

* * * * *

Microwave oven means a category of cooking products which is a household cooking appliance consisting of a compartment designed to cook or heat food by means of microwave energy, including microwave ovens with or without thermal elements designed for surface browning of food and convection microwave ovens. This includes any microwave oven(s) component of a combined cooking product.

* * * * *

Other cooking products means any category of cooking products other than conventional cooking tops, conventional ovens, and microwave ovens.

* * * * *

■ 3. Section 430.3 is amended:
■ a. By redesignating paragraphs (e)(16) through (e)(19) as paragraphs (e)(17) through (e)(20) and adding new paragraph (e)(16);
■ b. By removing paragraph (i)(7) and redesignating (i)(8) as (i)(7);
■ c. Redesignating paragraph (l) through (v) as paragraph (m) through (w), respectively; and
■ d. By adding new paragraph (l).

The revisions and additions read as follows:

§ 430.3 Materials incorporated by reference.

* * * * *

(e) * * *

(16) ANSI Z21.1–2016, (''ANSI Z21.1''), *Household cooking gas appliances,* (2016), IBR approved for appendix I to subpart B.

* * * * *

(l) *CENELEC.* European Committee for Electrotechnical Standardization, available from the HIS Standards Store, *https://www.ihs.com/products/cenelec-standards.html.*

(1) EN 60350–2:2013, (''EN 60350–2:2013''), *Household electric cooking appliances Part 2: Hobs—Methods for measuring performance,* (2013), IBR approved for appendix I to subpart B.

(2) [Reserved]

* * * * *

■ 4. Section 430.23 is amended by revising paragraph (i) to read as follows:

§ 430.23 Test procedures for the measurement of energy and water consumption.

* * * * *

(i) *Cooking products.* (1) Determine the integrated annual electrical energy consumption for conventional electric cooking tops, including any integrated annual electrical energy consumption for combined cooking products according to sections 4.1.2.1.2 and 4.2.2.1 of appendix I to this subpart. For conventional gas cooking tops, the integrated annual electrical energy consumption shall be equal to the sum of the conventional cooking top annual electrical energy consumption, $E_{CCE,}$ as defined in section 4.1.2.2.2 or 4.2.2.2, and the conventional cooking top annual combined low-power mode energy consumption, E_{CTSO}, as defined in section 4.1.2.2.3, or the annual combined low-power mode energy consumption for the conventional cooking top component of a combined cooking product, E_{CCTLP}, as defined in section 4.2.2.2 of appendix I to this subpart.

(2) Determine the annual gas energy consumption for conventional gas cooking tops according to section 4.1.2.2.1 of appendix I to this subpart.

(3) Determine the integrated annual energy consumption for conventional cooking tops according to sections 4.1.2.1.2, 4.1.2.2.2, 4.2.2.1, and 4.2.2.2, respectively, of appendix I to this subpart. Round the integrated annual energy consumption to one significant digit.

(4) The estimated annual operating cost corresponding to the energy consumption of a conventional cooking top, shall be the sum of the following products:

(i) The integrated annual electrical energy consumption for any electric energy usage, in kilowatt-hours (kWh) per year, as determined in accordance with paragraph (i)(1) of this section, times the representative average unit cost for electricity, in dollars per kWh, as provided pursuant to section 323(b)(2) of the Act; plus

(ii) The total annual gas energy consumption for any natural gas usage,

in British thermal units (Btu) per year, as determined in accordance with paragraph (i)(2) of this section, times the representative average unit cost for natural gas, in dollars per Btu, as provided pursuant to section 323(b)(2) of the Act; plus

(iii) The total annual gas energy consumption for any propane usage, in Btu per year, as determined in accordance with paragraph (i)(2) of this section, times the representative average unit cost for propane, in dollars per Btu, as provided pursuant to section 323(b)(2) of the Act.

(5) Determine the standby power for microwave ovens, excluding any microwave oven component of a combined cooking product, according to section 3.2.3 of appendix I to this subpart. Round standby power to the nearest 0.1 watt.

(6) For convertible cooking appliances, there shall be—

(i) An estimated annual operating cost and an integrated annual energy consumption which represent values for the operation of the appliance with natural gas; and

(ii) An estimated annual operating cost and an integrated annual energy consumption which represent values for the operation of the appliance with LP-gas.

(7) Determine the estimated annual operating cost for convertible cooking appliances that represents natural gas usage, as described in paragraph (i)(6)(i) of this section, according to paragraph (i)(4) of this section, using the total annual gas energy consumption for natural gas times the representative average unit cost for natural gas.

(8) Determine the estimated annual operating cost for convertible cooking appliances that represents LP-gas usage, as described in paragraph (i)(6)(ii) of this section, according to paragraph (i)(4) of this section, using the representative average unit cost for propane times the total annual energy consumption of the test gas, either propane or natural gas.

(9) Determine the integrated annual energy consumption for convertible cooking appliances that represents natural gas usage, as described in paragraph (i)(6)(i) of this section, according to paragraph (i)(3) of this section, when the appliance is tested with natural gas.

(10) Determine the integrated annual energy consumption for convertible cooking appliances that represents LP-gas usage, as described in paragraph (i)(6)(ii) of this section, according to paragraph (i)(3) of this section, when the appliance is tested with either natural gas or propane.

(11) Other useful measures of energy consumption for conventional cooking tops shall be the measures of energy consumption that the Secretary determines are likely to assist consumers in making purchasing decisions and that are derived from the application of appendix I to this subpart.

* * * * *

■ 7. Appendix I to subpart B of part 430 is revised to read as follows:

Appendix I to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Cooking Products

Note: Any representation related to active mode energy consumption of conventional cooking tops made after February 21, 2017 must be based upon results generated under this test procedure. Any representation related to standby and off mode power of conventional cooking tops, combined products, and microwave ovens must be based upon results generated under this test procedure.

Upon the compliance date(s) of any energy conservation standard(s) for cooking products, use of the applicable provisions of this test procedure to demonstrate compliance with the energy conservation standard will also be required.

1. Definitions

The following definitions apply to the test procedures in this appendix, including the test procedures incorporated by reference:

1.1 *Active mode* means a mode in which the product is connected to a mains power source, has been activated, and is performing the main function of producing heat by means of a gas flame, electric resistance heating, electric inductive heating, or microwave energy.

1.2 *ANSI Z21.1* means the test standard published by the American National Standards Institute titled, ''Household cooking gas appliances,'' Publication Z21.1 (2016) (incorporated by reference; see § 430.3).

1.3 *Built-in* means the product is enclosed in surrounding cabinetry, walls, or other similar structures on at least three sides, and can be supported by surrounding cabinetry or the floor.

1.4 *Combined cooking product* means a household cooking appliance that combines a cooking product with other appliance functionality, which may or may not include another cooking product. Combined cooking products include the following products: conventional range, microwave/conventional cooking top, microwave/conventional oven, and microwave/conventional range.

1.5 *Combined low-power mode* means the aggregate of available modes other than active mode, but including the delay start mode portion of active mode.

1.6 *Cooking area* is an area on a conventional cooking top surface heated by an inducted magnetic field where cookware is placed for heating, where more than one cookware item can be used simultaneously and controlled separately from other cookware placed on the cooking area, and that is either—

(1) An area where no clear limitative markings for cookware are visible on the surface of the cooking top; or

(2) An area with limitative markings.

1.7 *Cooking zone* is a conventional cooking top surface that is either a single electric resistance heating element or multiple concentric sizes of electric resistance heating elements, an inductive heating element, or a gas surface unit that is defined by limitative markings on the surface of the cooking top and can be controlled independently of any other cooking area or cooking zone.

1.8 *Cooking top control* is a part of the conventional cooking top used to adjust the power and the temperature of the cooking zone or cooking area for one cookware item.

1.9 *Cycle finished mode* is a standby mode in which a conventional cooking top provides continuous status display following operation in active mode.

1.10 *Drop-in* means the product is supported by horizontal surface cabinetry.

1.11 *EN 60350–2:2013* means the CENELEC test standard titled, ''Household electric cooking appliances Part 2: Hobs—Methods for measuring performance,'' Publication 60350–2 (2013) (incorporated by reference; see § 430.3).

1.12 *Freestanding* means the product is supported by the floor and is not specified in the manufacturer's instructions as able to be installed such that it is enclosed by surrounding cabinetry, walls, or other similar structures.

1.13 *IEC 62301 (First Edition)* means the test standard published by the International Electrotechnical Commission, titled ''Household electrical appliances—Measurement of standby power,'' Publication 62301 (First Edition 2005–06) (incorporated by reference; see § 430.3).

1.14 *IEC 62301 (Second Edition)* means the test standard published by the International Electrotechnical Commission, titled ''Household electrical appliances—Measurement of standby power,'' Publication 62301 (Edition 2.0 2011–01) (incorporated by reference; see § 430.3).

1.15 *Inactive mode* means a standby mode that facilitates the activation of active mode by remote switch (including remote control), internal sensor, or timer, or that provides continuous status display.

1.16 *Maximum power setting* means the maximum possible power setting if only one cookware item is used on the cooking zone or cooking area of a conventional cooking top.

1.17 *Normal non-operating temperature* means a temperature of all areas of an appliance to be tested that is within 5 °F (2.8 °C) of the temperature that the identical areas of the same basic model of the appliance would attain if it remained in the test room for 24 hours while not operating with all oven doors closed.

1.18 *Off mode* means any mode in which a cooking product is connected to a mains power source and is not providing any active mode or standby function, and where the mode may persist for an indefinite time. An

indicator that only shows the user that the product is in the off position is included within the classification of an off mode.

1.19 *Standard cubic foot (or liter (L)) of gas* means that quantity of gas that occupies 1 cubic foot (or alternatively expressed in L) when saturated with water vapor at a temperature of 60 °F (15.6 °C) and a pressure of 30 inches of mercury (101.6 kPa) (density of mercury equals 13.595 grams per cubic centimeter).

1.20 *Standby mode* means any mode in which a cooking product is connected to a mains power source and offers one or more of the following user-oriented or protective functions which may persist for an indefinite time:

(1) Facilitation of the activation of other modes (including activation or deactivation of active mode) by remote switch (including remote control), internal sensor, or timer;

(2) Provision of continuous functions, including information or status displays (including clocks) or sensor-based functions. A timer is a continuous clock function (which may or may not be associated with a display) that allows for regularly scheduled tasks and that operates on a continuous basis.

1.21 *Thermocouple* means a device consisting of two dissimilar metals which are joined together and, with their associated wires, are used to measure temperature by means of electromotive force.

1.22 *Symbol usage.* The following identity relationships are provided to help clarify the symbology used throughout this procedure.

A—Number of Hours in a Year
C—Specific Heat
E—Energy Consumed
H—Heating Value of Gas
K—Conversion for Watt-hours to Kilowatt-hours or Btu to kBtu
Ke—3.412 Btu/Wh, Conversion for Watt-hours to Btu
M—Mass
n—Number of Units
P—Power
Q—Gas Flow Rate
T—Temperature
t—Time
V—Volume of Gas Consumed

2. Test Conditions

2.1 *Installation.* Install a freestanding combined cooking product with the back directly against, or as near as possible to, a vertical wall which extends at least 1 foot above the appliance and 1 foot beyond both sides of the appliance, and with no side walls. Install a drop-in or built-in cooking top in the test enclosure specified in Figure 7 of ANSI Z21.1 (incorporated by reference; see § 430.3) according to the manufacturer's instructions. Install a built-in combined cooking product other than a microwave oven/conventional oven in the test enclosure specified in Figure 5 or 6 of ANSI Z21.1 in accordance with the manufacturer's instructions. If the manufacturer's instructions specify that the cooking product may be used in multiple installation conditions, install the appliance according to the built-in configuration. Completely assemble the product with all handles, knobs, guards, and similar components mounted in place. Position any electric resistance heaters, gas burners, and baffles in accordance with the manufacturer's instructions.

2.1.1 *Conventional electric cooking tops.* Connect these products to an electrical supply circuit with voltage as specified in section 2.2.1 of this appendix with a watt-hour meter installed in the circuit. The watt-hour meter shall be as described in section 2.8.1.1 of this appendix. For standby mode and off mode testing, install these products in accordance with Section 5, Paragraph 5.2 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3), disregarding the provisions regarding batteries and the determination, classification, and testing of relevant modes.

2.1.2 *Conventional gas cooking tops.* Connect these products to a gas supply line with a gas meter installed between the supply line and the appliance being tested, according to manufacturer's specifications. The gas meter shall be as described in section 2.8.2 of this appendix. Connect conventional gas cooking tops with electrical ignition devices or other electrical components to an electrical supply circuit of nameplate voltage with a watt-hour meter installed in the circuit. The watt-hour meter shall be as described in section 2.8.1.1 of this appendix. For standby mode and off mode testing, install these products in accordance with Section 5, Paragraph 5.2 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3), disregarding the provisions regarding batteries and the determination, classification, and testing of relevant modes.

2.1.3 *Microwave ovens, excluding any microwave oven component of a combined cooking product.* Install the microwave oven in accordance with the manufacturer's instructions and connect to an electrical supply circuit with voltage as specified in section 2.2.1 of this appendix. Install the microwave oven also in accordance with Section 5, Paragraph 5.2 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3), disregarding the provisions regarding batteries and the determination, classification, and testing of relevant modes. A watt meter shall be installed in the circuit and shall be as described in section 2.8.1.2 of this appendix.

2.1.4 *Combined cooking products standby mode and off mode.* For standby mode and off mode testing of combined cooking products, install these products in accordance with Section 5, Paragraph 5.2 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3), disregarding the provisions regarding batteries and the determination, classification, and testing of relevant modes.

2.2 *Energy supply.*

2.2.1 *Electrical supply.*

2.2.1.1 *Voltage.* For the test of conventional cooking tops, maintain the electrical supply requirements specified in Section 5.2 of EN 60350–2:2013 (incorporated by reference; see § 430.3). For microwave oven testing, maintain the electrical supply to the unit at 240/120 volts ±1 percent. For combined cooking product standby mode and off mode measurements, maintain the electrical supply to the unit at 240/120 volts ±1 percent. Maintain the electrical supply frequency for all products at 60 hertz ±1 percent.

2.2.1.1 *Gas burner adjustments.* Test conventional gas cooking tops with all of the gas burners adjusted in accordance with the installation or operation instructions provided by the manufacturer. In every case, adjust the burner with sufficient air flow to prevent a yellow flame or a flame with yellow tips.

2.2.2.2 *Natural gas.* For testing convertible cooking appliances or appliances which are designed to operate using only natural gas, maintain the natural gas pressure immediately ahead of all controls of the unit under test at 7 to 10 inches of water column (1743.6 to 2490.8 Pa). The regulator outlet pressure shall equal the manufacturer's recommendation. The natural gas supplied should have a heating value of approximately 1,025 Btu per standard cubic foot (38.2 kJ/L). The actual gross heating value, H_n, in Btu per standard cubic foot (kJ/L), for the natural gas to be used in the test shall be obtained either from measurements made by the manufacturer conducting the test using equipment that meets the requirements described in section 2.8.4 of this appendix or by the use of bottled natural gas whose gross heating value is certified to be at least as accurate a value that meets the requirements in section 2.8.4 of this appendix.

2.2.2.3 *Propane.* For testing convertible cooking appliances with propane or for testing appliances which are designed to operate using only LP-gas, maintain the propane pressure immediately ahead of all controls of the unit under test at 11 to 13 inches of water column (2740 to 3238 Pa). The regulator outlet pressure shall equal the manufacturer's recommendation. The propane supplied should have a heating value of approximately 2,500 Btu per standard cubic foot (93.2 kJ/L). Obtain the actual gross heating value, H_p, in Btu per standard cubic foot (kJ/L), for the propane to be used in the test either from measurements made by the manufacturer conducting the test using equipment that meets the requirements described in section 2.8.4 of this appendix, or by the use of bottled propane whose gross heating value is certified to be at least as accurate a value that meets the requirements described in section 2.8.4 of this appendix.

2.2.2.4 *Test gas.* Test a basic model of a convertible cooking appliance with natural gas or propane. Test with natural gas any basic model of a conventional cooking top that is designed to operate using only natural gas as the energy source. Test with propane gas any basic model of a conventional cooking top which is designed to operate using only LP gas as the gas energy source.

2.3 *Air circulation.* Maintain air circulation in the room sufficient to secure a reasonably uniform temperature distribution, but do not cause a direct draft on the unit under test.

2.5 *Ambient room test conditions*

2.5.1 *Active mode ambient room air temperature.* During the active mode test for conventional cooking tops, maintain the ambient room air temperature and pressure specified in Section 5.1 of EN 60350–2:2013 (incorporated by reference; see § 430.3).

2.5.2 *Standby mode and off mode ambient temperature.* For standby mode and off mode testing, maintain room ambient air temperature conditions as specified in Section 4, Paragraph 4.2 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3).

2.6 *Normal non-operating temperature.* All areas of the appliance to be tested must attain the normal non-operating temperature, as defined in section 1.17 of this appendix, before any testing begins. Measure the applicable normal non-operating temperature using the equipment specified in sections 2.8.3.1 and 2.8.3.2 of this appendix.

2.7 *Conventional cooking top test vessels*

2.7.1 *Conventional electric cooking top test vessels.* The test vessels and water amounts required for the test of conventional electric cooking tops must meet the requirements specified in Section 7.1.Z2 of EN 60350–2:2013 (incorporated by reference; see § 430.3).

2.7.2 *Conventional gas cooking top test vessels.* The test vessels for conventional gas cooking tops must be constructed according to Section 7.1.Z2 of EN 60350–2:2013 (incorporated by reference; see § 430.3). Use the following test vessel diameters and water amounts to test gas cooking zones having the burner input rates as specified:

Nominal gas burner input rate		Test vessel diameter inches (mm)	Mass of the water load lbs (kg)
Minimum Btu/h (kW)	Maximum Btu/h (kW)		
3,958 (1.16)	5,596 (1.64)	8.27 (210)	4.52 (2.05)
5,630 (1.65)	6,756 (1.98)	9.45 (240)	5.95 (2.70)
6,790 (1.99)	8,053 (2.36)	10.63 (270)	7.54 (3.42)
8,087 (2.37)	14,331 (4.2)	10.63 (270)	7.54 (3.42)
>14,331 (4.2)		11.81 (300)	11.33 (4.24)

2.8 *Instrumentation.* Perform all test measurements using the following instruments, as appropriate:

2.8.1 *Electrical Measurements.*

2.8.1.1 *Watt-hour meter.* The watt-hour meter for measuring the electrical energy consumption of conventional cooking tops must have a resolution as specified in Table Z1 of Section 5.3 of EN 60350–2:2013 (incorporated by reference; see § 430.3). The watt-hour meter for measuring the electrical energy consumption of microwave ovens must have a resolution of 0.1 watt-hour (0.36 kJ) or less and a maximum error no greater than 1.5 percent of the measured value.

2.8.1.2 *Standby mode and off mode watt meter.* The watt meter used to measure standby mode and off mode power must meet the requirements specified in Section 4, Paragraph 4.4 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3). For microwave oven standby mode and off mode testing, if the power measuring instrument used for testing is unable to measure and record the crest factor, power factor, or maximum current ratio during the test measurement period, measure the crest factor, power factor, and maximum current ratio immediately before and after the test measurement period to determine whether these characteristics meet the requirements specified in Section 4, Paragraph 4.4 of IEC 62301 (Second Edition).

2.8.2 *Gas Measurements.*

2.8.2.1 *Positive displacement meters.* The gas meter to be used for measuring the gas consumed by the gas burners of the conventional cooking top must have a resolution of 0.01 cubic foot (0.28 L) or less and a maximum error no greater than 1 percent of the measured valued for any demand greater than 2.2 cubic feet per hour (62.3 L/h).

2.8.3 *Temperature measurement equipment.*

2.8.3.1 *Room temperature indicating system.* For the test of microwave ovens, the room temperature indicating system must have an error no greater than ±1 °F (±0.6 °C) over the range 65° to 90 °F (18 °C to 32 °C). For conventional cooking tops, the room temperature indicating system must be as specified in Table Z1 of Section 5.3 of EN 60350–2:2013 (incorporated by reference; see § 430.3).

2.8.3.2 *Temperature indicator system for measuring surface temperatures.* Measure the temperature of any surface of a conventional cooking top by means of a thermocouple in firm contact with the surface. The temperature indicating system must have an error no greater than ±1 °F (±0.6 °C) over the range 65° to 90 °F (18 °C to 32 °C).

2.8.3.3 *Water temperature indicating system.* For the test of conventional cooking tops, the test vessel water temperature indicating system must be as specified in Table Z1 of Section 5.3 of EN 60350–2:2013 (incorporated by reference; see § 430.3).

2.8.3.4 *Room air pressure indicating system.* For the test of conventional cooking tops, the room air pressure indicating system must be as specified in Table Z1 of Section 5.3 of EN 60350–2:2013 (incorporated by reference; see § 430.3).

2.8.4 *Heating Value.* Measure the heating value of the natural gas or propane with an instrument and associated readout device that has a maximum error no greater than ±0.5% of the measured value and a resolution of ±0.2% or less of the full scale reading of the indicator instrument. Correct the heating value of natural gas or propane to standard pressure and temperature conditions in accordance with U.S. Bureau of Standards, circular C417, 1938.

2.8.5 *Scale.* The scale used to measure the mass of the water amount must be as specified in Table Z1 of Section 5.3 of EN 60350–2:2013 (incorporated by reference; see § 430.3).

3. Test Methods and Measurements

3.1. *Test methods.*

3.1.1 *Conventional cooking top.* Establish the test conditions set forth in section 2, *Test Conditions,* of this appendix. Turn off the gas flow to the conventional oven(s), if so equipped. The temperature of the conventional cooking top must be its normal non-operating temperature as defined in section 1.17 and described in section 2.6 of this appendix. For conventional electric cooking tops, select the test vessel and test position according to Sections 6.2.Z1, 7.1.Z2, 7.1.Z3, 7.1.Z4, and Annex ZA of EN 60350–2:2013 (incorporated by reference; see § 430.3). For conventional gas cooking tops, select the appropriate test vessel from the test vessels specified in section 2.7.2 of this appendix based on the burner input rate. Use the test methods set forth in Section 7.1.Z6 of EN 60350–2:2013 to measure the energy consumption of electric and gas cooking zones and electric cooking areas. Do not test specialty cooking zones that are for use only with non-circular cookware, such as bridge zones, warming plates, grills, and griddles.

3.1.1.1 *Conventional cooking top standby mode and off mode power except for any conventional cooking top component of a combined cooking product.* Establish the standby mode and off mode testing conditions set forth in section 2, *Test Conditions,* of this appendix. For conventional cooktops that take some time to enter a stable state from a higher power state as discussed in Section 5, Paragraph 5.1, Note 1 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3), allow sufficient time for the conventional cooking top to reach the lower power state before proceeding with the test measurement. Follow the test procedure as specified in Section 5, Paragraph 5.3.2 of IEC 62301 (Second Edition) for testing in each possible mode as described in sections 3.1.1.1.1 and 3.1.1.1.2 of this appendix. For units in which power varies as a function of displayed time in standby mode, set the clock time to 3:23 at the end of the stabilization period specified in Section 5, Paragraph 5.3 of IEC 62301 (First Edition), and use the average power approach described in Section 5, Paragraph 5.3.2(a) of IEC 62301 (First Edition), but with a single test period of 10 minutes +0/−2 sec after an additional stabilization period until the clock time reaches 3:33.

3.1.1.1.1 If the conventional cooking top has an inactive mode, as defined in section 1.15 of this appendix, measure and record the average inactive mode power of the conventional cooking top, P_{IA}, in watts.

3.1.1.1.2 If the conventional cooking top has an off mode, as defined in section 1.18

of this appendix, measure and record the average off mode power of the conventional cooking top, P_{OM}, in watts.

3.1.2 *Combined cooking product standby mode and off mode power.* Establish the standby mode and off mode testing conditions set forth in section 2, *Test Conditions,* of this appendix. For combined cooking products that take some time to enter a stable state from a higher power state as discussed in Section 5, Paragraph 5.1, Note 1 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3), allow sufficient time for the combined cooking product to reach the lower power state before proceeding with the test measurement. Follow the test procedure as specified in Section 5, Paragraph 5.3.2 of IEC 62301 (Second Edition) for testing in each possible mode as described in sections 3.1.2.1 and 3.1.2.2 of this appendix. For units in which power varies as a function of displayed time in standby mode, set the clock time to 3:23 at the end of the stabilization period specified in Section 5, Paragraph 5.3 of IEC 62301 (First Edition), and use the average power approach described in Section 5, Paragraph 5.3.2(a) of IEC 62301 (First Edition), but with a single test period of 10 minutes +0/−2 sec after an additional stabilization period until the clock time reaches 3:33.

3.1.2.1 If the combined cooking product has an inactive mode, as defined in section 1.15 of this appendix, measure and record the average inactive mode power of the combined cooking product, P_{IA}, in watts.

3.1.2.2 If the combined cooking product has an off mode, as defined in section 1.18 of this appendix, measure and record the average off mode power of the combined cooking product, P_{OM}, in watts.

3.1.3 *Microwave oven.*

3.1.3.1 *Microwave oven test standby mode and off mode power except for any microwave oven component of a combined cooking product.* Establish the testing conditions set forth in section 2, *Test Conditions,* of this appendix. For microwave ovens that drop from a higher power state to a lower power state as discussed in Section 5, Paragraph 5.1, Note 1 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3), allow sufficient time for the microwave oven to reach the lower power state before proceeding with the test measurement. Follow the test procedure as specified in Section 5, Paragraph 5.3.2 of IEC 62301 (Second Edition). For units in which power varies as a function of displayed time in standby mode, set the clock time to 3:23 and use the average power approach described in Section 5, Paragraph 5.3.2(a) of IEC 62301 (First Edition), but with a single test period of 10 minutes +0/−2 sec after an additional stabilization period until the clock time reaches 3:33. If a microwave oven is capable of operation in either standby mode or off mode, as defined in sections 1.20 and 1.18 of this appendix, respectively, or both, test the microwave oven in each mode in which it can operate.

3.2 *Test measurements.*

3.2.1 *Conventional cooking top test energy consumption.*

3.2.1.1 *Conventional cooking area or cooking zone energy consumption.,* Measure the energy consumption for each electric cooking zone and cooking area, in watt-hours (kJ) of electricity according to section 7.1.Z6.3 of EN 60350–2:2013 (incorporated by reference; see § 430.3). For electric cooking zones with multiple concentric sizes, each concentric size is treated as a separate cooking zone. Each unique size must be tested individually with the appropriate test vessel size based on the dimensions of each concentric cooking zone as measured in section 6.2.Z2 of EN 60350–2:2013. For the gas surface unit under test, measure the volume of gas consumption, V_{CT}, in standard cubic feet (L) of gas and any electrical energy, E_{IC}, consumed by an ignition device of a gas heating element or other electrical components required for the operation of the conventional gas cooking top in watt-hours (kJ).

3.2.1.2 *Conventional cooking top standby mode and off mode power except for any conventional cooking top component of a combined cooking product.* Make measurements as specified in section 3.1.1.1 of this appendix. If the conventional cooking top is capable of operating in inactive mode, as defined in section 1.15 of this appendix, measure the average inactive mode power of the conventional cooking top, $P_{IA,}$ in watts as specified in section 3.1.1.1.1 of this appendix. If the conventional cooking top is capable of operating in off mode, as defined in section 1.18 of this appendix, measure the average off mode power of the conventional cooking top, P_{OM}, in watts as specified in section 3.1.1.1.2 of this appendix.

3.2.2 *Combined cooking product standby mode and off mode power.* Make measurements as specified in section 3.1.2 of this appendix. If the combined cooking product is capable of operating in inactive mode, as defined in section 1.15 of this appendix, measure the average inactive mode power of the combined cooking product, $P_{IA,}$ in watts as specified in section 3.1.2.1 of this appendix. If the combined cooking product is capable of operating in off mode, as defined in section 1.18 of this appendix, measure the average off mode power of the combined cooking product, P_{OM}, in watts as specified in section 3.1.2.2 of this appendix.

3.2.3 *Microwave oven standby mode and off mode power except for any microwave oven component of a combined cooking product.* Make measurements as specified in Section 5, Paragraph 5.3 of IEC 62301 (Second Edition) (incorporated by reference; see § 430.3). If the microwave oven is capable of operating in standby mode, as defined in section 1.20 of this appendix, measure the average standby mode power of the microwave oven, P_{SB}, in watts as specified in section 3.1.3.1 of this appendix. If the microwave oven is capable of operating in off mode, as defined in section 1.18 of this appendix, measure the average off mode power of the microwave oven, P_{OM}, as specified in section 3.1.3.1.

3.3 *Recorded values.*

3.3.1 Record the test room temperature, T_R, at the start and end of each conventional cooktop or combined cooking product test, as determined in section 2.5 of this appendix.

3.3.2 Record the relative air pressure at the start of the test and at the end of the test in hectopascals (hPa).

3.3.3 For conventional cooking tops and combined cooking products, record the standby mode and off mode test measurements P_{IA} and P_{OM}, if applicable.

3.3.4 For each test of an electric cooking area or cooking zone, record the values listed in 7.1.Z6.3 in EN 60350–2:2013 (incorporated by reference; see § 430.3) and the total test electric energy consumption, E_{TV}.

3.3.5 For each test of a conventional gas surface unit, record the gas volume consumption, V_{CT}; the time until the power setting is reduced, t_c; the time when the simmering period starts, t_{90}; the initial temperature of the water; the water temperature when the setting is reduced, T_c; the water temperature at the end of the test, T_s; and the electrical energy for ignition of the burners, E_{IC}.

3.3.6 Record the heating value, H_n, as determined in section 2.2.2.2 of this appendix for the natural gas supply.

3.3.7 Record the heating value, H_p, as determined in section 2.2.2.3 of this appendix for the propane supply.

3.3.8 For microwave ovens except for any microwave oven component of a combined cooking product, record the average standby mode power, P_{SB}, for the microwave oven standby mode, as determined in section 3.2.3 of this appendix for a microwave oven capable of operating in standby mode. Record the average off mode power, P_{OM}, for the microwave oven off mode power test, as determined in section 3.2.3 of this appendix for a microwave oven capable of operating in off mode.

4. Calculation of Derived Results From Test Measurements

4.1 *Conventional cooking top.*

4.1.1 *Conventional cooking top energy consumption.*

4.1.1.1 *Energy consumption for electric cooking tops.* Calculate the energy consumption of a conventional electric cooking top, E_{CTE}, in Watt-hours (kJ), using the following equation:

$$E_{CTE} = \frac{2853g}{n_{tv}} \times \sum_{tv=1}^{n_{tv}} \frac{E_{tv}}{m_{tv}}$$

Where:

n_{tv} = the total number of tests conducted for the conventional electric cooking top

E_{tv} = the energy consumption measured for each test with a given test vessel, tv, in Wh

m_{tv} is the mass of water used for the test, in g.

4.1.1.2 Gas *energy consumption for conventional gas cooking tops.* Calculate the energy consumption of the conventional gas cooking top, E_{CTG}, in Btus (kJ) using the following equation:

$$E_{CTG} = \frac{2853g}{n_{tv}} \times \sum_{tv=1}^{n_{tv}} \frac{E_{tvg}}{m_{tv}}$$

Where:

n_{tv} = the total number of tests conducted for the conventional gas cooking top
m_{tv} = the mass of the water used to test a given cooking zone or area
E_{tvg} = ($V_{CT} \times H$), the gas energy consumption measured for each test with a given test vessel, tv, in Btu (kJ)

Where:

V_{CT} = total gas consumption in standard cubic feet (L) for the gas surface unit test as measured in section 3.2.1.1 of this appendix.
H = either H_n or H_p, the heating value of the gas used in the test as specified in sections 2.2.2.2 and 2.2.2.3 of this appendix, expressed in Btus per standard cubic foot (kJ/L) of gas.

4.1.1.3 *Electrical energy consumption for conventional gas cooking tops.* Calculate the energy consumption of the conventional gas cooking top, E_{CTGE}, in Watt-hours (kJ) using the following equation:

$$E_{CTGE} = \frac{2853g}{n_{tv}} \times \sum_{tv=1}^{n_{tv}} \frac{E_{IC}}{m_{tv}}$$

Where:

n_{tv} = the total number of tests conducted for the conventional gas cooking top
m_{tv} = the mass of the water used to test a given cooking zone or area
E_{IC} = the electrical energy consumed in watt-hours (kJ) by a gas surface unit as measured in section 3.2.1.1 of this appendix.

4.1.2 *Conventional cooking top annual energy consumption.*

4.1.2.1 *Conventional electric cooking top.*

4.1.2.1.1 *Annual energy consumption of a conventional electric cooking top.* Calculate the annual energy consumption of a conventional electric cooking top, E_{CA}, in kilowatt-hours (kJ) per year, defined as:

$E_{CA} = E_{CTE} \times K \times N_{CE}$

Where:

K = 0.001 kWh/Wh conversion factor for watt-hours to kilowatt-hours.
N_{CE} = 207.5 cooking cycles per year, the average number of cooking cycles per year normalized for duration of a cooking event estimated for conventional electric cooking tops.
E_{CTE} = energy consumption of the conventional electric cooking top as defined in section 4.1.1.1 of this appendix.

4.1.2.1.2 *Integrated annual energy consumption of a conventional electric cooking top.* Calculate the integrated annual electrical energy consumption, E_{IAEC}, of a conventional electric cooking top, except for any conventional electric cooking top component of a combined cooking product, in kilowatt-hours (kJ) per year, defined as:

$E_{IAEC} = E_{CA} + E_{CTLP}$

Where:

E_{CA} = the annual energy consumption of the conventional electric cooking top as defined in section 4.1.2.1.1 of this appendix.

E_{CTLP} = conventional cooking top annual combined low-power mode energy consumption = $[(P_{IA} \times S_{IA}) + (P_{OM} \times S_{OM})] \times K$,

Where:

P_{IA} = conventional cooking top inactive mode power, in watts, as measured in section 3.1.1.1.1 of this appendix.
P_{OM} = conventional cooking top off mode power, in watts, as measured in section 3.1.1.1.2 of this appendix.
If the conventional cooking top has both inactive mode and off mode annual hours, S_{IA} and S_{OM} both equal 4273.4;
If the conventional cooking top has an inactive mode but no off mode, the inactive mode annual hours, S_{IA}, is equal to 8546.9, and the off mode annual hours, S_{OM}, is equal to 0;
If the conventional cooking top has an off mode but no inactive mode, S_{IA} is equal to 0, and S_{OM} is equal to 8546.9;
K = 0.001 kWh/Wh conversion factor for watt-hours to kilowatt-hours.

4.1.2.2 *Conventional gas cooking top*

4.1.2.2.1 *Annual gas energy consumption of a conventional gas cooking top.* Calculate the annual gas energy consumption, E_{CCG}, in kBtus (kJ) per year for a conventional gas cooking top, defined as:

$E_{CCG} = E_{CTG} \times K \times N_{CG}$

Where:

N_{CG} = 214.5 cooking cycles per year, the average number of cooking cycles per year normalized for duration of a cooking event estimated for conventional gas cooking tops.
E_{CTG} = gas energy consumption of the conventional gas cooking top as defined in section 4.1.1.2 of this appendix.
K = 0.001 conversion factor for Btu to kBtu.

4.1.2.2.2 *Annual electrical energy consumption of a conventional gas cooking top.* Calculate the annual electrical energy consumption, E_{CCE}, in kilowatt-hours (kJ) per year for a conventional gas cooking top, defined as:

$E_{CCE} = E_{CTGE} \times K \times N_{CG}$

Where:

N_{CG} = 214.5 cooking cycles per year, the average number of cooking cycles per year normalized for duration of a cooking event estimated for conventional gas cooking tops.
E_{CTGE} = secondary electrical energy consumption of the conventional gas cooking top as defined in section 4.1.1.3 of this appendix.
K = 0.001 conversion factor for Wh to kWh.

4.1.2.2.3 *Integrated annual energy consumption of a conventional gas cooking top.* Calculate the integrated annual energy consumption, E_{IAEC}, of a conventional gas cooking top, except for any conventional gas cooking top component of a combined cooking product, in kBtus (kJ) per year, defined as:

$E_{IAEC} = E_{CC} + (E_{CTSO} \times K_e)$

Where:

$E_{CC} = E_{CCG} + (E_{CCE} \times K_e)$ the total annual energy consumption of a conventional gas cooking top

Where:

E_{CCG} = the primary annual energy consumption of a conventional gas cooking top as determined in section 4.1.2.2.1 of this appendix.
E_{CCE} = the secondary annual energy consumption of a conventional gas cooking top as determined in section 4.1.2.2.2 of this appendix.
K_e = 3.412 Btu/Wh (3.6 kJ/Wh), conversion factor of watt-hours to Btus.

E_{CTSO} = conventional cooking top annual combined low-power mode energy consumption = $[(P_{IA} \times S_{IA}) + (P_{OM} \times S_{OM})] \times K$,

Where:

P_{IA} = conventional cooking top inactive mode power, in watts, as measured in section 3.1.1.1.1 of this appendix.
P_{OM} = conventional cooking top off mode power, in watts, as measured in section 3.1.1.1.2 of this appendix.
If the conventional cooking top has both inactive mode and off mode annual hours, S_{IA} and S_{OM} both equal 4273.4;
If the conventional cooking top has an inactive mode but no off mode, the inactive mode annual hours, S_{IA}, is equal to 8546.9, and the off mode annual hours, S_{OM}, is equal to 0;
If the conventional cooking top has an off mode but no inactive mode, S_{IA} is equal to 0, and S_{OM} is equal to 8546.9;
K = 0.001 kWh/Wh conversion factor for watt-hours to kilowatt-hours.

4.2 *Combined cooking products.*

4.2.1 *Combined cooking product annual combined low-power mode energy consumption.* Calculate the combined cooking product annual combined low-power mode energy consumption, E_{CCLP}, defined as:

$E_{CCLP} = [(P_{IA} \times S_{IA})] + [(P_{OM} \times S_{OM})] \times K$,

Where:

P_{IA} = combined cooking product inactive mode power, in watts, as measured in section 3.1.2.1 of this appendix.
P_{OM} = combined cooking product off mode power, in watts, as measured in section 3.1.2.2 of this appendix.
S_{TOT} equals the total number of inactive mode and off mode hours per year, 8,329.2;
If the combined cooking product has both inactive mode and off mode, S_{IA} and S_{OM} both equal $S_{TOT}/2$;
If the combined cooking product has an inactive mode but no off mode, the

inactive mode annual hours, S_{IA}, is equal to S_{TOT}, and the off mode annual hours, S_{OM}, is equal to 0;

If the combined cooking product has an off mode but no inactive mode, S_{IA} is equal to 0, and S_{OM} is equal to S_{TOT};

K = 0.001 kWh/Wh conversion factor for watt-hours to kilowatt-hours.

4.2.2 *Integrated annual energy consumption of any conventional cooking top component of a combined cooking product.*

4.2.2.1 *Integrated annual energy consumption of any conventional electric cooking top component of a combined cooking product.* Calculate the integrated annual energy consumption of a conventional electric cooking top component of a combined cooking product, E_{IAEC}, in kilowatt-hours (kJ) per year and defined as:

$E_{IAEC} = E_{CA} + E_{CCTLP}$

Where,

E_{CA} = the annual energy consumption of the conventional electric cooking top as defined in section 4.1.2.1.1 of this appendix.

E_{CCTLP} = annual combined low-power mode energy consumption for the conventional cooking top component of a combined cooking product, in kWh (kJ) per year, calculated as:

$$E_{CCTLP} = E_{CCLP} \times \frac{H_{CT}}{H_T}$$

Where:

E_{CCLP} = combined cooking product annual combined low-power mode energy consumption, determined in section 4.2.1 of this appendix.

H_{CT} = 213.1 hours per year, the average number of cooking hours per year for a conventional cooking top.

$H_T = H_{OV} + H_{CT} + H_{MWO}$

Where:

H_{OV} = average number of cooking hours per year for a conventional oven, which is equal to 219.9 hours per year. If the combined cooking product does not include a conventional oven, then H_{OV} = 0.

H_{MWO} = average number of cooking hours per year for a microwave oven, which is equal to 44.9 hours per year. If the combined cooking product does not include a microwave oven, then H_{MWO} = 0.

4.2.2.2 *Integrated annual energy consumption of any conventional gas cooking top component of a combined cooking product.* Calculate the integrated annual energy consumption of a conventional gas cooking top component of a combined cooking product, E_{IAEC}, in kBtus (kJ) per year and defined as:

$E_{IAEC} = E_{CC} + E_{CCTLP} \times K_e)$

Where,

$E_{CC} = E_{CCG} + E_{CCE}$, the total annual energy consumption of a conventional gas cooking top,

Where:

E_{CCG} = the annual gas energy consumption of a conventional gas cooking top as determined in section 4.1.2.2.1 of this appendix.

E_{CCE} = the annual electrical energy consumption of a conventional gas cooking top as determined in section 4.1.2.2.2 of this appendix.

K_e = 3.412 kBtu/kWh (3,600 kJ/kWh), conversion factor for kilowatt-hours to kBtus.

E_{CCTLP} = annual combined low-power mode energy consumption for the conventional cooking top component of a combined cooking product, in kWh (kJ) per year, calculated as:

$$E_{CCTLP} = E_{CCLP} \times \frac{H_{CT}}{H_T}$$

Where:

E_{CCLP} = combined cooking product annual combined low-power mode energy consumption, determined in section 4.2.1 of this appendix.

H_{CT} = 213.1 hours per year, the average number of cooking hours per year for a conventional cooking top.

$H_T = H_{OV} + H_{CT} + H_{MWO}$

Where:

H_{OV} = average number of cooking hours per year for a conventional oven, which is equal to 219.9 hours per year. If the combined cooking product does not include a conventional oven, then H_{OV} = 0.

H_{MWO} = average number of cooking hours per year for a microwave oven, which is equal to 44.9 hours per year. If the combined cooking product does not include a microwave oven, then H_{MWO} = 0.

4.2.3 *Annual combined low-power mode energy consumption for any microwave oven component of a combined cooking product.* Calculate the annual combined low-power mode energy consumption of a microwave oven component of a combined cooking product, E_{CMWOLP}, in kWh (kJ) per year, and defined as:

$$E_{CMWOLP} = E_{CCLP} \times \frac{H_{MWO}}{H_T}$$

Where:

E_{CCLP} = combined cooking product annual combined low-power mode energy consumption, determined in section 4.2.1 of this appendix.

H_{MWO} = 44.9 hours per year, the average number of cooking hours per year for a microwave oven.

$H_T = H_{OV} + H_{CT} + H_{MWO}$

Where:

H_{OV} = average number of cooking hours per year for a conventional oven, which is equal to 219.9 hours per year. If the combined cooking product does not include a conventional oven, then H_{OV} = 0.

H_{CT} = average number of cooking hours per year for a conventional cooking top, which is equal to 213.1 hours per year. If the combined cooking product does not include a conventional cooking top, then H_{CT} = 0.

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Part V

Department of Homeland Security

Federal Emergency Management Agency

44 CFR Part 9

Updates to Floodplain Management and Protection of Wetlands Regulations To Implement Executive Order 13690 and the Federal Flood Risk Management Standard; Proposed Rule

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 9

[Docket ID: FEMA–2015–0006]

RIN 1660–AA85

Updates to Floodplain Management and Protection of Wetlands Regulations To Implement Executive Order 13690 and the Federal Flood Risk Management Standard

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Emergency Management Agency (FEMA) proposes to amend its regulations on ''Floodplain Management and Protection of Wetlands'' to implement Executive Order 13690, which establishes the Federal Flood Risk Management Standard (FFRMS). FEMA also proposes a supplementary policy (FEMA Policy: 078–3) that would further clarify how FEMA applies the FFRMS.

DATES: Comments must be received no later than October 21, 2016.

ADDRESSES: You may submit comments, identified by Docket ID: FEMA–2015–0006, by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail/Hand Delivery/Courier: Regulatory Affairs Division, Office of Chief Counsel, Federal Emergency Management Agency, 8NE–1604, 500 C Street SW., Washington, DC 20472–3100.

To avoid duplication, please use only one of these methods. All comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided. For instructions on submitting comments, see the Public Participation portion of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Kristin Fontenot, Director, Office of Environmental Planning and Historic Preservation, Federal Insurance and Mitigation Administration, DHS/FEMA, 400 C Street SW., Suite 313, Washington, DC 20472–3020. Phone: 202–646–2741; Email: *Kristin.Fontenot@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION:

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Table of Abbreviations

0.2PFA—0.2 Percent Annual Chance Flood Approach
ABA—Architectural Barriers Act
ADA—Americans With Disabilities Act
CEQ—Council on Environmental Quality
CFR—Code of Federal Regulations
CISA—Climate-Informed Science Approach
CRS—Community Rating System
EA—Environmental Assessment
EIS—Environmental Impact Statement
FBFM—Flood Boundary Floodway Map
FEMA—Federal Emergency Management Agency
FFRMS—Federal Flood Risk Management Standard
FHBM—Flood Hazard Boundary Map
FIMA—Federal Insurance & Mitigation Administration
FIRM—Flood Insurance Rate Map
FIS—Flood Insurance Study
FMA—Flood Mitigation Assistance
FVA—Freeboard Value Approach
GPD—Grant Programs Directorate
HMA—Hazard Mitigation Assistance
HUD—Department of Housing and Urban Development
IA—Individual Assistance
IPAWS—Integrated Public Alert Warning System
IRFA—Initial Regulatory Flexibility Analysis
MHU—Manufactured Housing Unit
MitFLG—Mitigation Framework Leadership Group
NEPA—National Environmental Policy Act of 1969
NFIA—National Flood Insurance Act, as Amended
NFIP—National Flood Insurance Program
NMF—National Mitigation Framework
NOAA—National Oceanic and Atmospheric Administration
NPRM—Notice of Proposed Rulemaking
OMB—Office of Management and Budget
PA—Public Assistance
PDM—Pre-Disaster Mitigation
PHC—Permanent Housing Construction
PIA—Privacy Impact Assessment
PRA—Paperwork Reduction Act of 1995
PV—Present Value
RFA—Regulatory Flexibility Act
SBREFA—Small Business Regulatory Enforcement Fairness Act of 1996
SORN—System of Records Notice
Stafford Act—Robert T. Stafford Disaster Relief and Emergency Assistance Act, as Amended
USGS—United States Geological Survey
WRC—Water Resources Council

I. Public Participation

We encourage you to participate in this rulemaking by submitting comments and related materials. We will consider all comments and materials received during the comment period.

If you submit a comment, identify the agency name and the Docket ID for this rulemaking, indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and materials by electronic means, mail, or delivery to the address under the **ADDRESSES** section. Please submit your comments and materials by only one means.

Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal e-Rulemaking Portal at *www.regulations.gov,* and will

include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via a link on the homepage of *www.regulations.gov.*

Viewing comments and documents: For access to the docket to read background documents or comments received, go to the Federal e-Rulemaking Portal at *http://www.regulations.gov.* Background documents and submitted comments may also be inspected at the Office of Chief Counsel, Federal Emergency Management Agency, 500 C Street SW., 8NE–1604, Washington, DC 20472–3100.

II. Executive Summary

The Federal Emergency Management Agency (FEMA) is proposing to amend 44 CFR part 9 ''Floodplain Management and Protection of Wetlands'' and issue a supplementary policy to implement the Federal Flood Risk Management Standard (FFRMS) that was established by Executive Order 13690. 44 CFR part 9 describes the 8-step process FEMA uses to determine whether a proposed action would be located within or affect a floodplain, and if so, whether and how to continue with or modify the proposed action. Executive Order 13690 and the FFRMS changed the Executive Branch-wide guidance for defining the ''floodplain'' with respect to ''federally funded projects'' (*i.e.*, actions involving the use of Federal funds for new construction, substantial improvement, or to address substantial damage to a structure or facility). For FEMA Federally Funded Projects, FEMA proposes to use the updated definition of ''floodplain'' contained in the FFRMS. As discussed further below, the FFRMS allows the agency to define ''floodplain'' using any of three ''approaches.'' In many cases, each of these approaches would result in a larger floodplain and a requirement to design projects such that they are resilient to a higher vertical elevation. For actions that do not meet the definition of FEMA Federally Funded Project, FEMA would continue to use the historical definition of floodplain, *i.e.*, the area subject to a one percent or greater chance of flooding in any given year (or the area subject to a 0.2 percent annual chance of flooding in any given year for critical actions). Finally, the proposed rule would require the use, where possible, of natural systems, ecosystem processes, and nature-based approaches in the development of alternatives for all actions proposed in a floodplain.

FEMA estimates that for the 10-year period after the rule goes into effect, the benefits would justify the costs. Flooding is the most common and costly type of natural disaster in the United States, and floods are expected to be more frequent and more severe over the next century due in part to the projected effects of climate change. This proposed rule would ensure that FEMA Federally Funded Projects are designed to be resilient to both current and future flood risks.

III. Background

Below, FEMA describes in more specific detail the basis for this proposed rule. Section III.A. describes Executive Order 11988 and the Water Resources Council's 1978 ''Floodplain Management Guidelines'' (1978 Guidelines). Executive Order 11988 along with the 1978 Guidelines established an 8-step decision-making process by which Federal agencies carry out Executive Order 11988's direction to avoid the long- and short-term adverse impacts associated with the occupancy and modification of the floodplain and avoid the direct or indirect support of floodplain development whenever there is a practicable alternative. Section III.B. describes FEMA implementing regulations at 44 CFR part 9, which closely follow the model decision-making process. Section III.C. describes how lessons learned from major events, including Hurricane Sandy, prompted reevaluation of the prevailing standard for determining whether a proposed action was located within a floodplain.

Section III.D. describes the development of Executive Order 13690 and the Federal Flood Risk Management Standard. Lessons learned from major flood events, including Hurricane Sandy, prompted reevaluation of the prevailing standard. Pursuant to direction from the President's Climate Action Plan and to build on the work of the Hurricane Sandy Rebuilding Task Force, the Mitigation Framework Leadership Group developed the Federal Flood Risk Management Standard. Subsequently, the President issued Executive Order 13690 to establish the Federal Flood Risk Management Standard, and to amend Executive Order 11988. Executive Order 13690 directs agencies to issue or amend their existing regulations and procedures to comply with the Order. Section III.E. describes the substantive components of the Federal Flood Risk Management Standard and Section III.F. describes FEMA's proposed approach to implement the required changes.

A. Executive Order 11988, ''Floodplain Management''

The President issued Executive Order 11988, (42 FR 26951, May 25, 1977) in furtherance of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4001 *et seq.*); the Flood Disaster Protection Act of 1973, as amended (Pub. L. 93–234, 87 Stat. 975); and the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*).[1] Executive Order 11988 requires Federal agencies to avoid, to the extent possible, the long- and short-term adverse impacts associated with the occupancy and modification of floodplains, where there is a practicable alternative. It requires each Federal agency to provide leadership and take action to reduce the risk of flood loss, to minimize the impact of floods on human safety, health, and welfare, and to restore and preserve the natural and beneficial values served by floodplains in carrying out its responsibilities for: (1) Acquiring, managing, and disposing of Federal lands and facilities; (2) providing federally undertaken, financed, or assisted construction and improvements; and (3) conducting Federal activities and programs affecting land use, including but not limited to water and related land resources planning, regulating, and licensing activities. It states that each agency has a responsibility to evaluate the potential effects of any actions it may take in a floodplain; to ensure that its planning, programs, and budget requests reflect consideration of flood hazards and floodplain management; and to prescribe procedures to implement the policies and requirements of the Executive Order.

In order to meet these requirements, each agency, before taking an action, must determine whether the proposed action will occur in a floodplain.[2] Prior to being revised in 2015, Executive Order 11988 defined the word ''floodplain'' to include, at a minimum, the ''area subject to a one percent or

[1] The National Flood Insurance Act and the Flood Disaster Protection Act establish a multi-purpose program to provide flood insurance, minimize the damage caused by flood losses, and guide the development of proposed construction, where practicable, away from floodplains. NEPA requires Federal agencies to analyze the environmental impacts of proposed actions and evaluate alternatives to those actions, which includes the evaluation of floodplains.

[2] Any action FEMA takes, including its provision of grants for disaster assistance, first undergoes an analysis pursuant to Executive Order 11988 (unless the action is specifically exempted from the requirements of the Order). The grant recipient, therefore, generally provides information to FEMA about the practicability of alternatives outside the floodplain and other information to assist in the analysis.

greater chance of flooding in any given year.'' [3] The Executive Order defines agency ''action'' to include actions that the agency takes directly (such as when a Federal agency builds a new facility for its own operations) as well as actions that a non-Federal entity takes using Federal funding (such as a State or local government building a new facility using Federal grant funding).

If the action will occur in a floodplain, the agency must consider alternatives to avoid adverse effects and incompatible development in the floodplain. If the agency finds that the only practicable alternative requires the action to occur in the floodplain, the agency must, prior to taking the action, design or modify the action in order to minimize potential harm to or within the floodplain. Additionally, the agency must prepare and circulate a notice containing an explanation of why the action is proposed to be located in the floodplain. Particularly relevant to FEMA, the Executive Order also requires agencies to provide appropriate guidance to applicants for grant funding to encourage them to evaluate the effects of their proposals in floodplains prior to submitting grant applications.

Executive Order 11988 requires agencies to prepare implementing procedures in consultation with the Water Resources Council (WRC),[4] FEMA, and the Council on Environmental Quality (CEQ). As noted, in 1978, the WRC issued ''Floodplain Management Guidelines,'' (1978 Guidelines), the authoritative interpretation of Executive Order 11988.[5] The 1978 Guidelines provided a section-by-section analysis, defined key terms, and outlined an 8-step decision-making process for carrying out the directives of Executive Order 11988.

B. 44 CFR Part 9, ''Floodplain Management and Protection of Wetlands''

FEMA promulgated regulations implementing Executive Order 11988 at 44 CFR part 9, ''Floodplain Management and Protection of Wetlands.'' [6] Part 9 closely follows the 1978 Guidelines in setting forth FEMA's policy and procedures for floodplain management relating to disaster planning, response and recovery, and hazard mitigation. Part 9 applies to FEMA disaster and non-disaster assistance programs, including Public Assistance (PA), Individual Assistance (IA), Hazard Mitigation Assistance (HMA), and grants processed by FEMA's Grant Programs Directorate (GPD) (involving grants for preparedness activities). Pursuant to section 8 of Executive Order 11988, Part 9 does not apply to assistance provided for emergency work essential to save lives and protect property and public health and safety, performed pursuant to sections 403 and 502 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended (42 U.S.C. 5170b and 5192). In addition, FEMA does not apply Part 9 to non-grant, site-specific actions under the National Flood Insurance Program (NFIP),[7] such as the issuance of individual flood insurance policies, the adjustment of claims, or the issuance of individual flood insurance maps. FEMA does not apply Part 9 to site-specific actions under the NFIP because the establishment of programmatic criteria, rather than the application of the programmatic criteria to individual situations, is the action with the potential to influence/affect floodplains.[8]

As noted, Part 9 outlines the 8-step decision-making process FEMA follows in applying Executive Order 11988 to its actions:

Step (1) Floodplain determination (44 CFR 9.7). Under Step 1, FEMA must determine if a proposed agency action is located in or affects the base floodplain (or, for critical actions, the 500-year floodplain). The base floodplain is the area subject to inundation by the base flood, which is that flood which has a 1 percent chance of occurrence in any given year (also known as the 1 percent annual chance flood or 100-year flood). A ''critical action'' is any activity for which even a slight chance of flooding would be too great.[9] The minimum floodplain of concern for critical actions is 500-year floodplain, which is the area subject to inundation from a flood having a 0.2 percent chance of occurring in any given year. The 500-year floodplain generally covers a larger area than the base floodplain. FEMA's regulations state that in each instance where the 8-step process refers to the base floodplain, an agency should substitute the 500-year floodplain for the base floodplain if the proposed action is a critical action.

FEMA follows a specific regulatory sequence in order to make its floodplain determination. First, FEMA must consult the Flood Insurance Rate Map (FIRM), the Flood Boundary Floodway Map (FBFM), and the Flood Insurance Study (FIS) for the area. A FIRM is an official, detailed map issued by the NFIP, showing elevations and boundaries of the 1 percent annual chance floodplain and the 0.2 percent annual chance floodplain.[10] The FBFM is a version of a flood map that shows only the floodway [11] and flood boundaries. An FIS report is an examination, evaluation and determination of flood hazards and, if appropriate, corresponding water surface elevations. If a FIRM is not available, FEMA must obtain a Flood Hazard Boundary Map (FHBM) which is a less detailed map than a FIRM and shows the approximate areas of the base floodplain. If data on flood elevations, floodways, or coastal high hazard areas are needed, or if the map does not delineate the flood hazard boundaries in the vicinity of the proposed site, FEMA must seek detailed information from a list of sources included in the

[3] This is also referred to as the 100-year floodplain or the base floodplain.

[4] The Water Resources Council, established by statute (42 U.S.C. 1962a–1), is charged with maintaining a continuing study and preparing an assessment biennially, or at such less frequent intervals as the Council may determine, of the adequacy of supplies of water necessary to meet the water requirements in each water resource region in the United States and the national interest therein; and maintaining a continuing study of the relation of regional or river basin plans and programs to the requirements of larger regions of the Nation and of the adequacy of administrative and statutory means for the coordination of the water and related land resources policies and programs of the several Federal agencies. It is responsible for appraising the adequacy of existing and proposed policies and programs to meet such requirements, and making recommendations to the President with respect to Federal policies and programs.

[5] 43 FR 6030, Feb. 10, 1978. A PDF copy of the 1978 Guidelines can be found at this link: *http://portal.hud.gov/hudportal/documents/huddoc?id=DOC_14216.pdf.*

[6] FEMA published an interim final rule on December 27, 1979 (44 FR 76510) and a final rule on September 9, 1980 (45 FR 59520). Note that this part also implements a related Executive Order 11990, ''Protection of Wetlands.'' See 42 FR 26961, May 25, 1977.

[7] A complete list of FEMA programs to which part 9 does not apply appears at 44 CFR 9.5. The exemption for actions under the NFIP is located at 44 CFR 9.5(f).

[8] For example, part 9 requires FEMA to apply the 8-step process to a programmatic determination of categories of structures to be insured, but does not require FEMA to apply an 8-step review to a determination of whether to insure each individual structure. See 45 FR 59520, Sept. 9, 1980 (59523).

[9] The concept of critical actions evolved during the drafting of the 1978 Guidelines and reflects a concern that the impacts of floods on human safety, health, and welfare for many activities could not be minimized unless a higher degree of protection than the base flood was provided. See Interagency Task Force on Floodplain Management, Further Advice on Executive Order 11988 Floodplain Management (1980) available at *http://www.gsa.gov/graphics/pbs/FEDERAL_EMERGENCY_MANAGEMENT_AGENCY_R2F-a8-k_0Z5RDZ-i34K-pR.pdf.*

[10] FEMA estimates that only 18 percent of mapped flood zones have detailed floodplain boundaries of the 0.2 percent annual chance floodplain.

[11] The floodway is the channel of a river or other watercourse and the adjacent land areas that must be reserved in order to discharge the base flood without cumulatively increasing the water surface elevation more than a designated height. See 44 CFR 59.1.

regulations. See 44 CFR 9.7(c)(1)(ii). If the sources listed do not have or know of detailed information and are unable to assist in determining whether or not the proposed site is in the base floodplain, FEMA must seek the services of a licensed consulting engineer experienced in this type of work. If, however, a decision involves an area or location within extensive Federal or State holdings or a headwater area, and no FIS, FIRM, FBFM, or FHBM is available, FEMA will seek information from the land administering agency before seeking information and/or assistance from the list of sources included in the regulations. Then, if none of the sources listed has information or can provide assistance, FEMA will seek the services of an experienced Federal or other engineer.

Step (2) Early public review (44 CFR 9.8). FEMA must make public its intent to locate a proposed action in the base floodplain. FEMA must provide adequate information to enable the public to have an impact on the decision outcome for all proposed actions having potential to affect, adversely, or be affected by floodplains. For each action having national significance for which notice is provided, FEMA uses the **Federal Register** as the minimum means for notice, and will provide notice by mail to national organizations reasonably expected to be interested in the action. 44 CFR 9.8(c)(5) describes the contents of the public notice, such as a description of the action, the degree of hazard involved, a map of the area, or other identification of the floodplain, and identification of the responsible agency official.

Step (3) Practicable alternatives (44 CFR 9.9). If the action is in the floodplain, FEMA will identify and evaluate practicable alternatives to carrying out a proposed action in floodplains, including the following: Alternative sites outside the floodplain; alternative actions which serve essentially the same purpose as the proposed action, but which have less potential to affect or be affected by the floodplain; and ''no action.'' The floodplain site itself must be a practicable location in light of the other factors. Under 44 CFR 9.9(c), FEMA will analyze several factors in determining the practicability of the alternatives described in 44 CFR 9.9(b), namely natural environment, social concerns, economic aspects, and legal constraints. 44 CFR 9.9(d) states that FEMA will not locate the proposed action in the floodplain, if a practicable alternative exists outside the floodplain or wetland. For critical actions, FEMA will not locate the proposed action in the 500-year floodplain, if a practicable alternative exists outside the 500-year floodplain. Even if no practicable alternative exists outside the floodplain, in order to carry out the action the floodplain or wetland must itself be a practicable location in light of the review required under Step 3.

Step (4) Impact of chosen alternative (44 CFR 9.10). FEMA must identify if the action has impacts in the floodplain or directly or indirectly supports floodplain development that has additional impacts in the floodplain. If the proposed action is outside the floodplain and has no identifiable impacts or support, the action can be implemented (Step 8). 44 CFR 9.10(b) provides that FEMA will identify the potential direct and indirect adverse impacts associated with the occupancy and modification of floodplains and the potential direct and indirect support of floodplain development that could result from the proposed action. FEMA's identification of such impacts shall be to the extent necessary to comply with the requirements of Executive Order 11988 to avoid floodplain locations unless they are the only practicable alternatives and to minimize harm to and within floodplains and wetlands.

Step (5) Minimize impacts (44 CFR 9.11). If the proposed action has identifiable impacts in the base floodplain or directly or indirectly supports development in the floodplain, FEMA must minimize these effects and restore and preserve the natural and beneficial floodplain values served by floodplains. 44 CFR 9.11(b) states generally that FEMA will design or modify its actions so as to minimize harm to or within the floodplain; will minimize destruction, loss, or degradation of wetlands; will restore and preserve natural and beneficial floodplain values; and will preserve and enhance natural and beneficial wetland values. Pursuant to 44 CFR 9.11(c), FEMA will more specifically minimize potential harm to lives and the investment at risk from the base flood, or, in the case of critical actions, from the 500-year flood; potential adverse impacts the action may have on others; and potential adverse impacts the action may have on floodplain values. Pursuant to 44 CFR 9.11(d), FEMA will not allow new construction or substantial improvement in a floodway, and will not allow new construction in a coastal high hazard area, except for a functionally dependent use [12] or a structure or facility which facilitates an open space use. For a structure which is a functionally dependent use, or which facilitates an open space use, FEMA will not allow construction of a new or substantially improved structure in a coastal high hazard area unless it is elevated on adequately anchored pilings or columns, and securely anchored to such piles or columns so that the lowest portion of the structural members of the lowest floor (excluding the pilings or columns) is elevated to or above the base flood level (the 500-year flood level for critical actions) (including wave height). Regarding elevation of structures, 44 CFR 9.11(d)(3) states that there will be no new construction or substantial improvement of structures unless the lowest floor of the structures (including basement) is at or above the level of the base flood, and there will be no new construction or substantial improvement of structures involving a critical action unless the lowest floor of the structure (including the basement) is at or above the level of the 500-year flood.

Step (6) Reevaluate alternatives (44 CFR 9.9). FEMA must reevaluate the proposed action. Pursuant to 44 CFR 9.9(e), upon determination of the impact of the proposed action to or within the floodplain and of what measures are necessary to comply with the requirement to minimize harm to and within the floodplains, FEMA will determine whether: the action is still practicable at a floodplain site in light of the exposure to flood risk and the ensuing disruption of natural values, the floodplain site is the only practicable alternative, there is a potential for limiting the action to increase the practicability of previously rejected non-floodplain sites and alternative actions, and minimization of harm to or within the floodplain can be achieved using all practicable means. Pursuant to 44 CFR 9.9(e)(2), FEMA will take no action in a floodplain unless the importance of the floodplain site clearly outweighs the requirement of Executive Order 11988 to avoid direct or indirect support of floodplain development; reduce the risk of flood loss; minimize the impact of floods on human safety, health, and welfare; and restore and preserve floodplain values.

Step (7) Findings and public explanation (44 CFR 9.12). If FEMA finds that the only practicable alternative is to take the action in the floodplain, it must give public notice of the reasons for this finding. 44 CFR

[12] A functionally dependent use means a use which cannot perform its intended purpose unless it is located or carried out in close proximity to water (*e.g.*, bridges and piers). See 44 CFR 9.4.

9.12(e) describes the requirements for the content of such notice, such as a statement of why the proposed action must be located in an area affecting or affected by a floodplain or wetland, a description of all significant facts considered in making this determination, identification of the responsible official, and a map of the relevant area.

Step (8) Implementation (Multiple sections of 44 CFR and applicable program guidance). FEMA may implement the proposed action after it allows a reasonable period for public response and reviews the implementation and post-implementation to ensure compliance with the minimization standards in 44 CFR 9.11. Implementation of the requirements of Executive Order 11988 is integrated into the specific regulations and procedures of the grant program under which the action is proposed to take place. After the proposed action is implemented, the FEMA program providing the funding determines, under its applicable regulations and procedures, whether the grant recipient has completed the prescribed mitigation.

C. Reevaluation of the 1 Percent Chance or 100-Year Flood Standard

In the aftermath of Hurricane Sandy, the President issued Executive Order 13632,[13] which created the Federal Interagency Hurricane Sandy Rebuilding Task Force (Sandy Task Force). The Sandy Task Force was chaired by the Secretary of the Department of Housing and Urban Development (HUD), which led the effort in coordination with multiple Federal partners. The Sandy Task Force was supported by an advisory group composed of State, local, and Tribal elected leaders. Pursuant to direction from Executive Order 13632 to remove obstacles to resilient rebuilding, the Sandy Task Force reevaluated the 1 percent chance/100-year standard. In April 2013, the Sandy Task Force announced a new Federal flood risk reduction standard which required elevation or other flood-proofing to 1 foot above [14] the best available and most recent base flood elevation and applied that standard to all Federal disaster recovery investments in Sandy-affected communities.[15] The Sandy Task Force called for all major Sandy rebuilding projects in Sandy-affected communities using Federal funding to be elevated or otherwise flood-proofed according to this new flood risk reduction standard.

In May 2013, DHS issued the National Mitigation Framework (NMF) to establish a common platform and forum for coordinating and addressing how the Nation manages risk through mitigation capabilities.[16] The NMF established the Mitigation Framework Leadership Group (MitFLG) to promote coordination of mitigation efforts across the Federal Government. Its goal is broader than the goal of the Sandy Task Force, as it focuses on enabling achievement of a secure and resilient Nation by developing, employing and coordinating core mitigation capabilities to reduce the loss of life and property. The MitFLG is responsible for assessing the effectiveness of mitigation core capabilities as they are developed and deployed across the Nation. The MitFLG facilitates information exchange, coordinates policy implementation recommendations on national-level issues, and oversees the successful implementation of the NMF. The MitFLG is composed of representatives from the Department of Agriculture, the Department of Commerce, the Department of Defense, the Department of Energy, the Environmental Protection Agency, the General Services Administration, the Department of Health and Human Services, DHS, HUD, the Department of the Interior, the Department of Justice, the Small Business Administration, and the Department of Transportation. FEMA also chairs the MitFLG.[17]

In June 2013, the President issued a Climate Action Plan [18] that directs agencies to take appropriate actions to reduce risk to Federal investments, specifically directing agencies to build on the work done by the Sandy Task Force and to update their flood risk reduction standards for ''federally-funded . . . projects'' to ensure that ''projects funded with taxpayer dollars last as long as intended.'' [19] In November 2013, the President's State, Local, and Tribal Leaders Task Force on Climate Preparedness and Resilience (Climate Task Force) convened, with 26 Governors, mayors, and local and Tribal leaders serving as members. After a year-long process of receiving input from State, local, Tribal, and territorial governments; private businesses; trade associations; academic organizations; civil society; and other stakeholders, the Task Force provided a recommendation to the President in November 2014. In order to ensure resiliency, Federal agencies, when taking actions in and around floodplains, should include considerations of the effects of climate change, including sea level rise, more frequent and severe storms, and increasing river flood risks. The Climate Task Force also recommended that the best available climate data should be used in siting and designing projects receiving Federal funding, and that margins of safety, such as freeboard and setbacks, should be included.[20]

D. Issuance of Executive Order 13690 and the Federal Flood Risk Management Standard, and Revision of the 1978 Guidelines

The MitFLG developed the FFRMS reflecting the best available science, lessons learned, and input and recommendations gathered from the Sandy Task Force, the Climate Action Plan, and the Climate Task Force. As a result of MitFLG's efforts, on January 30, 2015, the President issued Executive Order 13690, ''Establishing a Federal Flood Risk Management Standard (FFRMS) and a Process for Further Soliciting and Considering Stakeholder Input.'' [21] Executive Order 13690 amended Executive Order 11988 and established the FFRMS. It also set forth a process by which additional input from stakeholders is solicited and considered before agencies implement the FFRMS. It required FEMA to publish, on behalf of the MitFLG, an updated version of the Implementing Guidelines (revised to incorporate the changes required by Executive Order 13690 and the FFRMS) in the **Federal Register** for notice and comment. After receipt and adjudication of comments, Executive Order 13690 required the MitFLG to submit to the WRC

[13] 77 FR 74341, Dec. 14, 2012.

[14] This is also known as ''freeboard.'' ''Freeboard'' is a factor of safety usually expressed in feet above a flood level for purposes of floodplain management. Freeboard tends to compensate for the many unknown factors that could contribute to flood heights greater than the height calculated for a selected size flood and floodway conditions, such as wave action, bridge openings, and the hydrologic effect of urbanization of the watershed. See *www.fema.gov/freeboard.*

[15] HUD release entitled, ''Federal Government Sets Uniform Flood Risk Reduction Standard for Sandy Rebuilding Projects,'' April 4, 2013.

[16] Department of Homeland Security, *National Mitigation Framework* (2013), available at *http://www.fema.gov/media-library-data/20130726–1914–25045–9956/final_national_mitigation_framework_20130501.pdf.* Mitigation reduces the impact of disasters by supporting protection and prevention activities, easing response, and speeding recovery to create better prepared and more resilient communities. This Framework describes mitigation roles across the whole community.

[17] See *National Mitigation Framework,* p. 30.

[18] Executive Office of the President, *The President's Climate Action Plan* (2013), available at *https://www.whitehouse.gov/sites/default/files/image/president27sclimateactionplan.pdf.*

[19] See *The President's Climate Action Plan* at 15.

[20] President's State, Local, and Tribal Leaders Task Force on Climate Preparedness and Resilience, *Recommendations to the President,* (2014), available at *http://www.whitehouse.gov/sites/default/files/docs/task_force_report_0.pdf at 7.*

[21] 80 FR 6425 Feb. 4, 2015.

recommendations for finalizing the draft Guidelines. Finally, Executive Order 13690 required the WRC to issue final Guidelines to provide guidance to agencies on the implementation of Executive Order 11988, as amended, consistent with the FFRMS. After the completion of this process, Executive Order 13690 directs agencies to issue or amend their existing regulations and procedures to comply with the Order. The MitFLG is required to reassess the FFRMS annually, after seeking stakeholder input, and provide recommendations to the WRC to update the FFRMS if warranted. The WRC is required to update the FFRMS at least every 5 years.

FEMA, on behalf of MitFLG, published a **Federal Register** notice for a 60-day notice and comment period seeking comments on a draft of the Revised Guidelines on February 5, 2015.[22] In response to multiple requests, the MitFLG later extended the comment period for an additional 30 days to end on May 6, 2015.[23] Periodically during the public comment period, the Administration (through FEMA and CEQ) sent advisories to representatives from Governors' offices nationwide announcing the issuance of Executive Order 13690 and inviting comments on the draft Revised Guidelines. The Administration also attended or hosted over 25 meetings across the country with State, local, and Tribal officials (including 26 mayors) and interested stakeholders to discuss Executive Order 13690 and the draft Revised Guidelines. The MitFLG held 9 public listening sessions across the country[24] that were attended by over 700 participants from State, local, and Tribal governments and other stakeholder organizations to facilitate feedback on the draft Revised Guidelines. The MitFLG published notice of these public listening sessions in the **Federal Register**.[25]

The public comment period closed on May 6, 2015. The MitFLG received over 2700[26] comments. The MitFLG adjudicated the comments and presented its recommendations to the WRC, as required by Executive Order 13690. The WRC issued the final Revised Guidelines on October 8, 2015.[27] The Revised Guidelines contain an updated version of the FFRMS (located at Appendix G of the Revised Guidelines), reiterate key concepts from the 1978 Guidelines, and explain the new concepts resulting from the Executive Order 13690 and the FFRMS. In response to public comments, the FFRMS was updated to clarify the distinction between actions and Federally Funded Projects.

E. Substantive Components of the FFRMS

The FFRMS is a flexible framework to increase resilience against flooding and help preserve the natural values of floodplains. Incorporating this standard into existing agency processes will ensure that agencies expand management from the current base flood level to a higher vertical elevation and corresponding horizontal floodplain so that Federally Funded Projects will last as long as intended. In addition, the FFRMS encourages the use of natural features and nature-based approaches in the development of alternatives for all Federal actions.

Under the FFRMS, an agency may establish the floodplain for Federally Funded Projects using any of the following approaches: (1) Climate-Informed Science Approach (CISA): Utilizing the best-available, actionable hydrologic and hydraulic data and methods that integrate current and future changes in flooding based on climate science; (2) Freeboard Value Approach (FVA): Freeboard (base flood elevation + X, where X is 3 feet for critical actions and 2 feet for other actions); (3) 0.2 percent annual chance Flood Approach (0.2PFA): 0.2 percent annual chance flood (also known as the 500-year flood); or (4) the elevation and flood hazard area that result from using any other method identified in an update to the FFRMS.[28] Each of the approaches is described in further detail below.

FFRMS Approach 1: CISA

The FFRMS states that the CISA is the preferred approach, and that Federal agencies should use this approach when data to support such an analysis are available. For areas vulnerable to coastal flood hazards, the CISA includes the regional sea-level rise variability and lifecycle of the Federal action. This includes use of the Department of Commerce's National Oceanic and Atmospheric Administration's (NOAA's) or similar global mean sea-level-rise scenarios. These scenarios would be adjusted to the local relative sea-level conditions and would be combined with surge, tide, and wave data using state-of-the-art science in a manner appropriate to policies, practices, criticality, and consequences (risk).[29] For areas vulnerable to riverine flood hazards (*i.e.,* flood hazards stemming from a river source), the CISA would account for changes in riverine conditions due to current and future changes in climate and other factors such as land use, by applying state-of-the-art science in a manner appropriate to policies, practices, criticality, and consequences (risk).

The CISA for critical actions would utilize the same methodology as used for non-critical actions that are subject to Executive Order 11988, but with an emphasis on criticality as one of the factors for agencies to consider when conducting the analysis.

FFRMS Approach 2: FVA

The FFRMS defines freeboard values as an additional 2 feet added to the base flood elevation, or, for critical actions, an additional 3 feet added to the base flood elevation. In other words, the floodplain established by the FFRMS–FVA is the equivalent of the 1 percent annual chance floodplain, plus either 2 or 3 feet of vertical elevation, as applicable based on criticality, as well as a corresponding increase in the horizontal extent of the floodplain. The increased horizontal extent will not be the same in every case. As shown in the next two illustrations, when the same vertical increase is applied in multiple Federally Funded Projects in different areas, the amount of the increase in the horizontal extent of the respective floodplains will depend upon the topography of the area surrounding the proposed location of the Federally Funded Project. FFRMS–FVA Illustration A reflects an area with relatively flat topography on either side of the flooding source (*i.e.,* river or stream) channel. This is generally representative of coastal plains, portions of the Midwest, and other areas with less variation in topography. FFRMS–FVA Illustration B reflects an area with steep topography on either side of the

[22] 80 FR 6530, Feb. 5, 2015.

[23] 80 FR 16018, Mar. 26, 2015.

[24] The meetings were held in Iowa, Mississippi, California, Virginia (Hampton Roads), Virginia (Fairfax), New York, Texas, Washington, and via webinar.

[25] 80 FR 19090, Apr. 9, 2015.

[26] The MitFLG received approximately 556 separate submissions, which raised over 2700 separate issues and positions. Written comments were received at a series of 8 in-person listening sessions across the country (135 submissions); verbal comments were shared during the public comment periods of these same listening sessions (74 commenters); comments were submitted through the FFRMS email address (20 submissions); comments were submitted through regulations.gov (326 submissions); and comments were submitted as part of a petition of support (1 submission).

[27] Available in the docket for this rulemaking at *www.regulations.gov* under Docket ID FEMA–2015–0006.

[28] See Executive Order 13690 Section 2(i), 80 FR 6425, Feb. 4, 2015 (6426).

[29] The Revised Guidelines expand further upon the methods for calculating sea-level rise for areas vulnerable to coastal flood hazards in Section II (C) of Appendix H, ''Climate-Informed Science Approach and Resources.''

flooding source channel. This is representative of mountainous areas or areas with changes in elevation near the flooding source. With the same addition of 2 feet to the base flood elevation applied to both example locations, the increase to the horizontal extent of the floodplain in FFRMS–FVA Illustration A is comparatively larger than the increase to the horizontal extent of the floodplain in FFRMS–FVA Illustration B. These illustrations visually depict the fact that the horizontal increase to the floodplain will not be uniform when applying the same increase to establish the FVA and will vary depending on local topography.

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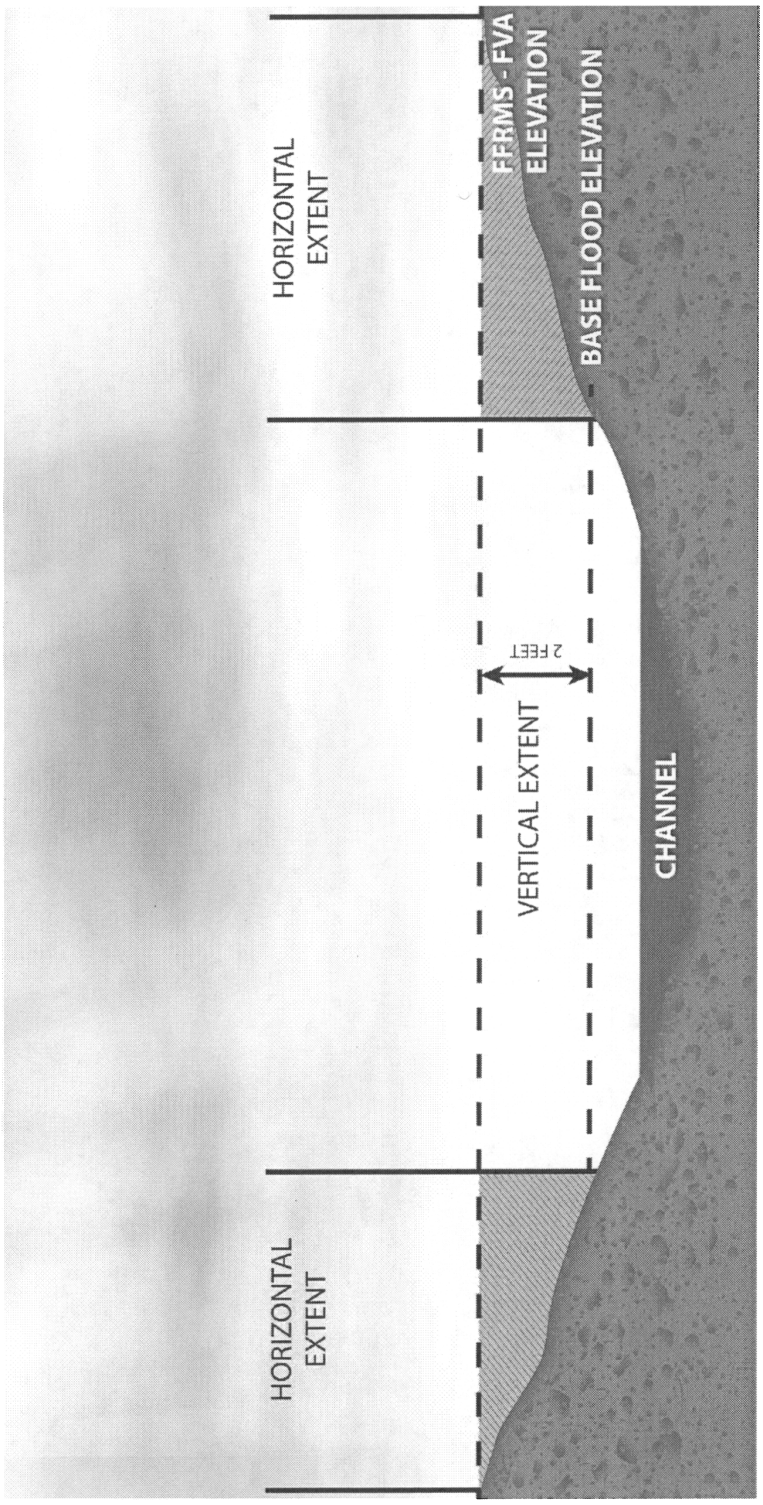
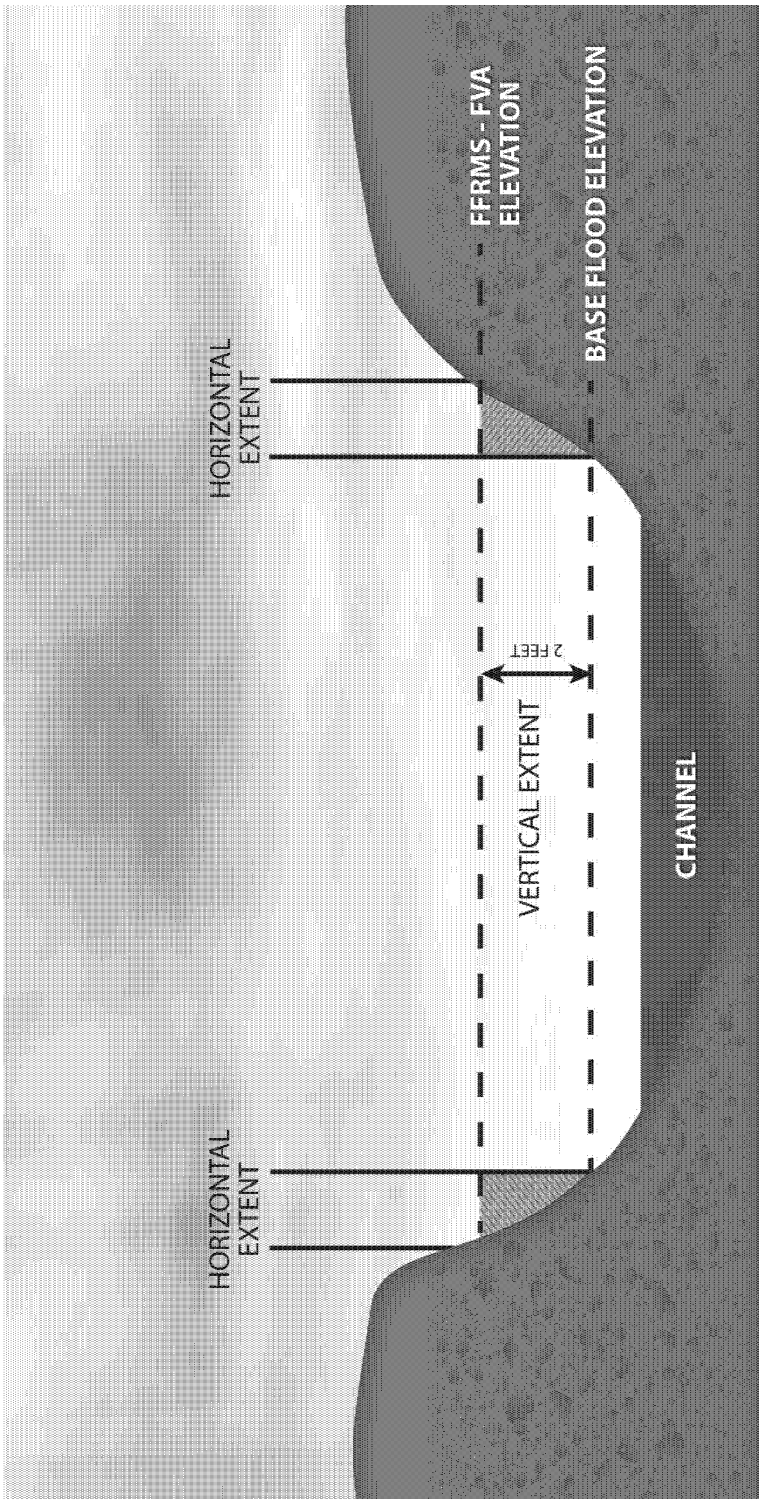
FFRMS-FVA Illustration A





FFRMS-FVA Illustration B

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FFRMS Approach 3: 0.2PFA

Agencies may use available 0.2 percent annual chance (or ''500-year'') flood data as the basis of the FFRMS elevation and corresponding floodplain extent. The FFRMS notes that the 0.2 percent annual chance flood hazard data produced by FEMA in coastal areas only considers storm-surge hazards; these data do not include local wave action or storm-induced erosion that are considered in the computation of base flood elevations. The FFRMS encourages agencies to obtain or develop the necessary data, including wave heights, to ensure that any 0.2 percent annual chance flood data applied will achieve an appropriate level of flood resilience for the proposed investment.

FFRMS Approach 4: Update to FFRMS

Executive Order 13690 requires the MitFLG to reassess the FFRMS annually, after seeking stakeholder input, and provide recommendations to the WRC to update the FFRMS if

warranted. It requires the WRC to update the FFRMS at least every 5 years.

Further Guidance on Application of the FFRMS Approaches To Establishing the Floodplain

The FFRMS states that when an agency does not use CISA in a coastal flood hazard area, the agency must use, at a minimum, the applicable FVA (*i.e.,* the base flood elevation plus 3 feet for critical actions, or the base flood elevation plus 2 feet for other actions). In cases where the FEMA 0.2 percent annual chance flood elevation does not include wave height, or a wave height has not been determined, the FFRMS notes that the result will likely either be lower than the current base flood elevation or the base flood elevation plus applicable freeboard. The FFRMS states that the 0.2 percent annual chance elevation should not be used in these cases.

When actionable science is not available and an agency opts not to follow the CISA for riverine flood hazard areas, the FFRMS states that an agency may also select either the FVA, or 0.2 percent annual chance flood elevation approach, or a combination of approaches, as appropriate. It states that the agency is not required to use the higher of the elevations, but may opt to do so.

F. FEMA's Implementation of Executive Order 13690 and FFRMS

When Executive Order 13690 was issued, FEMA evaluated the application of Executive Order 13690 and the FFRMS with respect to its existing authorities and programs. The FFRMS establishes a flexible standard to improve resilience against the impact of flooding—to design for the intended life of the Federal investment. FEMA supports this principle. With more than $260 billion in flood damages across the Nation since 1980, it is necessary to take action to responsibly use Federal funds, and FEMA must ensure it does not needlessly make repeated Federal investments in the same structures after flooding events. In addition, the FFRMS will help support the thousands of communities across the Country that have strengthened their State and local floodplain management codes and standards to ensure that infrastructure and other community assets are resilient to flood risk. FEMA recognizes that the need to make structures resilient also requires a flexible approach to adapt for the needs of the Federal agency, local community, and the circumstances surrounding each project or action.

FEMA intends to implement Executive Order 13690, the FFRMS, and the Revised Guidelines through this proposed rule and supplementary policy, which would (1) add or revise definitions to be consistent with those included in Executive Order 13690 and the Revised Guidelines; (2) incorporate the use of the FFRMS approaches for establishing the floodplain into FEMA's existing 8-step process; and (3) include the requirement to consider the use of nature-based approaches where possible when developing alternatives for developing in the floodplain.

Making the Initial Floodplain Determination

As stated above, Executive Order 13690 and the FFRMS changed the definition of ''floodplain'' with respect to ''Federally Funded Projects'' (*i.e.,* actions involving the use of Federal funds for new construction, substantial improvement, or to address substantial damage to a structure or facility). The FFRMS allows the agency to define ''floodplain'' using any of three approaches. For actions which do not meet the definition of a Federally Funded Project, an agency should continue to use the historical definition of floodplain, *i.e.* the area subject to a 1 percent or greater chance of flooding in any given year (or the area subject to a 0.2 percent annual chance of flooding in any given year for critical actions). This means that one of the first steps an agency must take is to determine whether to use the FFRMS definition of the floodplain or the historical definition of the floodplain. Figure 1 illustrates the process by which FEMA would decide which floodplain would apply to an action or FEMA Federally Funded Project.

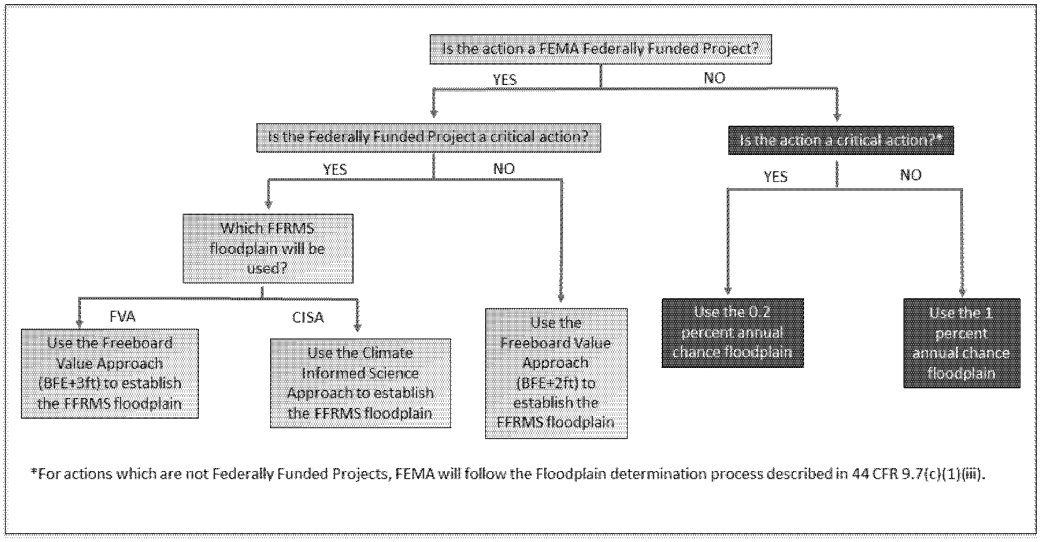

Figure 1: Process to Establish the Appropriate Floodplain for the 8-Step Decision-Making Process

Selection Between the FFRMS Approaches

Executive Order 13690 requires the MitFLG to reassess the FFRMS annually, after seeking stakeholder input, and provide recommendations to the WRC to update the standard if warranted based on accurate and actionable science that takes into account changes to climate and other changes in flood risk. At a minimum, Executive Order 13690 requires an update to the FFRMS at least every 5 years.[30] This requires a balancing approach in selecting between the FFRMS approaches: Agencies must be flexible enough to account for updates to the FFRMS and yet also implement a framework that is standardized enough to be easily understood by and consistently applied to stakeholders.

Consistent with the flexibility built into Executive Order 13690, FEMA proposes to implement the FFRMS by adopting the flexible framework proposed in Executive Order 13690 in its entirety instead of mandating a particular approach in its regulations. Under this proposal, FEMA would provide additional guidance (more readily capable of revisions and updates) that addresses which approach FEMA would use for different types of actions and how FEMA would tailor its application of the various approaches depending on the type and criticality of the action. Specifically, FEMA's supplementary policy selects the use of the FFRMS–FVA to establish the floodplain for non-critical actions. For critical actions, FEMA would allow the use of the FFRMS–FVA floodplain or the FFRMS–CISA, but only if the elevation established under the FFRMS–CISA is higher than the elevation established under the FFRMS–FVA.

FEMA proposes to use the FFRMS–FVA as the baseline approach for both critical and non-critical FEMA Federally Funded Projects for several reasons. First, a choice to use the FFRMS–FVA would reflect the practical need for standardization at this stage of implementation. The FFRMS–FVA elevation is computed using the 1 percent annual chance elevation, and FEMA may use the same historical sequence it has followed to determine the 1 percent annual chance elevation for the purposes of establishing the FFRMS–FVA elevation. This would still allow for the use of widely available FEMA products such as FIRMs, FBFMs, and FISs. By following the same historical sequence and utilizing known mapping products, FEMA staff would need relatively minimal additional training to be able to use these products to determine the horizontal extent of the FFRMS–FVA floodplain. In addition, the familiarity of the process and products to be used in most projects would benefit stakeholders by providing a consistent methodology which stakeholders would similarly be able to use to determine where FEMA will require application of the FFRMS. Second, requiring the use of the FFRMS–FVA as the minimum elevation for critical actions would be consistent with FEMA's policy to encourage communities to adopt higher standards, including freeboard standards, than the minimum floodplain management criteria under the NFIP.[31] Generally, adoption of a freeboard tends to compensate for the many unknown factors that could contribute to flood heights greater than the height calculated for a selected size flood and floodway conditions, such as wave action, bridge openings, and the hydrological effect of urbanization of the watershed.[32] Consistent with FEMA's policy, 22 States and an additional 596 localities have adopted freeboard requirements ranging from 1 to 3 feet.[33] FEMA supports that adoption by requiring that all of its projects are consistent with more restrictive Federal, State, or local floodplain management standards.[34]

FEMA considered proposing the use of the FFRMS–CISA instead of FFRMS–FVA to reflect the FFRMS's designation of the FFRMS–CISA as the preferred approach and to reflect that the FFRMS–FVA sets a general level of protection, whereas FFRMS–CISA uses a more site-specific approach to predict flood risk based on future conditions.

However, there are several reasons why that course of action is not appropriate at this time. First, actionable climate data are not currently available for all locations. For coastal floodplains, one of the primary considerations associated with the FFRMS–CISA is determining what the projected future sea level rise will be for the area in which the project will be completed. There are multiple interagency reports, published scientific journals, and agency tools that provide scenario-based projections of sea level rise for coastal floodplains. However, FEMA is not aware of an analogous approach for riverine floodplains that accounts for uncertainties due to climate change with respect to projected future precipitation and associated flooding.[35] Instead, the Revised Guidelines suggest the agency would need to conduct a hydrology study that is informed by expected changes in climate and land use factors and incorporate this analysis into its current method for determining the floodplain.[36] FEMA expects that more data will be developed supporting broader-based inland and riverine application of the FFRMS–CISA as agencies implement the FFRMS and that this data will be considered and incorporated into future updates of the FFRMS. FEMA requests comment on the availability of actionable, planning, and project-scale climate data with respect to coastal and riverine floodplains.

Second, in addition to the data challenges, there are a number of factors to be considered in deciding how to apply the FFRMS–CISA that might result in a decision-making process that could unnecessarily delay recovery in the wake of a disaster event for non-critical actions. The Revised Guidelines recommend that the FFRMS–CISA methodology account for project-specific factors such as the risk to which the action will be exposed, the anticipated level of investment, and the lifecycle of the action.[37] For example, an applicant might consider a construction project that is in a coastal floodplain and find that there are multiple projections for what the sea level rise may be in 100 years. The most aggressive projection might indicate that the project should be elevated 10 feet above the 1 percent annual chance flood elevation. However, the applicant might decide that this project is not intended to be functional for 100 years or that the applicant's budget might justify using a lesser projection now and plan for future upgrades to the structure or facility. There may be a way to standardize this type of decision-making process as the FFRMS–CISA is more broadly used; however, the current lack of a standardized methodology for making these decisions and the need to engage in such project-specific considerations in conjunction with stakeholders could result in uncertainty and delay. In light of the above concerns, FEMA requests comment regarding how FEMA could implement

[30] See Executive Order 13690 Section 4(b), 80 FR 6425, Feb. 4, 2015 (6426).

[31] See 44 CFR 60.1(d).

[32] See 44 CFR 59.1.

[33] Association of State Floodplain Managers, States and Other Communities in FEMA CRS with Building Freeboard Requirements, (2015), available at *http://www.floods.org/ace-files/documentlibrary/FloodRiskMngmtStandard/States_with_freeboard_and_CRS_Communities_with_Freeboard_in_Other_states_2–27–15.pdf.*

[34] See 44 CFR 9.11(d)(6).

[35] See Revised Guidelines at Appendix H, 15.

[36] See Revised Guidelines at 55.

[37] See Revised Guidelines at 55.

the FFRMS–CISA for non-critical actions using a publicly-accessible, standardized, predictable, flexible, and cost-effective methodology.

FEMA also considered whether it should alter its proposal for use of the FFRMS–CISA in relation to the FFRMS–FVA (or FFRMS–0.2PFA). FEMA specifically welcomes comment on each of the potential alternatives outlined below. FEMA could choose a more protective approach in which it would determine the elevations established under FFRMS–CISA, FFRMS–FVA and the FFRMS–0.2PFA for critical actions and only allow the applicant to use the highest of the three elevations. This approach would ensure that applicants were building to the most protective level, would avoid potential inconsistencies with FEMA's policy to encourage adoption of freeboard standards by local communities, and would prevent a scenario where an applicant was allowed to build to a lower elevation than previously required for critical actions under FEMA's implementation of Executive Order 11988.[38] FEMA believes that its proposed policy is sufficiently protective and would be less expensive to administer and implement than the alternative approach described above, but nonetheless welcomes comment on this alternative approach.

Also alternatively, FEMA could choose to allow use of the FFRMS–CISA, even if the resulting elevation is lower than the application of the FFRMS–FVA. This approach would give FEMA and its grantees more flexibility in implementing the standard, would enable FEMA and its grantees to build to an elevation based on the best available science taking criticality into account, and would provide a pathway to relief for those areas that experience declining flood risks.[39] FEMA believes that the need for standardization, administrability, and adequate protection all counsel in favor of its policy, but welcomes comments on this alternative approach as well.

FEMA is not proposing to use the FFRMS–0.2PFA because of the limited national availability of information on the 0.2 percent annual chance flood elevation and the additional costs associated with producing this information when not available. The FFRMS–0.2PFA floodplain, like the FFRMS–FVA floodplain, would have a greater horizontal extent and require higher elevation standards when compared to the 1 percent annual chance floodplain. However, while most areas of the country have 1 percent annual chance floodplain information and the necessary topographical information to determine the horizontal extent under the FVA, far fewer are mapped with 0.2 percent annual chance floodplain information. This is because although all FEMA-mapped flood zones have either detailed or approximate 1 percent annual chance floodplain boundaries, FEMA estimates that only 18 percent of mapped flood zones have detailed floodplain boundaries of the 0.2 percent annual chance floodplain.[40] Finally, in coastal areas, the FFRMS requires Federal agencies to use the FFRMS–FVA as the minimum elevation, when not using the FFRMS–CISA, because the 0.2 percent annual chance flood information depicted on FEMA FIRMs and in the FISs in coastal areas consider storm-surge hazards, but not wave action.[41] FEMA recognizes that the FFRMS–0.2PFA may result in a higher elevation than the FFRMS–FVA in some circumstances. However, based on the foregoing reasons, FEMA expects it will be clearer, less costly, and provide more certainty to stakeholders, if FEMA selects the FFRMS–FVA as the primary approach.

Based on the foregoing reasons, FEMA proposes to combine approaches and use the FFRMS–FVA to establish the floodplain for non-critical actions and allow the use of the FFRMS–FVA floodplain or the FFRMS–CISA for critical actions, but only if the elevation established under the FFRMS–CISA is higher than the elevation established under the FFRMS–FVA. This proposal balances flexibility with standardization, is consistent with FEMA's encouragement to communities to adopt higher floodplain management standards, reflects the priority that FEMA places on ensuring adequate planning for critical actions, and may yield important lessons with respect to potential future applications of the FFRMS–CISA.

In addition to seeking comments on FEMA's proposed approach to implementation generally, FEMA specifically seeks public comments on the impact of the proposed elevation requirement on the accessibility of covered facilities under the Fair Housing Act, the Americans with Disabilities Act (ADA), the Architectural Barriers Act (ABA), and Section 504 of the Rehabilitation Act of 1973. Elevating buildings as a flood damage mitigation strategy will likely have a negative impact on affected communities' disabled and elderly populations, unless those buildings are made accessible. Although all ADA title II and III facilities, ABA facilities, and Section 504 covered facilities are subject to accessibility requirements, single-family properties are generally not subject to accessibility requirements unless they are public housing (ADA title II) or a social service establishment (ADA title III). Consequently, even if the homes of people with disabilities are made accessible, a community's single- and multi-family housing stock may become largely inaccessible through elevation requirements. If the only accessible homes in a community are those currently occupied by people with disabilities, those people will likely be isolated. As occupants age or become disabled, they may have no option to remain in their homes or to age in place because adding an accessible route into an existing single- or multi-family building will be costly or impossible. It is therefore crucial for community sustainability and integration of people with disabilities that those buildings that *are* subject to accessibility requirements be made to comply.

In light of the substantial community impact of elevating housing and other buildings, along with the challenges associated with the traditional options for making elevated buildings accessible (*i.e.,* elevators, lifts, and ramps), FEMA invites comments on strategies it could employ to increase the accessibility of properties so affected in the event the proposed increase in elevation is adopted. Additionally, FEMA invites comments on the cost and benefits of such strategies, including data that supports the costs and benefits.

Determining the Corresponding Horizontal Extent of the FFRMS Floodplain

Once an agency has made the determination that an action is a Federally Funded Project that requires use of the FFRMS floodplain, and then made a determination which of the FFRMS approaches to apply, the agency must then decide where the FFRMS floodplain lies. There are no federally produced maps depicting the boundary of the FFRMS-floodplain established by the FVA or CISA, and FEMA maps depicting the 0.2 percent annual

[38] There may be some areas of the country where application of the FFRMS–CISA and the FFRMS–FVA could result in a lower elevation than the FFRMS–0.2PFA which under existing regulations is the elevation requirement for critical actions.

[39] While FEMA believes that the average flood risk will generally continue to increase nationwide due to climate change, there is considerable uncertainty in projecting flood risk at more granular levels. Some areas may experience declines in flood risk due to reduced rainfall or other unpredictable changes to the floodplain.

[40] FEMA riverine flood hazard data inventory information comes from the Coordinated Needs Management Strategy dataset.

[41] See Revised Guidelines at 57.

floodplain are only available in some areas. However, a map of the FFRMS floodplain is not required to determine if the location of a proposed Federally Funded Project is within the FFRMS floodplain. The floodplain determination can generally be made by comparing the ground elevation at the proposed site to the elevation established using the applicable FFRMS approach. If the ground elevation is less than the FFRMS elevation, than the site is in the FFRMS floodplain. Therefore, in order to complete the floodplain determination, FEMA intends to rely on two-dimensional information on a map to determine the location of the proposed site relative to the FFRMS floodplain. To do so, FEMA will need point information on (1) the FFRMS elevation and (2) the ground elevation of the proposed site. Once FEMA establishes the FFRMS elevation and the ground elevation based on available information, FEMA would compare the two values to determine if the proposed FEMA Federally Funded Project location is in the FFRMS floodplain.

Establishing the FFRMS Elevation Under Each of the Approaches

In order to make the floodplain determination and establish the proper elevation under each approach, FEMA intends to leverage its existing processes in each of its grant programs for ensuring compliance with Executive Order 11988. Although the specifics of the processes may vary somewhat from program to program, FEMA generally uses the following steps. During the initial stages of project development, FEMA informs applicants of all applicable Federal, State and local requirements which might apply to their projects to include Executive Order 11988 and the 8-step process. Once applicants have identified potential projects, FEMA works with them to assess the proposed project location and determine whether it is in the floodplain and therefore whether it is necessary to apply the 8-step process. FEMA is available to assist applicants with the 8-step process and FEMA reviews the project application to ensure that the project scope of work is in compliance with Executive Order 11988 requirements. FEMA will continue to perform these steps in its implementation of Executive Order 13690 and the FFRMS. When making the floodplain determination under the FFRMS, FEMA intends to investigate what flood information is available in order to select the best available information.[42] FEMA would rely on a range of available data to establish the FFRMS elevation for each of the approaches.

The FFRMS–CISA elevation is established using the best available, actionable climate-informed science. The Revised Guidelines provide guidance to agencies on the application of the CISA approach in coastal and riverine areas.[43] In particular, FEMA will use Appendix H of the Revised Guidelines titled ''Climate-Informed Science Approach and Resources'' to guide its decision-making. Appendix H outlines guidance on risk-based framing (*i.e.,* how agencies may consider current and future flood risks over the lifetime of the investment/project) followed by specific considerations and methods to consider climate change. Because the CISA uses a scenario-based analysis to establish an elevation by assessing a range of possible future conditions and considering the nature of the affected action, the anticipated lifecycle of the action, and the tolerance for risk associated with the action, use of the CISA would be based on project-specific decisions. FEMA may consider information presented by the applicant or any other Federal agency in this evaluation and will ultimately determine whether the methodology is appropriate for the action being considered and meets the relevant criteria.

FEMA recognizes that the FFRMS–CISA is a new and developing process and that there is uncertainty in the considerations and factors that will come up during an FFRMS–CISA analysis. As such, FEMA is not able to develop an exhaustive set of regulatory criteria for determining whether a given methodology or elevation is appropriate. However, FEMA recognizes that regulatory transparency reduces uncertainty for its grantees, and it will consider providing further guidance and information in the future as the agency's experience in implementing FFRMS–CISA grows.

Appendix H of the Revised Guidelines provides the following criteria to define the CISA, which FEMA will consider when developing further guidance and information: (1) Uses existing sound science and engineering methods (*e.g.,* hydrologic and hydraulic analysis and methodologies) as have historically been used to implement Executive Order 11988, but supplemented with best available climate-related scientific information when appropriate (depending on the agency-specific procedures and type of federal action); (2) is consistent with the climate science and related information found in the latest National Climate Assessment report or other best-available, actionable science; (3) combines information from different disciplines (*e.g.,* new perspectives from the atmospheric sciences, oceanographic sciences, coastal sciences, and hydrologic sciences in the context of climate change) in addition to traditional science and engineering approaches; and, (4) includes impacts from projected land cover and land use changes (which may alter hydrology due to increased impervious surface), long-term coastal and/or riverine erosion, and vertical land movement (for determining local changes to sea level) expected over the lifecycle of the action.

The FFRMS describes the FFRMS–FVA elevation as the addition of 2 or 3 feet to the 1 percent annual chance flood elevation. FEMA would leverage the process described in 44 CFR 9.7(c)(1)(iii) to search for the best available flood hazard information to establish the 1 percent annual chance flood elevation. This process recognizes that information on flood hazards at proposed sites may range from detailed data obtained from FEMA flood studies, to information which approximates the geographic area of the floodplain, to areas with no information. Where FEMA has issued a detailed study, FEMA could obtain the 1 percent annual chance flood elevation from the FIRM or FIS. In areas where FEMA has issued a limited study, FEMA would then seek detailed information from the list of sources in 44 CFR 9.7(c)(1)(iii)(B)(*1*)–(*8*).

For example, where an effective FIRM displays a 1 percent annual floodplain with limited detail, local sources such as a Floodplain Administrator, Flood Control Districts, or Transportation departments may have detailed information on file which was produced for development within the floodplain, for watershed plans, or for infrastructure designs. Where detailed information is not available from FEMA studies or other sources, but approximate flood information is available from a FEMA FIRM, FEMA may use simplified methods to develop a 1 percent annual chance flood elevation as presented in FEMA publication 265, entitled ''Managing Floodplain Development in Approximate A zones: A Guide for Obtaining and Developing Base (100-Year) Flood Elevations.''[44] A 1 percent

[42] See § 9.7(c)(1)(iii) of this proposed rule.

[43] See the Revised Guidelines at Appendix H ''Climate-Informed Science Approach and Resources.''

[44] FEMA, Managing Floodplain Development in Approximate Zone A: A Guide for Obtaining and Developing Base (100-Year) Flood Elevations

Continued

annual chance flood elevation developed using a simplified approach may yield an acceptable level of accuracy for the purpose of establishing whether a proposed FEMA Federally Funded Project is within the FFRMS–FVA floodplain. Where no flood hazard information is available, or where more accurate information on the 1 percent annual chance elevation is necessary for the purposes of complying with other sections of Part 9, such as § 9.11, FEMA publication 265 also provides guidance on detailed engineering methodologies to develop a 1 percent annual chance flood elevation. FEMA may rely on staff engineers to complete the engineering analysis, or FEMA may rely on information submitted as part of an application, where the applicant has obtained design and engineering services to develop the project scope of work.

The FFRMS–0.2PFA elevation is the elevation of the 0.2 percent annual chance flood. If FEMA were to use this approach in the future, FEMA could follow the same process to establish the 0.2 percent annual chance flood elevation as it would to establish the 1 percent annual chance flood elevation. FEMA would first rely on the 0.2 percent annual chance flood elevation reported in a FEMA FIS, then seek information from additional sources, before finally seeking the assistance of an engineer.

Establishing the Ground Elevation

FEMA may use available topographic information from the USGS to establish the ground elevation for a proposed location of a FEMA Federally Funded Project. Additionally, FEMA may also rely on information on the ground elevation submitted by an applicant as part of their project application.

IV. Discussion of the Proposed Rule

As noted above, this proposed rule would implement Executive Order 13690, the FFRMS, and the Revised Guidelines as part of FEMA's floodplain management regulations. Below, we provide a brief summary of a number of the major provisions of the proposed rule, followed by a section-by-section description of these and other changes.

Major Provisions

Conforming Changes to Definitions

FEMA proposes to amend § 9.4 to reflect the new definitions required by Executive Order 13690 and the FFRMS. As noted above, the most significant definitional change introduced by Executive Order 13690 and the FFRMS is the change to the meaning of ''floodplain.'' As discussed in more detail below, in order to harmonize this change in § 9.4 FEMA proposes to revise a number of existing definitions, and remove other definitions. In addition, FEMA proposes to revise the remaining sections of 44 CFR part 9 that refer generally to the floodplain, or refer specifically to the base (or 100-year) floodplain or the 500-year floodplain, for clarity.

Distinction Between ''FEMA Federally Funded Projects'' and Other FEMA Actions

As noted above, the first Step in the 8-step process is to determine whether the proposed action is in the floodplain. Because Executive Order 13690 and the October 8, 2015 version of FFRMS revise the definition of the ''floodplain'' that must be used for ''Federally Funded Projects,'' FEMA proposes to revise the first Step to require FEMA to first determine whether the proposed action falls within the definition of ''FEMA Federally Funded Project.'' Under the proposed rule, if FEMA determines that the action is a FEMA Federally Funded Project, *i.e.,* if FEMA determines that the action uses FEMA funds for new construction, substantial improvement, or to address substantial damage to a structure or facility, the FFRMS floodplain applies. If, on the other hand, FEMA determines that the action does not fall under the definition of a FEMA Federally Funded Project, the 1 percent annual chance floodplain (or the 0.2 percent annual chance floodplain for critical actions) applies.

Emphasis on Nature-Based Approaches

Executive Order 13690 requires that agencies use, where possible, natural systems, ecosystem processes, and nature-based approaches in the development of alternatives for Federal actions in the floodplain. FEMA proposes to incorporate this requirement into § 9.9, which addresses the requirement to consider practicable alternatives when determining whether to locate an action in the floodplain. This requirement applies regardless of whether the proposed action is a FEMA Federally Funded Project. To further explain this requirement, FEMA proposes to add a definition of ''nature-based approaches,'' meaning features designed to mimic natural processes and provide specific services such as reducing flood risk and/or improving water quality.

Section-by-Section Analysis

A. Authority Citation

FEMA proposes to add a reference to Executive Order 13690.

B. Section 9.1—Purpose of Part

FEMA proposes to add ''as amended'' to reflect Executive Order 13690's amendment of Executive Order 11988.

C. Section 9.2—Policy

FEMA proposes to add language to paragraph 9.2(b)(3) to reflect the policy statement from Executive Order 13690 that the United States must improve the resilience of communities and Federal assets against the impacts of flooding based on the best-available and actionable science. This statement of policy is complementary to the longstanding goals of Executive Order 11988 to reduce the risk of flood loss, but reflects an updated Federal policy of resilience and risk reduction that takes the effects of climate change and other threats into account.

D. Section 9.3—Authority

FEMA proposes to add reference to Executive Order 13690, which amended Executive Order 11988.

E. Section 9.4—Definitions

In Section 9.4, FEMA proposes to add terms for ''0.2 Percent Annual Chance Flood,'' ''0.2 Percent Annual Chance Floodplain,'' ''1 Percent Annual Chance Flood or Base Flood,'' ''1 Percent Annual Chance Flood Elevation or Base Flood Elevation,'' ''1 Percent Annual Chance Floodplain or Base Floodplain,'' ''Associate Administrator,'' ''Emergency Work,'' ''Federal Flood Risk Management Standard (FFRMS),'' ''Federal Flood Risk Management Standard Floodplain,'' ''FEMA Federally Funded Project,'' FIMA, and ''Nature-Based Approaches;'' to remove the definitions of ''Base Flood,'' ''Base Floodplain,'' ''Emergency Actions,'' ''Five Hundred Year Floodplain,'' and ''Mitigation Directorate;'' and to revise the definitions of ''Critical Action,'' ''Floodplain,'' ''New Construction,'' ''Orders,'' and ''Substantial Improvement.''

0.2 Percent Annual Chance Flood. FEMA proposes to define the term ''0.2 percent annual chance flood'' to mean the flood which has a 0.2 percent chance of being equaled or exceeded in any given year. This was previously known as the ''500-year flood.'' FEMA proposes to use the term ''0.2 percent annual chance flood'' and discontinue using that term interchangeably with the term ''500-year flood.'' The term ''500-year flood'' can cause confusion as it

(1995), available at *https://www.fema.gov/media-library/assets/documents/1911.*

could be interpreted to mean that the area will only flood once every 500 years, instead of reflecting its true meaning, which is the annual risk of flooding in the area.

0.2 Percent Annual Chance Floodplain. FEMA proposes to define the term ''0.2 percent annual chance floodplain'' to mean the area subject to flooding by the 0.2 percent annual chance flood.

1 Percent Annual Chance Flood or Base Flood. FEMA proposes to retitle the current definition of ''base flood'' as ''1 percent annual chance flood or base flood.'' This reflects the fact that Executive Order 13690 uses the term ''base flood'' and the Revised Guidelines use the term ''1 percent annual chance flood.'' There is no substantive difference between the two terms and they may be used interchangeably. The ''1 percent annual chance flood'' means the flood that has a 1 percent chance of being equaled or exceeded in any given year. In the current definition of ''base flood,'' the term is also equated with the ''100-year flood;'' however, FEMA proposes to discontinue use of the term ''100-year flood'' because this term can cause confusion. It can be interpreted to mean that the area will only flood once every 100 years instead of reflecting its true meaning, which is the annual risk of flood in the area.

1 Percent Annual Chance Flood Elevation or Base Flood Elevation. FEMA proposes to define the term ''1 percent annual chance flood elevation or base flood elevation'' to mean the computed elevation to which floodwater is anticipated to rise during the 1 percent annual chance flood or base flood. FEMA also proposes to incorporate the explanation from the current definition of ''base flood'' about how the term is used in the NFIP to indicate the minimum level of flooding to be used by a community in the community's floodplain management regulations. The elevation indicates how high to elevate a structure in order to protect it from the risk of flooding in a base flood.

1 Percent Annual Chance Floodplain or Base Floodplain. FEMA proposes to define the term ''1 percent annual chance floodplain or base floodplain'' to mean the area subject to flooding by the 1 percent annual chance flood or base flood. A floodplain is generally a lowland or flat area near water that has a greater chance of flooding than higher areas and areas farther from water. This definition would describe the minimum area that FEMA looks at when it determines whether an action will take place in a floodplain.

Associate Administrator. FEMA proposes to define ''Associate Administrator'' as the Associate Administrator of the Federal Insurance and Mitigation Administration. This reflects the current title of this position, and adding it to the definitions section allows for ease of use throughout Part 9, rather than having to reprint the entire title each time it is used.

Base Flood and Base Floodplain. FEMA proposes to remove the definitions of the ''base flood'' and ''base floodplain'' as FEMA proposes to incorporate them in the definitions of the ''1 percent annual chance flood or base flood'' and ''1 percent annual chance floodplain or base floodplain.''

Critical Action. FEMA proposes to revise the definition of ''critical action'' to remove the requirement that the minimum floodplain of concern in the event of a critical action is the 500-year floodplain. There would no longer be a set requirement that an applicant use a particular approach to establishing the floodplain when the project is a critical action. Instead, FEMA and the applicant would follow the sequence described in § 9.7 when making the floodplain determination. FEMA would be required to determine whether the project meets the new definition of ''FEMA Federally Funded Project'' in § 9.4. If the project is a Federally Funded Project, then FEMA would establish the floodplain by using one of the FFRMS approaches (which require the applicant to consider whether an action is a critical action). If the project is not a Federally Funded Project, then FEMA would use, at a minimum, the 1 percent annual chance floodplain for non-critical actions and the 0.2 percent annual chance floodplain for critical actions.

Emergency Work. The current definition of ''emergency actions'' is emergency work essential to save lives and protect property and public health and safety performed under certain sections of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) and corresponding FEMA regulations. FEMA proposes to change the term to ''emergency work'' to clearly differentiate between the work under the specific sections of the Stafford Act that was exempted entirely from the requirements of Executive Order 11988 and the new exceptions to the application of the FFRMS (which include non-specific references to emergency actions) created by Executive Order 13690. FEMA also proposes to update the citations to the specific sections of the Stafford Act and FEMA regulations, as the citations are outdated in the current definition.

Federal Flood Risk Management Standard (FFRMS). FEMA proposes to add a definition of ''FFRMS,'' which is the Federal flood risk management standard established by Executive Order 13690 to be incorporated into existing processes used to implement Executive Order 11988. FEMA proposes to add a definition for FFRMS because this rule proposes to implement it and therefore refers to it throughout the proposed changes to Part 9.

Federal Flood Risk Management Standard (FFRMS) Floodplain. FEMA proposes to define the ''FFRMS floodplain'' consistent with the definition in Executive Order 13690, which is the floodplain that is established using one of four approaches: CISA, FVA, 0.2PFA, and the elevation and flood hazard area that result from using any other method identified in an update to the FFRMS.

FEMA proposes to define the ''CISA'' as the elevation and flood hazard area that result from using the best-available, actionable hydrologic and hydraulic data and methods that integrate current and future changes in flooding based on climate science. This approach will also include an emphasis on whether the action is a critical action as one of the factors to be considered when conducting the analysis.

FEMA proposes to define the ''FVA'' as the elevation and flood hazard area (the horizontal extent of the floodplain) that result from using the freeboard value, reached by adding an additional 2 feet to the base flood elevation for non-critical actions and by adding an additional 3 feet to the base flood elevation for critical actions.

FEMA proposes to define the ''0.2PFA'' as the area subject to flooding by the 0.2 percent annual chance flood. The 0.2 percent annual chance flood is a flood that has a 0.2 percent chance of happening in any given year. It is a flood that covers greater area that is less frequent than the 1 percent chance floodplain.

Finally, FEMA proposes to add a fourth approach, the elevation and flood hazard area that result from using any other method identified in an update to the FFRMS.

FEMA Federally Funded Project. FEMA proposes to add a definition of ''FEMA Federally Funded Project'' to mean actions where FEMA funds are used for new construction, substantial improvement, or to address substantial damage to a structure or facility. FEMA's proposed definition mirrors the language in the FFRMS and the Revised Guidelines.

FIMA. FEMA proposes to revise the definition of the Federal Insurance Administration to mean the Federal Insurance and Mitigation Administration to reflect the current title of the organization.

Five Hundred Year Floodplain. FEMA proposes to remove the definition of the five hundred year floodplain as a standalone term and designated floodplain and to instead substitute the term to 0.2 percent annual chance floodplain. The 0.2 percent annual chance floodplain is the floodplain covering an area where the chance of flood is 0.2 percent in any given year.

Floodplain. FEMA currently defines ''floodplain'' as the lowland and relatively flat areas adjoining inland and coastal waters including, at a minimum, that area subject to a 1 percent or greater chance of flooding in any given year. FEMA proposes to revise the definition to remove the phrase ''including, at a minimum, the area subject to a one percent or greater chance of flooding in any given year.'' This is because the FFRMS expands the consideration from the 1 percent annual chance (base) floodplain.

The current definition also states that wherever the term ''floodplain'' appears in Part 9, if a critical action is involved, ''floodplain'' means the area subject to inundation from a flood having a 0.2 percent chance of occurring in any given year (500-year floodplain). FEMA proposes to remove this provision from the definition of floodplain because there is no longer a set requirement that an applicant use a particular approach to establishing the floodplain when there is a critical action. Instead, FEMA and the applicant must follow the sequence described in § 9.7 when making the floodplain determination. FEMA must determine whether the project meets the new definition of ''FEMA Federally Funded Project'' in § 9.4. If the project is a FEMA Federally Funded Project, then FEMA must establish the floodplain by using one of the FFRMS approaches (which require the applicant to consider whether an action is a critical action). If the project does not meet the definition of FEMA Federally Funded Project (*i.e.* the project is not ''new construction, substantial improvement, or repairs to address substantial damage to a structure or facility''), then FEMA must use, at a minimum, the 1 percent annual chance floodplain for non-critical actions and the 0.2 percent annual chance floodplain for critical actions.

FEMA proposes to add that the floodplain may be more specifically categorized as the 1 percent annual chance (base) floodplain, the 0.2 percent annual chance floodplain, or the FFRMS floodplain (as defined above). ''Floodplain'' is a flexible, general term, but in establishing the correct floodplain to use, it will be necessary to determine whether the action is a Federally Funded Project and whether it is a critical action.

Mitigation Directorate. FEMA proposes to remove the definition of the ''Mitigation Directorate'' as it is now included in the definition of ''FIMA.''

Nature-Based Approaches. FEMA proposes to add a definition of ''nature-based approaches.'' Executive Order 13690 added a provision requiring agencies to use nature-based approaches where possible and this term has not previously been defined. FEMA proposes to define nature-based approaches as the features (sometimes referred to as ''green infrastructure'') designed to mimic natural processes and provide specific services such as reducing flood risk and/or improving water quality. Nature-based approaches are created by human design (in concert with and to accommodate natural processes) and generally, but not always, must be maintained in order to reliably provide the intended level of service. Nature-based approaches are sometimes referred to as green infrastructure and may include, for example, green roofs, or downspout disconnection that reroutes drainage pipes to rain barrels, cisterns, or permeable areas instead of the storm sewer. The proposed definition mirrors the language of the WRC Revised Guidelines.

New Construction. FEMA proposes to remove the parenthetical ''including the placement of a mobile home'' from the definition of new construction because retaining the clause would have unintended effects, given the new definition of FEMA Federally Funded Projects. The application of the FFRMS is required for any action which meets the definition of ''Federally Funded Project.'' ''FEMA Federally Funded Project'' is defined as an action where FEMA funds are used for new construction, substantial improvement, or to address substantial damage to a structure or facility. If FEMA continued to define the placement of a mobile home as ''new construction,'' it would be required to apply the FFRMS to any placement of a mobile home. As described further in the discussion of § 9.13, FEMA does not intend to require the application of the FFRMS in the placement of mobile homes for the purpose of temporary housing.

Orders. FEMA proposes to revise the definition of ''orders'' to include Executive Order 13690.

Substantial Improvement. FEMA proposes to update the reference to the Stafford Act, because the citation is outdated in the current definition.

F. Section 9.5—Scope

FEMA proposes to add an effective date provision to this section, indicating that the revisions proposed to Part 9, which implement the changes required by Executive Order 13690 and the FFRMS, would apply to new actions that are commenced on or after the effective date of the final rule. This is to clarify that current Part 9, including use of the base floodplain (or 500-year floodplain for critical actions), would still apply to actions that are in the planning or development stage or undergoing implementation as of the effective date of the final rule revising Part 9. Only new actions would be subject to revised Part 9 so that the changes would not be applied retroactively to projects which have already been reviewed for compliance with Executive Order 11988 and may have incurred designed expenses to meet the current floodplain management standards. Any new actions would be subject to revised Part 9, including the changes required under Executive Order 13690 and the FFRMS, such as determining whether to use the base floodplain or FFRMS floodplain for the action and using nature-based approaches to mitigate harm when development in the floodplain is not avoidable.

FEMA proposes to update the citations to the Stafford Act sections and references to organizations and titles in paragraphs (c)–(g) as they are not current. FEMA also proposes to update paragraph (c)(8) as it refers to a defunct title for the Individuals and Households program and includes programs that no longer exist.

FEMA also proposes to eliminate the cross references in the last sentence of paragraph 9.5(f)(1), because they relate to regulatory provisions (44 CFR 9.9(e)(6) and 9.11(e)(4)) that FEMA proposes to remove in this rule. FEMA describes its rationale for eliminating the cited text later in this preamble.

G. Section 9.6—Decision-Making Process

Section 9.6 sets out the floodplain management and wetlands protection decision-making process to be followed by FEMA in applying Executive Orders 11988 and 11990 to its actions. There are eight Steps the agency must follow. Step 1 states that FEMA will determine whether the proposed action is located in the 100-year floodplain or, for critical actions, the 500-year floodplain. FEMA

proposes to remove the specific requirement to use the 100-year (1 percent annual chance) floodplain or 500-year (0.2 percent annual chance) floodplain for critical actions and instead use the general term ''floodplain.'' Instead, FEMA proposes to refer the reader to section 9.7(c) of the regulations, which describes (1) the flexible framework that FEMA would apply to FEMA Federally Funded Project under Executive Order 13690 and the FFRMS, as well as (2) the historical framework that FEMA would continue to apply to actions that do not qualify as FEMA Federally Funded Projects.

H. Section 9.7—Determination of Proposed Action's Location

Paragraph (a) of section 9.7 states that the purpose of the section is to establish FEMA's procedures for determining whether any action as proposed is located in or affects the base floodplain (or the 500-year floodplain for a critical action) or a wetland (*i.e.,* Step 1 of the 8-step decision-making process described in section 9.6). As in section 9.6, FEMA proposes to simply refer to ''floodplain'' rather than base floodplain or 500-year floodplain, because Executive Order 13690 and the FFRMS's flexible framework to determining which floodplain is appropriate depending on the type and criticality of the action means the floodplain must be established using the process set forth in paragraph 9.7(c) and may be something other than the floodplain established using the 1 percent annual chance flood or 0.2 percent annual chance flood.

Paragraph (b) of § 9.7 states that information about the 100-year and 500-year floods may be needed to comply with the regulations in Part 9. FEMA proposes to update this statement to reflect that information about the 1 percent annual chance (base) floodplain, 0.2 percent annual chance floodplain, and the FFRMS floodplain may be needed.

Paragraph (c) of § 9.7 outlines the sequence FEMA must follow in making the floodplain determination. FEMA proposes to implement the change to the definition of floodplain required by Executive Order 13690 and the FFRMS in § 9.7(c), ''Floodplain determination.'' As an initial step, FEMA would determine whether the project is a *FEMA Federally Funded Project* as defined in § 9.4. If the project is a FEMA Federally Funded Project, FEMA would establish the FFRMS floodplain and associated flood elevation using one of the four approaches outlined in the proposed section. For example, FEMA would likely be required to apply the FFRMS floodplain to construction projects under FEMA's Public Assistance program authorized under Section 406 of the Stafford Act, Hazard Mitigation Grant Program authorized under Section 404 of the Stafford Act, and Flood Mitigation Assistance Program authorized under Section 1366 of the National Flood Insurance Act. However, it is likely that certain other grant programs or actions would not be required to apply the FFRMS floodplain, because the actions funded do not involve construction activities. This may include grants provided for disaster planning through FEMA's Pre-Disaster Mitigation Program authorized under Section 203 of the Stafford Act and grants for planning and training awarded through programs administered by FEMA's Protection and National Preparedness Office. Each grant program FEMA funds would be required to determine whether the 1 percent annual chance, 0.2 percent annual chance, or FFRMS floodplain applies to the particular action.

FEMA proposes to implement the FFRMS in its regulations by adopting the flexible framework proposed in Executive Order 13690 in its entirety, instead of mandating a particular approach. Under this proposal, FEMA would provide additional guidance (more readily capable of revisions and updates) that addresses which approach FEMA would use for different types of actions and how FEMA would tailor its application of the various approaches depending on the type and criticality of the action. Executive Order 13690 makes clear that the intent of providing a flexible framework is to acknowledge that the impacts of flooding are anticipated to increase over time due to the effects of climate change and other threats. In order to determine what those impacts may be, there is value in using the best-available, actionable hydrologic and hydraulic data and methods that integrate current and future changes in flooding based on climate science, rather than relying solely upon the 1 percent annual chance flood standard, which does not account for or provide any factor of safety to mitigate against the possibility that flood risk may increase over time.

Executive Order 13690 provides an exception to use of the FFRMS when the action is in the interest of national security, where the action is an emergency action, where application to a Federal facility or structure is demonstrably inappropriate, or where the action is a mission-critical requirement related to a national security interest or an emergency action. FEMA proposes to adopt these exceptions in their entirety. It is important to note that an exception to using the FFRMS under any of the reasons listed in this section does not exempt the action from the requirements of Executive Order 11988 altogether. Instead, if one of FEMA's actions were excepted under this provision, FEMA would still be required to apply the 1 percent annual chance floodplain for non-critical actions and the 0.2 percent annual chance floodplain for critical actions. FEMA does have the authority to exempt certain actions from any application of the requirements of Executive Order 11988 and those actions which are exempted are enumerated in Section 9.5(c).

FEMA proposes that if it determines that the action is not a FEMA Federally Funded Project, *i.e.,* that the action does not involve the use of FEMA funds for new construction, substantial improvement, or to address substantial damage to a structure or facility, the proposed action may be evaluated using the 1 percent annual chance floodplain for non-critical actions and the 0.2 percent annual chance floodplain for critical actions. The sequence for making that determination remains relatively unchanged. The Regional Administrator (RA) first consults the FEMA FIRM, the FBFM and the FIS. If neither a FIRM nor a FBFM is available, the RA consults the FHBM. The regulation provides a list of sources to consult in the event the FHBM is not available. FEMA proposes to update this list of sources to those suggested in the Revised Guidelines, which were updated to reflect current titles and new available resources.[45] Finally, if none of these sources have the information necessary to comply with the Orders, the RA seeks the services of an engineer experienced in this type of work. If a decision involves an area or location within extensive Federal or State holdings or a headwater area, and no FIS, FIRM, FBFM, or FHBM is available, FEMA seeks information from the land administering agency before seeking information and/or assistance from the list of sources or an engineer.

Additionally, FEMA is proposing to change the paragraph structure of § 9.7 for clarity.

I. Section 9.8—Public Notice Requirements

The only proposed change is to paragraph 9.8(c)(5)(ii), to correct a typographical error.

[45] FEMA proposes to update this list of sources to reflect the WRC's Revised Guidelines.

J. Section 9.9—Analysis and Reevaluation of Practicable Alternatives

FEMA proposes to add the requirement to use natural systems, ecosystem processes, and nature-based approaches in the development of alternatives for Federal actions in the floodplain to § 9.9(b). Under § 9.9, FEMA must make a preliminary determination (Step 3 of the 8-step process) as to whether the floodplain is the only practicable location for the action. Part of that analysis involves considering whether there are alternative actions that serve essentially the same purpose as the proposed action but which have less potential to affect or be affected by a floodplain. Under this proposed rule, during the course of the aforementioned analysis, FEMA would consider whether using natural systems, ecosystem processes and nature-based approaches might have less of an effect on the floodplain.

FEMA proposes to remove paragraph (d)(2) of § 9.9, which prohibits FEMA from locating a proposed critical action in the 500-year floodplain. This is because under this proposed rule, critical actions would no longer be subject to a specific requirement related to the 500-year floodplain. Instead, FEMA would follow the sequence described in § 9.7 when making the floodplain determination. As noted above, FEMA would determine whether the project meets the new definition of ''FEMA Federally Funded Project'' in § 9.4. If FEMA determined that the project is a FEMA Federally Funded Project, then FEMA would establish the floodplain by using one of the FFRMS approaches (which require the applicant to consider whether an action is a critical action). If FEMA determined that the project is not a FEMA Federally Funded Project, then FEMA would use, at a minimum, the 1 percent annual chance floodplain for non-critical actions and the 0.2 percent annual chance floodplain for critical actions. After FEMA completed that process, it would apply the appropriate floodplain to the remainder of the 8-step process. Therefore, FEMA proposes to revise paragraph (d)(1) to specify that the ''floodplain'' is the floodplain established in § 9.7(c).

FEMA proposes to eliminate paragraph 9.9(e)(6). Section 9.9(e)(6) prohibits FEMA from providing a new or renewed contract for flood insurance for a structure if the Regional Director has chosen the ''no action'' option provided for in § 9.9(e)(5). This provision was temporarily suspended via a November 28, 1980 **Federal Register** Notice of intent not to enforce certain regulation concerning denial of flood insurance coverage. (45 FR 79069) FEMA ultimately did not ever implement this provision and does not intend to do so now; therefore, FEMA is proposing to remove it from the regulation.

K. Section 9.11—Mitigation

FEMA proposes to remove the reference to the base flood and the 500-year flood from paragraph 9.11(c) and instead reference the floodplain as established in § 9.7(c) when describing its intent to minimize potential harm to lives and the investment at risk. Again, this is because there is no longer a set requirement related only to the base floodplain or the 500-year floodplain when there is a critical action. Instead, FEMA must follow the sequence described in § 9.7 when making the floodplain determination.

In paragraph 9.11(d), FEMA proposes to revise the text to reflect that the minimization standards are applicable to all of FEMA's grant programs. Currently, paragraph 9.11(d) states that the minimization standards are applicable to only FEMA's implementation of the Disaster Relief Act of 1974. Some of FEMA's grant programs are authorized under other legislation.

In paragraphs 9.11(d)(2) and 9.11(d)(3)(i)–(ii), FEMA proposes to specifically require elevation of the lowest floor of a building to the FFRMS floodplain during the construction of new or substantially improved structures. As described above, FEMA must follow the sequence described in § 9.7 when making the floodplain determination. FEMA must determine whether the project meets the new definition of ''FEMA Federally Funded Project'' in § 9.4. The definition of ''FEMA Federally Funded Project'' is an action where FEMA funds are used for new construction, substantial improvement, or to address substantial damage to a structure or facility. ''Substantial Improvement'' as defined in § 9.4 includes all actions taken to address substantial damage to a structure or facility. Because paragraphs 9.11(d)(2) and 9.11(d)(3)(i)–(ii) specifically reference new construction or substantial improvement, FEMA must establish the floodplain in these circumstances by using one of the FFRMS approaches (which require the applicant to consider whether an action is a critical action). FEMA multi-hazard mitigation guidance can be consulted for technical information on elevation methods for new construction and the retrofitting of existing structures with various types of foundations.[46] For example, in the case of structures with basements, the structure may be elevated on solid foundation walls by creating a new masonry-enclosed area on top of an abandoned and filled-in basement or elevated on an open foundation by filling in the old basement.[47] If the structure with a basement is non-residential, the applicant may elect to dry floodproof the structure rather than elevate. In this case, basements may be dry floodproofed using the same techniques as spaces above grade, including the creation of continuous impermeable walls, creating flood resistance in core interior areas, adding sealants on openings, installing flood shields for openings in exterior walls, and installing backflow valves and internal drainage systems.[48]

For the same reasons as stated above, in paragraph 9.11(d)(9), FEMA proposes to remove the reference to the base flood or, in the case of critical actions, the 500-year flood from paragraph 9.11(d)(9) and instead reference the floodplain as established in § 9.7(c) when describing the requirements for the replacement of building contents, material and equipment.

FEMA proposes to revise paragraphs 9.11(e)(1) and (e)(2) by adding ''and Mitigation'' to the title of the ''Federal Insurance Administration'' to reflect the current title of the organization, the ''Federal Insurance and Mitigation Administration.'' FEMA also proposes to revise paragraphs 9.11(e)(2)(ii), 9.11(e)(3)(i)(E), and 9.11(e)(3)(ii) by replacing ''FIA'' with ''FIMA'' to again reflect the change in title.

Finally, FEMA proposes to eliminate paragraph 9.11(e)(4). Paragraph 9.11(e)(4) provides that where the Regional Director has been precluded from providing assistance for a new or substantially improved structure in a floodway, FEMA may not provide a new or renewed policy of flood insurance for that structure. As noted in the regulation, this provision was temporarily suspended via a November 28, 1980 **Federal Register** Notice of intent not to enforce certain regulation concerning denial of flood insurance

[46] A catalogue of FEMA Building Science Branch publications including descriptions of available publications for natural hazards can be accessed at *http://www.fema.gov/media-library/assets/documents/12909.*

[47] See FEMA, *FEMA P–259 Engineering Principles and Practices of Retrofitting Floodprone Residential Structures* (2012), available at *http://www.fema.gov/media-library/assets/documents/3001,* at 5E–8.

[48] FEMA, FEMA P–936, Flood Proofing of Non-Residential Buildings (2013), available at *http://www.fema.gov/media-library/assets/documents/34270,* at 3–2.

coverage. (45 FR 79069) FEMA ultimately did not implement this provision and does not intend to do so now; therefore, FEMA is removing it from the regulation.

L. Section 9.13—Particular Types of Temporary Housing

FEMA proposes to specifically designate the use of the 1 percent annual chance (base) floodplain when evaluating whether to take a temporary housing action. See proposed § 9.13(d)(1). FEMA proposes to specifically prohibit housing an individual or family in the 1 percent annual chance (base) floodplain, unless the Regional Administrator has complied with the provisions in proposed § 9.9 to determine that the site is the only practicable alternative. See proposed § 9.13(d)(3). FEMA proposes to designate the 1 percent annual chance (base) floodplain as the floodplain of choice when taking temporary housing actions for several reasons: (1) The temporary nature of the assistance means there is not an opportunity to improve community resilience or floodplain management long term, which is the intent of the FFRMS; (2) expansion of the base floodplain to the FFRMS floodplain and prohibiting placement of temporary housing in the FFRMS floodplain may result in the temporary housing of individuals and families many miles from their homes, which is not practicable; and (3) it is not always feasible to elevate mobile homes, when they are being placed as temporary housing.

FEMA proposes to add the sentence ''actual elevation levels will be based on manufacturer specifications and applicable Agency guidance'' to reflect the fact that it is not always feasible to elevate mobile homes. See proposed § 9.13(d)(4)(i). Since mobile homes are often the last resort for temporary housing and they are being placed temporarily, it is not always practicable to elevate mobile homes to a given level. However, the proposed rule would require that such homes be elevated to the fullest extent practicable.

In paragraph 9.13(d)(4)(ii), FEMA proposes to substitute ''44 CFR parts 59–60'' for ''44 CFR part 59 *et seq.''* to be clear what specific sections of the regulations the language references.

FEMA also proposes to require the elevation of a mobile home to at least the level of the FFRMS floodplain, if FEMA intends to sell or otherwise dispose of mobile homes in the FFRMS floodplain. See proposed § 9.13(e)(2). The reason for this requirement is that any sale or disposal of a mobile home no longer constitutes temporary housing; FEMA believes that any unit intended for permanent placement should be protected to the fullest extent practicable, because the probability that a flood will occur within the floodplain is greater over the anticipated lifespan of a permanent structure than a temporary structure, and so the benefit of hazard mitigation is greater to the permanent structure than the temporary structure. Further, any sale or disposal of a mobile home must meet NFIP requirements of residential structures by elevating the lowest floor. Mobile homes placed in the floodplain for the purposes of temporary housing must meet the criteria of the NFIP or any more restrictive standards unless the community has granted a variance. See proposed § 9.13(d)(4)(ii).

Additionally, FEMA is proposing to change the paragraph structure of § 9.13. No substantive changes are intended as a result of this restructuring.

M. Section 9.17—Instructions to Applicants

In paragraph 9.17(a), FEMA proposes to add ''as amended'' to reflect Executive Order 13690's amendment of Executive Order 11988.

In paragraph 9.17(b), FEMA proposes to update the reference to the WRC's 1978 Guidelines to the full title for the Revised Guidelines.

N. Section 9.18—Responsibilities

In paragraph 9.18(b), FEMA proposes to update the references to the FIA and the title of Associate Administrator.

In paragraph 9.18(b)(2), FEMA proposes to add ''as amended'' to reflect Executive Order 13690's amendment of Executive Order 11988.

O. Appendix A to Part 9—Decision-Making Process for E.O. 11988

FEMA proposes to remove ''Appendix A to Part 9—Decision-Making Process for E.O. 11988'' in its entirety. The graphic is no longer accurate. Further, given that Executive Order 13690 deliberately created a flexible approach to establishing the FFRMS and also requires update of the FFRMS every 5 years, there is no utility to including the appendix in regulation. Instead, FEMA would include a revised version of the appendix to include the new decision-making process and the definition of the FFRMS floodplain in its policy implementing the FFRMS.

V. Response to Leadership Intent Comments

On November 17, 2015, FEMA's Federal Insurance and Mitigation Administration released for public comment FEMA's Overview of FEMA's Intent to Implement the FFRMS (Intent). Continuing our commitment to an open, collaborative, stakeholder-focused process in implementing the FFRMS, FEMA shared this framework for public comment on FEMA's Web site through December 17, 2015.

FEMA received 12 comments in response to the Intent. Of the 12 comments received, 10 comments were supportive, 1 comment was opposed, and 1 comment was not germane.[49]

The 10 comments received in support of the Intent came from a variety of sources, including local governments, associations, environmental action organizations, and commenters that chose to reply in their private capacity. Following is a discussion of the comments submitted.

The adverse comment came from a local government official. The official stated that the CISA would be ''a means to extort money from citizens based on a junk science forecasts/models of which so called projections have been outrageously inaccurate.'' The commenter did not provide any support for the statement. FEMA disagrees with the commenter's assessment that Climate-Informed Science Approach (CISA) is based on ''junk science forecasts/models.'' Scientists compare models' projections of historical climate trends to the historical records climate variables to measure the confidence of the models' abilities to accurately predict future climate conditions.[50] Many peer reviewed studies of climate models have found in general that climate model simulations of historical global temperature and other climactic variables are comparable to the historical recorded observations of those variables.[51] These studies provide confidence in accuracy of climate models' projections of future climate conditions.

The 2014 United States National Climate Assessment (Assessment) concluded that ''[g]lobal trends in temperature and many other climate variables provide consistent evidence of

[49] The comments are available in the docket for this rulemaking.

[50] Risbey et al. 2014. Well-estimated global surface warming in climate projections selected for ENSO phase. ''Nature Climate Change'', 4, 835–840.

[51] See Covey et al. 2003. An overview of results from the coupled model intercomparison project (CIMP). ''Global and Planetary Change'', 37, 103–133; and Cubasch *et al.* 2013. Introduction. In: ''Climate Change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change'' [Stocker *et al.* (eds)]. Cambridge University Press, Cambridge at 131.

a warming planet.'' [52] These trends ''are based on a wide range of observations, analyzed by many independent research groups around the world.'' [53] The Assessment reported that confidence is very high [54] that global sea level has risen during the past century and that it will continue to rise, and there is medium confidence that global sea level rise will be in the range of 1–4 feet by 2100.[55] The Assessment further reports that although changes in overall precipitation are uncertain in many U.S. areas, there is high degree of certainty that the heaviest precipitation events will increase everywhere, and by large amounts.[56] The approaches to establish a higher vertical elevation and corresponding floodplain provided in the FFRMS are intended to address these future flood risks.

Within the 10 supportive comments, the commenters provided suggestions and asked questions concerning FEMA's proposed framework. One local government agreed that the CISA should be used in ''calculating the [FFRMS] flood level and floodplain,'' but stated that:

> [Allowing a different set of standards for FFRMS and NFIP not only allows for non-compliance with the NFIP i[t] encourages it. How will FEMA discipline a community for not complying with the NFIP when they provided the funding for the project under FFRMS. This is a double standard and will create legal issues if not revised.

FEMA disagrees that implementing the FFRMS encourages noncompliance with NFIP standards. FEMA acknowledges that it is proposing to provide an option to use the CISA for critical facilities, but notes that under this proposal, the CISA would only be allowed if the elevation is higher than the elevation established using the FVA. This precaution would eliminate the possibility that the CISA elevation used for a FEMA Federally Funded Project would be less than the base flood elevation required as the minimum standard of the NFIP. Additionally, FEMA has complied and will continue to comply with local floodplain management standards that are more restrictive. FEMA is not proposing to amend § 9.11(d)(6), which prohibits FEMA from taking any action that is inconsistent with the NFIP standards or any more restrictive Federal, State, or local floodplain management standards.

One commenter was concerned with the issue of coordination between Federal agencies, stating:

> The Background [to the Intent document] states that ''Federal agencies have the flexibility to select from the approaches of the FFRMS to establish the floodplain for a given action.'' While flexibility may be warranted, the interagency coordination provision must come into play in establishing the ''floodplain'' by various agencies. The Framework language needs to be revised from ''. . . should coordinate early . . .'' to ''. . . shall coordinate early.'' This needs to be a required action whereby the most protective, conservative delineation of the floodplain is achieved and applied by all [F]ederal agencies for all purposes.

FEMA agrees with this comment and in the supplementary policy, FEMA proposes that when FEMA is funding a FEMA Federally Funded Project with, or in the same area as, another Federal agency, FEMA will coordinate with the applicable Federal agency early in the planning process.

Multiple commenters stated that the use of the FVA may create a disincentive to update flood maps. Their concern was that the use of the FFRMS–FVA rather than the FFRMS–CISA might create a sense that flood map updates and associated funding are less critical because of the safety standard provided by freeboard. Commenters stated that:

> [t]he freeboard provision is a positive, protective step, however, it should not become a default standard to replace updated flood mapping.

FEMA disagrees with the statement that using the FVA will eliminate the desire to update flood maps. FEMA has stated that the FFRMS will not affect FEMA's flood mapping standards. While FEMA's FIS and FIRMs may be used as sources of best available information to establish the FFRMS elevation, the primary function of FIS and FIRMs is not to establish the FFRMS. The production of FIS and FIRMs are managed for other purposes, such as to serve the mission of the NFIP.

Two commenters requested that FEMA address how changing flood hazard information will be used in establishing the FFRMS elevation. One commenter stated:

> [i]n all the talk I hear about flood mitigation and resolution I never hear any discussion as how standard measurements, what you call base line, do not take into account or even look at how those base lines have moved due to erosion.

Another commenter asked:

> On occasion, FEMA has issued Advisory Base Flood Elevations (ABFEs) following a major flooding event, when it has been determined that the effective [Base Flood Elevations (BFEs)] significantly underestimate the base flood [. . .] What will FEMA consider to be the advisory ''BFE'' when adding freeboard under EO 13690?

Section 2(a)(1) of the Executive Order directs agencies to use approaches based on the best available information and FEMA's effective FIRM. Because flood risk can change over time, FEMA's mapping program continually updates its inventory of flood hazard information. Flood zone designations may be established or revised when new and more accurate information becomes available because of a FEMA-contracted restudy or because the community makes the information available to FEMA. More accurate information may include more accurate or updated topographic information which would capture changes in the ground elevation due to factors including erosion. Information from a preliminary FIRM or ABFE may serve as best available information if the information shows that a site previously located outside the floodplain is now in the floodplain, or that the existing FEMA Base Flood Elevation has increased. In response to the commenter's question, when determining what is the appropriate ''BFE'' when adding freeboard under Executive Order 13690, FEMA would use the best available information.

One comment received from a local government stated that the FVA is one-size fits-all, and the FVA would not reflect local conditions when establishing the FFRMS elevation. FEMA uses the best available information to establish the base flood elevation, which reflects local flooding conditions. Therefore, FEMA disagrees with the comment that the FVA would not reflect local conditions.

Five commenters stated that FEMA should use the 0.2 percent annual chance floodplain approach (500-year floodplain) to establish the minimum FFRMS elevation and floodplain for critical actions. One commenter stated that:

> In some instances, the 500-year floodplain may provide a higher elevation than the other options, and in those instances the 500-year floodplain should be used. Critical actions are actions for which even a slight chance of flooding would be too great. As such, an all three FFRMS approaches should be considered to achieve the highest level of protection.

Another commenter stated the FVA may provide too restrictive a standard when the FVA elevation is higher than the 0.2 percent annual chance floodplain elevation:

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[52] Walsh et al. 2014: Ch. 2: Our Changing Climate. ''Climate Change Impacts in the United States: The Third National Climate Assessment,'' J. M. Melillo, Terese (T.C.) Richmond, and G. W. Yohe, Eds., U.S. Global Change Research Program, 19–67.

[53] *Id.*

[54] ''Very high'' is the highest confidence level used in the Assessment. *See id.* at 61.

[55] *Id.* at 66.

[56] *Id.* at 33.

For example, in areas where the 500-year water surface is less than 2 feet above the 100-year water surface, the freeboard value approach may be overly conservative and go well above the 500-year level protection.

FEMA recognizes that the FVA may be more or less conservative than the 0.2PFA. However, FEMA is proposing in the supplementary policy to select to use the FVA but not the 0.2PFA. FEMA feels it is more pragmatic to only establish the elevation using one approach to manage the level of effort and costs needed to establish the FFRMS elevation. Additionally, by establishing only one FFRMS approach as the default approach, FEMA believes the supplementary policy would be clearer for stakeholders and applicants to identify which FFRMS approach FEMA would require for FEMA Federally Funded Projects. When using the CISA, the supplementary policy proposes that FEMA would evaluate if the CISA methodology is appropriate to the action being considered. In accordance with the Revised Guidelines, the CISA methodology should consider the criticality of the action. Flood elevations informed by the CISA can be adjusted to be higher to account for the increased consequences associated with flood damage.[57] This consideration should assist FEMA in making appropriate decisions about data sources to use in the CISA analysis to account for the flood risk to the FEMA Federally Funded Project.

Four commenters generally stated FEMA should require use of the CISA for critical and/or non-critical actions. Specifically, one commenter stated:

FEMA has an obligation to protect taxpayer dollars and thus to use climate informed science when its experts determine the data is adequate to accurately calculate the FFRMS flood level and floodplain.

Another commenter stated:

Failure to evaluate sea level rise over the next several decades would be an egregious oversight when deciding what to build, where to build, and how to build in coastal environments.

Executive Order 13690 and the FFRMS do not prescribe a particular approach regardless of the individual circumstance. Instead, they intentionally provide for flexibility in application to allow Federal agencies to develop an implementation approach that meets the needs and mission of the particular agency. FEMA had to take into account many considerations when making its determination, such as: (1) Consistency: The need to create an approach which would allow stakeholders and applicants to consistently determine which standard FEMA would apply to FEMA Federally Funded Projects; (2) disaster considerations: the ability to implement the approaches in both a non-disaster and post-disaster environment. In a post-disaster environment, FEMA needs to be able to make decisions quickly to assist communities in their recovery. Other considerations included cost as well as resilience. FEMA balanced consideration of the preference in the FFRMS for the CISA against these implementation considerations when making the decision to propose optional use of the CISA. FEMA is not proposing to require the CISA for non-critical projects; however, as the FFRMS is reevaluated annually and updated in 5 years as required by Executive Order 13690, this may change.

Four commenters stated that FEMA should comply with State, Tribal, territorial, or local government flood risk standards, when those standards are more restrictive than the FFRMS. One comment stated:

Any critical or non-critical FEMA actions or FEMA-funded projects should thus comply with all applicable [S]tate and local floodplain protection standards.

FEMA has and will continue to comply with more restrictive local floodplain management standards. FEMA is not proposing to amend § 9.11(d)(6), which prohibits FEMA from taking an action if it is inconsistent with any more restrictive Federal, State, local, Tribal, and territorial, floodplain management standards.

One comment received from an environmental action organization stated that:

The threshold for what constitutes substantial improvement/damage should be a maximum of 50%. A cumulative approach to calculate substantial improvement/damage over projects' lifetimes should be utilized.

FEMA is not proposing to amend the definition of substantial improvement in § 9.4. Substantial improvement is defined as any repair, reconstruction or other improvement of a structure or facility, which has been damaged in excess of, or the cost of which equals or exceeds, 50 percent of the market value of the structure or replacement cost of the facility. FEMA is not proposing to adopt a cumulative approach to calculate substantial improvement because FEMA does not track improvements made by applicants, without FEMA funding, to their own public facilities. If a local community has adopted a cumulative approach to calculating substantial improvement or substantial damage, FEMA will comply with the more restrictive local standard in accordance with § 9.11(d)(6).

Another commenter addressed use of the emergency action exception of the FFRMS:

While we support the provision in EO 13690 that exempts emergency action from the Federal Flood Risk Management Standard, we urge the agency to narrowly define what constitutes an emergency action [. . .] [P]ermanent work under the PA Program (PA) [. . .] should not be classified as emergency work for the purposes of exemption.

FEMA is not proposing to exempt permanent work (Categories C–G) funded by the Public Assistance program under the emergency action exception of the FFRMS.

Two commenters encouraged FEMA to address how structural flood risk management systems will affect the FFRMS floodplain. One commenter stated:

Structural flood risk management systems are intended to reduce flood risk—not eliminate flood risk. As such, the agency should evaluate flood risks if building behind such structures, including the risk of flooding should the structure fail or be breached.

FEMA will consider the factors described in section 1.B.6 of the Revised Guidelines, Structural Flood Risk Management Systems, when considering whether an action which is landward of a structural flood risk management system is in the FFRMS floodplain. Per the direction in the Revised Guidelines, flood control structures' status on effective FIRMs will not be the sole resource used to determine if a project is within the FFRMS floodplain. FEMA determinations of accreditation status, Zone AR,[58] and Zone A99 [59] may not convey the full hazard to projects landward of a flood control structure.[60] Additional information, as fully listed in the Revised Guidelines, would need to be gathered to inform the determination of if the project is within the FFRMS floodplain.

One commenter suggested FEMA should adopt a comprehensive definition of resilience, stating:

[57] Revised Guidelines at 55.

[58] Zone AR is defined as the area of special flood hazard that results from the decertification of a previously accredited flood protection system that is determined to be in the process of being restored to provide base flood protection. Mandatory flood insurance purchase requirements and floodplain management standards apply. See 44 CFR 64.3(a)(1).

[59] Zone A99 is defined as the area of special flood hazard where enough progress has been made on a protective system, such as dikes, dams, and levees, to consider it complete for insurance rating purposes. See 44 CFR 64.3(a)(1).

[60] See Revised Guidelines at 58.

> The more comprehensive definition laid out in [the Water Resources, Reform and Development Act of 2014] provides guidelines that FEMA can incorporate into its guidance [and][. . .] gives more detail and guidance to regulators and the regulated community, thereby increasing certainty.

FEMA is not proposing to define resilience in Part 9. There is no universal definition of resilience, nor is one associated with FEMA's implementation of Executive Order 13690. Section 9.11 requires FEMA to minimize potential harm to the investment at risk from flooding. With the exception of specific minimization standards in § 9.11(d), FEMA does not specify the techniques which must be used to achieve minimization of harm and improve the resilience of actions within the floodplain.

The same commenter also supported the inclusion of structures and facilities in the Revised Guidelines, stating:

> FEMA has expanded the scope of the guidelines by including their application to [F]ederal ''facilities,'' in addition to structures [. . .] By expanding the scope of the guidelines to include roads and bridges, FEMA has made an important step toward establishing more resilient and disaster-resistant communities located within [F]ederal floodplains.

However, FEMA disagrees with the comment that FEMA has expanded the scope of the guidelines. Executive Order 11988 applies to Federal actions, meaning (a) acquiring, managing and disposing of Federal lands and facilities; (b) providing federally undertaken, financed or assisted construction and improvements; and (c) conducting Federal activities and programs affecting land use, including, but not limited to, water and related land resources, planning, regulating and licensing activities. The definition of action encompasses providing federally assisted construction to both structures and facilities.

Finally, one commenter suggested FEMA should incorporate the FFRMS into agency regulations and procedures within 18 months, requesting:

> [p]lease identify which regulations, and guidance, documents will require amendment.

FEMA has identified the regulations which will require amendment to implement Executive Order 13690 and the FFRMS in this Notice of Proposed Rulemaking.

VI. FFRMS FY 2016 Appropriations Language

Section 750 of Division E of the Consolidated Appropriations Act, 2016 (Act) (Pub. L. 114–113, 129 Stat. 2242) provides that none of the funds made available under that Act or any other Act could be used to (1) implement, administer, carry out, modify, revise or enforce Executive Order 13690 other than for (a) acquiring, managing, or disposing of Federal lands or facilities; (b) providing federally undertaken, financed, or assisted construction or improvements; or (c) conducting Federal activities or programs affecting land use, including water and related land resources planning, regulating, and licensing activities; or (2) implement Executive Order 13690 in a manner that modifies the non-grant components of the National Flood Insurance Program.

FEMA does not interpret this prohibition on the use of appropriated funds to have any effect on this rulemaking or its policy development. Paragraph 750(a)(1) effectively allows for action to be taken to implement Executive Order 13690 as long as it is within the original scope of responsibilities outlined in Section 1 of Executive Order 11988. Subsection (a)(2) prohibits FEMA from implementing Executive Order 13690 in a way that modifies the non-grant components of the NFIP. Neither this rulemaking nor FEMA's policy development goes beyond the scope of Section 1 of Executive Order 11988 or modifies the non-grant components of the NFIP. Although FEMA has always applied the 8-step decision-making process to program-wide NFIP actions, such actions do not qualify as FEMA Federally Funded Projects under this rule. Therefore, the prohibition on the use of appropriated funds does not apply to this Notice of Proposed Rulemaking.

VII. Regulatory Analyses

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

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a ''significant regulatory action'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

As noted, FEMA is proposing to amend 44 CFR part 9, ''Floodplain Management and Protection of Wetlands'' and issue a supplementary policy to implement the Executive Order 13690 and the FFRMS.

The FFRMS is a flexible framework to increase resilience against flooding and to help preserve the natural values of floodplains. FEMA is proposing to incorporate the FFRMS into its existing processes, to ensure that the floodplain for FEMA Federally Funded Projects is expanded from the current base flood level to a higher vertical elevation and corresponding horizontal floodplain and that, where possible, natural systems, ecosystem processes, and nature-based approaches would be used when developing alternatives to locating Federal actions in the floodplain.

FEMA estimates that for the 10-year period after the rule goes into effect, the benefits would justify the costs. Flooding is the most common type of natural disaster in the United States, and floods are expected to be more frequent and more severe over the next century due to the projected effects of climate change.[61] The ocean has warmed, polar ice has melted, and porous landmasses have subsided.[62] Global sea level has risen by about 8 inches since reliable record keeping began in 1880 and is projected to rise another 1 to 4 feet by 2100.[63] Floods are costly natural disasters; between 1980 and 2013, the United States suffered more than $260 billion in flood-related damages.[64] This proposed rule would help protect Federal investments from future floods, and would help minimize harm in floodplains, by changing how FEMA defines the floodplain for FEMA-funded new construction and substantial improvement (*i.e.,* ''Federally Funded Projects''). The expected costs of this proposed rule are primarily due to increased elevation or floodproofing requirements of structures in the FFRMS floodplain, with the majority of these costs expected to be incurred by FEMA itself through several

[61] Walsh, J., D. Wuebbles, K. Hayhoe, J. Kossin, K. Kunkel, G. Stephens, P. Thorne, R. Vose, M. Wehner, J. Willis, D. Anderson, S. Doney, R. Feely, P. Hennon, V. Kharin, T. Knutson, F. Landerer, T. Lenton, J. Kennedy, and R. Somerville, 2014: Ch. 2: Our Changing Climate. ''Climate Change Impacts in the United States: The Third National Climate Assessment'', J. M. Melillo, Terese (T.C.) Richmond, and G. W. Yohe, Eds., U.S. Global Change Research Program, 19–67. Doi.10.7930/J0KW5CXT. Page 20.

[62] Ibid [page 21].

[63] Ibid [page 21].

[64] NOAA, National Weather Service. ''Hydrologic Information Center—Flood Loss Data''. *http://www.nws.noaa.gov/hic/.*

grant programs, which will be either passed through to taxpayers or result in lower levels of Government services. FEMA grant recipients would bear approximately 25 percent of the project costs for those grant programs that have a cost-share requirement. The cost components of this proposed rule relate to grants under FEMA's IA, PA, HMA, and GPD programs, as well as FEMA facilities and the Integrated Public Alert Warning System (IPAWS). To estimate the cost of the proposed elevation requirements FEMA uses data from the NFIP. Table 1 and Table 2 show the costs and benefits by program, that FEMA has available, annualized for the first 10 years. Most of the estimated costs come from PA Category C, which includes replacements of bridges.

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Table 1. Summary of Costs and Non-Monetized Benefits by Program (Low Estimate, 2015$)

		3% Discount Rate		7% Discount Rate	
Cost	**Undiscounted**	**Present Value**	**Annualized**	**Present Value**	**Annualized**
IA MHU	$2,376	$2,027	$238	$1,669	$238
IA PHC	$16,901	$14,417	$1,690	$11,871	$1,690
PA Category C	$56,455,153	$48,157,391	$5,645,515	$39,651,737	$5,645,515
PA Category D			Not estimated		
PA Category E	$2,593,108	$2,211,974	$259,311	$1,821,290	$259,311
PA Category F			Not estimated		
PA Category G			Not estimated		
HMA Elevation	$1,498,569	$1,278,309	$149,857	$1,052,532	$149,857
HMA Floodproofing	$23,637	$20,163	$2,364	$16,602	$2,364
FEMA Training	$173,215	$151,286	$17,735	$128,615	$18,312
Floodplain Determination	$15,156	$13,112	$1,537	$10,972	$1,562
Implementation Costs	$178,652	$170,923	$20,037	$161,503	$22,994
Benefits					
IA MHU	Not estimated				
IA PHC	Not estimated				
PA Category C	Damage Avoidance				
PA Category D	Potential Lives Saved				
PA Category E	Increased Public Health and Safety				
PA Category F	Decreased Cleanup Time				
PA Category G	Protection of Critical Facilities				
HMA Elevation	Reduction of Personal and Community Impacts				
HMA Floodproofing					
FEMA Training	Administrative Requirement of Rule				
Floodplain Determination					
Implementation Costs					

*Costs for roads not estimated

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Table 2. Summary of Costs and Non-Monetized Benefits by Program (High Estimate, 2015$)

		3% Discount Rate		7% Discount Rate	
Cost	**Undiscounted**	**Present Value**	**Annualized**	**Present Value**	**Annualized**
IA MHU	$33,833	$28,861	$3,383	$23,763	$3,383
IA PHC	$240,712	$205,332	$24,071	$169,066	$24,071
PA Category C	$338,730,847	$288,944,283	$33,873,085	$237,910,372	$33,873,085
PA Category D			Not estimated		
PA Category E	$34,371,967	$29,319,985	$3,437,197	$24,141,432	$3,437,197
PA Category F			Not estimated		
PA Category G			Not estimated		
HMA Elevation	$20,648,203	$17,613,336	$2,064,820	$14,502,434	$2,064,820
HMA Floodproofing	$32,562	$277,761	$32,562	$228,702	$32,562
FEMA Training	$173,215	$151,286	$17,735	$128,615	$18,312
Floodplain Determination	$15,156	$13,112	$1,537	$10,972	$1,562
Implementation Costs	$178,652	$170,923	$20,037	$161,503	$22,994
Benefits					
IA MHU	Not estimated				
IA PHC	Damage Avoidance				
PA Category C	Potential Lives Saved				
PA Category D	Increased Public Health and Safety				
PA Category E	Decreased Cleanup Time				
PA Category F	Protection of Critical Facilities				
PA Category G	Reduction of Personal and Community Impacts				
HMA Elevation					
HMA Floodproofing					
FEMA Training	Administrative Requirement of Rule				
Floodplain Determination					
Implementation Costs					

*Costs for roads not estimated

IA Projects

IA Permanent Housing Construction (PHC) projects and sales of Manufactured Housing Units (MHUs) would be affected by the proposed rule. Although floodproofing is a valid option in some instances, FEMA regulations prohibit the floodproofing of residential structures. In these cases, elevation is the only option. FEMA calculated the cost of elevating structures under PHC

structures by adding the cost of elevating projects between 1 foot and 3 feet above the BFE, depending on location and type of project. FEMA subtracted certain costs that it determined to be part of the baseline. Specifically, numerous States and localities have existing freeboard requirements that would result in elevation costs and benefits regardless of this proposed rule, so costs and benefits for these areas were reduced based on existing requirements. The total PHC cost is estimated to range between $1,690 and $24,071 per year for FEMA (PHCs are funded fully by FEMA). FEMA estimates that an average of 2.22 PHCs per year would be subject to FFRMS requirements. IA also includes the sale of MHUs. The total MHU cost is estimated to range between $238 and $3,383 per year. FEMA estimates that an average of 4.88 MHUs per year would be subject to FFRMS requirements. An MHU elevation must be paid fully by an IA grant recipient who ultimately purchases the MHU.

PA Projects

PA Categories C, D, E, F, and G projects would be affected by the proposed rule, but FEMA is only able to provide partial estimates of costs associated with Categories C (Roads and Bridges) and E (Public Buildings).

FEMA cannot estimate the costs of improving flood resiliency of roads because of the highly project-specific nature of road projects, and numerous options for making roads resilient. Damage to roads during flood events can be caused by erosion and scour, inundation by floodwater, or debris blockage, and can be worsened by issues such as misaligned culverts, insufficient culvert capacity, embankment erosion, road and shoulder damage, and obstructions that reduce culvert capacity. A sampling of mitigation actions that can improve the resiliency of a road to flooding include installing low water crossings, increasing culvert size, installing a relief culvert, adding rip rap to a road embankment to provide slope protection, installing structures such as aprons and baffle structures that dissipate the energy of floodwater, realigning culverts, and installing road shoulder subsurface drains.[65]

FEMA considers all PA Category C grants used to replace publicly-owned bridges to be critical actions for the purposes of this analysis. There are a variety of techniques that can be used to floodproof a bridge, but the specific techniques depends on the specific bridge, location, and circumstances. FEMA estimates that the costs of this proposed rule for Category C bridge grants would range from a low of $5,645,515 per year to a high of $33,873,085 per year. FEMA estimates that an average of 7.10 PA Category C bridge projects per year would be subject to FFRMS requirements. The total cost to the PA program is estimated to be between $5,904,826 and $37,310,281 per year. With the 75 percent cost share, the cost to FEMA would be between $4,428,620 and $27,982,711 per year, while the cost to grant recipients would be between $1,476,207 and $9,327,570 per year.

FEMA used data from PA grant approvals from 2006–2015 and used a multi-step process to estimate the range of costs for elevating Category E structures. FEMA estimates that the elevation cost for Category E non-critical actions would be a low of $219,301 per year and a high of $3,123,171 per year. FEMA estimates that an average of 19.19 PA Category E projects per year would be subject to FFRMS requirements. In addition, FEMA estimates that the total cost for Category E critical actions would range from a low of $40,009 per year to a high of $314,026 per year.

HMA Projects

FEMA used data from HMA grant approvals for elevation and floodproofing of structures from 2006–2015 and a multi-step process to estimate the range of costs for elevating or floodproofing these structures. FEMA estimates that the total cost for HMA non-critical actions for elevation projects would range from a low of $138,999 per year to a high of $1,979,591 per year. In addition, FEMA estimates that the total cost for HMA critical actions for elevation projects would range from a low of $10,858 per year to a high of $85,229 per year. FEMA estimates that an average of 73.69 HMA elevation projects per year would be subject to FFRMS requirements. The total cost for HMA non-critical actions for floodproofing projects would be a low of $2,188 per year and a high of $31,165 per year. In addition, FEMA estimates that the total cost for HMA critical actions for floodproofing projects would be a low of $176 per year and a high of $1,397 per year. FEMA estimates that an average of 4.70 HMA floodproofing projects per year would be subject to FFRMS requirements. FEMA estimates the total cost of this rule for the HMA program to be between $152,221 and $2,097,382 per year. With the 75 percent cost share, the cost to FEMA would be between $114,165 and $1,573,037 per year, while the cost to grant recipients would be between $38,055 and $524,346 per year.

HMA also funds various other types of projects, such as minor flood control, property acquisition, generators, and mitigation reconstruction, but FEMA is unable to estimate the potential costs associated with these projects because the manner in which each applicant meets the resiliency standards will be fact-specific and dependent upon the nature of the design and purpose of the project. Additional minor mitigation measures would have to be taken for these projects, if located in the expanded FFRMS floodplain. FEMA requests public comments.

The costs of the proposed rule would be from IA, PA, and HMA programs, as well as administrative costs. FEMA expects minimal costs associated with GPD and IPAWS because these programs do not fund new construction or substantial improvement projects. These projects are also by nature typically resilient from flooding. FEMA facilities may also be subject to additional requirements due to the implementation of the proposed rule.

FEMA estimates that the total additional grants costs as a result of the proposed rule would be between $906,696 and $7.8 million per year for FEMA and between $301,906 and $2.6 million per year for grant recipients due to the increased elevation or floodproofing requirements of FEMA Federally Funded Projects.

In addition, FEMA expects to incur some administrative costs as a result of this proposed rule. FEMA estimates initial training costs of around $100,000 the first two years after the rule is implemented, and administrative and training costs of around $16,000 per year thereafter. FEMA estimates that the total annual cost of this rule after year two would be between $6.1 million and $39.5 million.

FEMA estimates the quantified cost of this proposed rule over the next 10 years would range between $60.1 million and $394.7 million. The present value (PV) of these estimated costs using a 7 percent discount rate would range between $42.9 million and $277.3 million. The PV using a 3 percent discount rate would range between $52.0 million and $336.7 million. These costs would be split between FEMA (75 percent) and recipients (25 percent) of FEMA grants in the floodplain. The low estimates of the 10-year costs of this rule, discounted at 3 percent and 7 percent are presented in Table 3. The high estimates of the 10-year costs of

[65] See FEMA, ''FEMA B–797 Hazard Mitigation Field Book: Roadways'', (2010), available at *http://www.fema.gov/media-library/assets/documents/19299.*

this rule, discounted at 3 percent and 7 percent are presented in Table 4.

TABLE 3—10-YEAR COST TOTALS USING 3 PERCENT AND 7 PERCENT DISCOUNT RATES (LOW ESTIMATE, 2015$)

Year	FEMA Admin. costs	FEMA Grant costs	Recipient cost share	Undiscounted annual costs	Annual costs discounted at 3%	Annual costs discounted at 7%
1	$135,291	$4,544,475	$1,514,499	$6,194,265	$6,013,850	$5,789,033
2	105,336	4,544,475	1,514,499	6,164,310	5,810,454	5,384,147
3	16,010	4,544,475	1,514,499	6,074,984	5,559,471	4,958,997
4	16,010	4,544,475	1,514,499	6,074,984	5,397,545	4,634,576
5	16,010	4,544,475	1,514,499	6,074,984	5,240,335	4,331,380
6	16,010	4,544,475	1,514,499	6,074,984	5,087,704	4,048,019
7	16,010	4,544,475	1,514,499	6,074,984	4,939,518	3,783,195
8	16,010	4,544,475	1,514,499	6,074,984	4,795,649	3,535,696
9	16,010	4,544,475	1,514,499	6,074,984	4,655,970	3,304,389
10	16,010	4,544,475	1,514,499	6,074,984	4,520,359	3,088,214
Total	368,707	45,444,751	15,144,992	60,958,451	52,020,854	42,857,646
Annualized					6,098,431	6,101,965

TABLE 4—10-YEAR COST TOTALS USING 3 PERCENT AND 7 PERCENT DISCOUNT RATES (HIGH ESTIMATE, 2015$)

Year	FEMA Admin. costs	FEMA Grant costs	Recipient cost share	Undiscounted annual costs	Annual costs discounted at 3%	Annual costs discounted at 7%
1	$135,291	$29,579,819	$9,855,299	$39,570,409	$38,417,873	$36,981,691
2	105,336	29,579,819	9,855,299	39,540,454	37,270,670	34,536,164
3	16,010	29,579,819	9,855,299	39,451,128	36,103,371	32,203,872
4	16,010	29,579,819	9,855,299	39,451,128	35,051,817	30,097,077
5	16,010	29,579,819	9,855,299	39,451,128	34,030,890	28,128,109
6	16,010	29,579,819	9,855,299	39,451,128	33,039,699	26,287,953
7	16,010	29,579,819	9,855,299	39,451,128	32,077,378	24,568,180
8	16,010	29,579,819	9,855,299	39,451,128	31,143,085	22,960,916
9	16,010	29,579,819	9,855,299	39,451,128	30,236,005	21,458,800
10	16,010	29,579,819	9,855,299	39,451,128	29,355,345	20,054,953
Total	368,707	295,798,190	98,552,993	394,719,890	336,726,132	277,277,715
Annualized					39,474,575	39,478,109

Benefits

FEMA anticipates that the benefits of the proposed rule would justify the costs. FEMA has provided qualitative benefits, including the reduction in damage to properties and contents from future floods, potential lives saved, public health and safety benefits, reduced recovery time from floods, and increased community resilience to flooding.

FEMA believes this proposed rule would result in savings in time and money from a reduced recovery period after a flood and increased safety of individuals. Generally, if properties are protected, there would be less damage, resulting in less clean-up time. In addition, higher elevations help to protect people, leading to increased safety. FEMA is unable to quantify these benefits, but improving the resiliency of bridges has significant qualitative benefits, including: Protecting evacuation and escape routes; limiting blockages of floodwaters passing under the bridge that may lead to more severe flooding upstream; and, avoiding the cost of replacing the bridge again if it is damaged during a subsequent flood. Any estimates of these savings would be dependent on the specific circumstances and FEMA is not able to provide a numeric value on these savings.

A 2008 FEMA report analyzes potential savings from damage avoidance associated with including freeboard in the construction of new residential structures in coastal areas at various freeboard levels.[66] According to this report, in some contexts a dollar spent on elevation activities could result in a $1.30 to $8.92 return on investment, due to damage avoidance only. This report shows that the benefits of incorporating freeboard exceed the costs for certain projects located in coastal flood zones. However, the report's scope is limited to new construction of houses in coastal areas. Due to the relatively narrow scope of the study, FEMA has not used the results of this report to estimate monetized benefits of freeboard to the nationwide projects that would be affected by this rule. FEMA requests information and studies from the public that examine the benefits of freeboard for a more diverse set of projects, such as non-residential structures, retrofitting substantial improvement projects, projects in non-coastal floodplains. If FEMA receives additional information that informs an estimate of the monetized benefits of freeboard to a broad range of structures, we may provide a monetized estimate of benefits in the final rule.

For more in-depth review of these costs and benefits, please see the Regulatory Evaluation, which can be found in the docket for this rulemaking.

[66] FEMA, ''2008 Supplement to the 2006 Evaluation of the National Flood Insurance Program's Building Standards''. *http://www.fema.gov/media-library-data/20130726-1911-25045-9876/2008_freeboard_report.pdf.*

B. Regulatory Flexibility Act

This section considers the effects that this proposed rule would have on small entities as required by the Regulatory Flexibility Act (RFA, 5. U.S.C. 601 *et seq.,* Pub. L. 96–354) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a ''significant economic impact on a substantial number of small entities.'' 5 U.S.C. 605(b). Small entities include small businesses, small organizations, and small governmental jurisdictions.

FEMA prepared an Initial Regulatory Flexibility Analysis (IRFA) for this proposed rule. This analysis is detailed in this section and represents FEMA's assessment of the impacts of this proposed rule on small entities. Section 1 outlines FEMA's initial assessment of small entities that would be affected by the proposed regulations. Section 2 presents FEMA's analysis and summarizes the steps taken by FEMA to comply with the RFA.

1. Initial Assessment of Small Entities Affected by the Proposed Regulations

The proposed rule would affect FEMA grant recipients that receive Federal funds for new construction, substantial improvement to structures, or to address substantial damage to structures and facilities. Many of these grants are available to local governmental jurisdictions and non-profit organizations. FEMA does not provide grants to for-profit businesses.

2. Analysis and Steps Taken To Comply With the Regulatory Flexibility Act

The following IRFA addresses the following requirements of the RFA:

(1) A description of the reasons why action by the agency is being considered;

(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;

(3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

(4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

(5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule;

(6) a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as: The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; the use of performance rather than design standards; and an exemption from coverage of the rule, or any part thereof, for such small entities.

2.1 Description of the Reasons Why Action by the Agency Is Being Considered

On January 30, 2015, the President issued Executive Order 13690, which amended Executive Order 11988 and established a new flood risk management standard called the FFRMS. Executive Order 13690 directs agencies to issue or amend their existing regulations and procedures to comply with the Order; therefore, FEMA is updating its regulations at 44 CFR part 9 and issuing an FFRMS policy.

The FFRMS is intended to reduce flood risk by expanding the floodplain with respect to Federally Funded Projects, revising the definition of the floodplain, adding a definition of ''critical action,'' and requiring agencies to use natural systems, ecosystem processes, and nature-based approaches in the development of alternatives for Federal actions in the floodplain.

2.2 Succinct Statement of the Objectives of, and Legal Basis for, the Proposed Rule

FEMA is responsible for publishing information on floodplain areas and identifying special hazards. FEMA is also responsible for several grant programs that use Federal funds to assist in construction or reconstruction following a disaster, as well as grants for hazard mitigation and recovery. These grants can potentially be used for locations within a floodplain.

To meet the requirements of section 2(d) of Executive Order 11988, requiring agencies to issue or amend existing regulations and procedures to implement the Executive Order, FEMA promulgated regulations which are located at 44 CFR part 9. FEMA is revising 44 CFR part 9 to reflect the changes to Executive Order 11988 made via Executive Order 13690.

The objective of the proposed rule is to revise the regulations for locating FEMA Federally Funded Projects in an expanded floodplain to reduce the risk of flooding to those projects. In addition, for actions that are determined to be ''critical actions'' as defined by the proposed rule, the proposed rule would impose more stringent elevation and resiliency requirements. This is necessary to protect actions where even a slight chance of flooding is too great.

The rule would also require the use of nature-based approaches, where possible, when considering alternatives for development in the floodplain. Nature-based approaches can include both natural and engineered features. The objective of requiring the use, where possible, of nature-based approaches is to help to restore the floodplain's natural processes. The use of nature-based approaches may result in reduced flood risks. In addition, nature-based approaches have less potential to degrade the natural and beneficial values of floodplains. Some examples of nature-based approaches could include restoring wetland functions along a coastal or riverine system to create a living shoreline or using green infrastructure measures to reduce runoff.

2.3 Description Of and Where Feasible, an Estimate of the Number of Small Entities To Which the Proposed Rule Will Apply

This rule would affect certain recipients of FEMA grants. These would primarily be PA and HMA grant recipients, which include States, Tribal governments, local governments and certain non-profit organizations. The PA grant recipients would include Categories C, D, E, F, and G projects however, FEMA is only able to provide reasonable estimates of the number of entities and costs associated with Categories C (roads and bridges) and E (public buildings). IA and GPD are not discussed in this analysis. IA provides grants directly to individuals and individuals are not small entities as defined in 5 U.S.C. 601(6). FEMA finds that this rule would likely have no effect on GPD grants because GPD projects are not typically substantial improvement or new construction.

PA provides grants to States, Tribal governments, local governments and certain non-profit organizations for rebuilding, replacement, or repair of public and non-profit facilities damaged

by disasters. Where such rebuilding, replacement or repair involves new construction, substantial improvement, and repair of substantial damage of structures in the expanded FFRMS floodplain, PA recipients would incur additional costs to comply with proposed elevation and floodproofing requirements. Out of a population [67] of 20,341 individual PA Category E grant recipients, a random sample of 96 recipients [68] shows that 79 projects (approximately 82 percent) would meet the definition of small entities under the Regulatory Flexibility Act. This was made up of 45 small governments, 33 private non-profits, and one Tribal government. According to historical data, there have been an average of 44 new construction, substantial improvement, or repair of substantial damage PA Category E projects annually over the past 10 years with approximately 19 of these located in the 1 percent annual chance floodplain or expanded FFRMS floodplain. Therefore, FEMA estimates that 16 small entities would be affected each year through PA Category E projects (19 × 82 percent). As discussed earlier, FEMA did not include Categories D, F, and G projects therefore the total number of affected entities could be higher.

HMA provides mitigation grants to States, Tribal governments, local governments and certain non-profit organizations to, among other things, relocate property outside of the floodplain, or to elevate or floodproof structures to the flood level. As noted in the Regulatory Evaluation, HMA has funded an average of 67 projects per year from 2006–2015. Unlike PA grants, the majority of HMA grants are for projects located in the floodplain, so for this analysis FEMA assumes that all HMA projects are in the floodplain. FEMA has estimated that the freeboard requirements would expand the floodplain by 16.8 percent based on studies conducted in 24 U.S. counties with varied topography. With the 16.8 percent expansion of the floodplain, HMA would have an additional 11 projects per year (67 × 16.8 percent = 11) for a total of 78 projects located in the 1 percent annual chance floodplain or expanded FFRMS floodplain. Assuming 82 percent [69] of HMA grant recipients are small entities, the proposed rule would affect approximately 64 small entities per year (78 projects × 82 percent).

2.4 Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record

FEMA will not be changing the application process for its grant programs. The majority of the costs of this proposed rule would fall on FEMA. Small entities, like all entities, would be subject to additional costs associated with floodproofing, elevation of structures, and flood resiliency measures required by the proposed rule. For the purposes of this analysis, and based on historical data, FEMA presents the costs such that most projects would choose to elevate because of the additional level of safety elevation provides over floodproofing and a historically higher number of projects that involved elevation as opposed to floodproofing.[70] FEMA uses an NFIP report to estimate the cost of the proposed elevation requirements.[71] The report provides estimates for the cost of elevating structures as a percentage of total construction cost.

According to HMA data, the average cost of floodproofing is 50 percent of the cost of freeboard elevation. Floodproofing involves sealing off areas below the flood level so that water cannot enter, or altering the use of these areas so that flood waters may pass through without causing serious damage. Non-residential structures where elevation is not feasible may be floodproofed rather than elevated. Additionally, floodproofing preexisting properties may be less costly than elevating an existing property. So, where a project may floodproof rather than elevate, costs may be lower for some projects than the costs presented here. However, for existing properties that choose to elevate rather than floodproof, costs may be higher for some projects than the costs presented here because the NFIP report cost estimates are for when freeboard is included in the design of a structure. FEMA requests comments on these assumptions.

The Federal cost-share of eligible PA work is generally 75 percent, so PA recipients would be required to fund 25 percent of the costs to comply with the requirements of the proposed rule.[72] FEMA estimates that the average annual cost of the proposed rule for PA Category E projects would be between $13,648 and $180,905 [73] per project. Using the Federal cost share, each small entity would have an average expected cost between $3,412 ($13,648 × 25 percent cost share) and $45,226 ($180,905 × 25 percent).

The cost-sharing arrangement for HMA is 75 percent Federal and 25 percent recipient, so HMA recipients would be required to fund 25 percent of the costs to comply with the requirements of the proposed rule. FEMA estimates the average cost of the proposed rule for HMA projects would be between $1,952 and $26,890 annually.[74] Using the Federal cost share, each small entities would have an average cost between $488 ($1,952 × 0.25) and $6,722 ($26,890 × 0.25).

Reporting and recordkeeping is not expected to change with the exception of minor changes to FEMA's Mitigation Grant Program/e-Grants system. This is an automated grant application and management system that would have one question changed as a result of this proposed rule. FEMA would still make the determination if a project would take place in an FFRMS floodplain. (See

[67] PA Category C grant recipients (Roads & Bridges) were not included in this population as the dataset that FEMA used lists the project grantees (States and Tribes), and not subgrantees (local governments and private non-profits). Therefore FEMA is not able to estimate the number of small entities affected by Category C grants. Over the past 10 years, PA has funded the replacement of 71 bridges. FEMA requests data and/or comments to determine how many bridge replacement project grants go to small entities.

[68] The population of PA Category E projects includes all ''Public Buildings'' grants from 2006–2015. Because of the large population, a random sample of 96 projects was drawn, using a confidence level of 95 percent and a 10 percent confidence interval.

[69] In FEMA's dataset, HMA recipients only included project titles and not the name of the grantee. This prevented FEMA from determining if a grant recipient was a small entity. Since PA and HMA provide funding to similar entities (States, Tribal governments, local governments and certain non-profit organizations) for disaster related activity, FEMA used the percentages of small entity grant recipients found in PA Category E as a proxy for HMA small entities.

[70] According to historical HMA data, there have been an average of 63 elevation projects and only 4 floodproofing projects per year.

[71] FEMA, ''2008 Supplement to the 2006 Evaluation of the national Flood Insurance Program's Building Standards'' Table 3. *http://www.fema.gov/media-library-data/20130726-1911-25045-9876/2008_freeboard_report.pdf.*

[72] In extraordinary circumstances the Federal share for PA may be 90 percent when actual Federal obligations exceed a qualifying threshold. See 44 CFR 206.47.

[73] According to the Regulatory Evaluation for this proposed rule, FEMA estimates the average annual cost for 19 PA Category E projects is between $259,311 and $3,437,197. The estimated cost per project is between $13,648 ($259,311/19) and $180,905 ($3,437,197/19). For information about how FEMA arrived at these estimates, please see the Regulatory Evaluation for this proposed rule located in the docket.

[74] According to the Regulatory Evaluation for this proposed rule, FEMA estimates the annual cost for 78 HMA projects is between $152,221 and $2,097,382. The estimated cost per project is between $1,952 ($152,221/78 projects) and $26,890 ($2,097,382/78 projects). For information about how FEMA arrived at these estimates, please see the Regulatory Evaluation for this proposed rule located in the docket.

the Paperwork Reduction Act section of this preamble below for information about the proposed revision to this collection of information.)

2.5 Identification, to the Extent Practicable, of Relevant Federal Rules Which may Duplicate, Overlap, or Conflict With the Proposed Rule

This rule does not duplicate, overlap, or conflict with other Federal rules as the proposed rule only relates for FEMA Federally Funded Projects. Existing FEMA rules relating to compliance with Executive Order 11988, Floodplain Management are being modified to comply with Executive Order 13690, which amends Executive Order 11988.

2.6 Description of Any Significant Alternatives to the Proposed Rule Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact of the Proposed Rule on Small Entities

The standards proposed in this rule represent FEMA's efforts to implement Executive Order 13690, which establishes executive branch-wide policy in this area. Small entities would have the option to relocate outside of the floodplain. This may be preferable in cases where property can be obtained and new facilities built for less cost than elevating or floodproofing to the freeboard level in the floodplain, and the recipient has the ability to relocate.

Executive Order 13690 allows several approaches to determine the FFRMS floodplain, but FEMA is proposing to adopt the FFRMS–FVA in most cases. The FFRMS–FVA uses the most easily attainable data for elevation and floodproofing standards and is the most consistent with existing State and local regulations. As a result, FEMA's proposed approach would reduce the burden on small entities by not requiring a separate set of Federal requirements that are more likely to be different from existing State and local requirements. Section F of this NPRM, FEMA's Implementation of Executive Order 13690 and FFRMS, describes the FFRMS approaches allowed by Executive Order 13690 and FEMA's considerations when selecting between the FFRMS approaches.

FEMA invites all interested parties to submit data and information regarding the potential economic impact that would result from adoption of the proposals in this proposed rule. FEMA will consider all comments received in the public comment process.

C. Unfunded Mandates Reform Act

Pursuant to Section 201 of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4, 2 U.S.C. 1531), each Federal agency shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law). Section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532) further requires that before promulgating any general notice of proposed rulemaking that is likely to result in the promulgation of any rule that includes any Federal mandate that may result in expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement detailing the effect on State, local, and Tribal governments and the private sector. The proposed rule would not result in such an expenditure, and thus preparation of such a statement is not required.

D. National Environmental Policy Act (NEPA) of 1969

Section 102 of the National Environmental Policy Act of 1969 (NEPA), Public Law 91–190, 83 Stat. 852 (Jan. 1, 1970) (42 U.S.C. 4321 *et seq.*) requires agencies to consider the impacts of their actions on the quality of the human environment. The Council on Environmental Quality's procedures for implementing NEPA, 40 CFR 1500 through 1508, require Federal agencies to prepare Environmental Impact Statements (EIS) for major Federal actions significantly affecting the quality of the human environment. Each agency can develop categorical exclusions to cover actions that have been demonstrated to not typically trigger significant impacts to the human environment individually or cumulatively. Agencies develop environmental assessments (EA) to evaluate those actions that do not fit an agency's categorical exclusion and those actions for which a categorical exclusion applies but extraordinary circumstances exist. At the end of the EA process the agency will determine whether to make a Finding of No Significant Impact or whether to initiate the EIS process.

Rulemaking is a major Federal action subject to NEPA. Categorical exclusion A3 included in the list of exclusion categories at Department of Homeland Security Instruction Manual 023–01–001–01, Revision 01, Implementation of the National Environmental Policy Act, Appendix A, issued November 6, 2014, covers the promulgation of rules, issuance of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures, manuals, and advisory circulars. The purpose of this proposed rule is to update the Floodplain Management and Protection of Wetland requirements to adopt the approaches outlined in Executive Order 13690 to establish the floodplain and associated flood elevation that must be used in the decision-making process to be followed by FEMA in applying Executive Orders 11988 and 13690 to its actions. The decision-making process requires FEMA to determine whether a proposed action is located in a wetland and/or the floodplain. FEMA is required to take mitigative measures, if it makes the determination to carry out an action in the floodplain. The rule would also add a requirement to use natural systems, ecosystem processes, and nature-based approaches in the development of alternatives for Federal actions in a floodplain. The result of applying the approaches outlined in Executive Order 13690 to establish the floodplain and associated flood elevation may be additional structures elevated or structures elevated to a higher level. Federal assistance for the reconstruction, elevation, retrofitting, upgrading to current codes and standards, and improvements to pre-existing facilities when the immediate project area has already been disturbed and when those actions do not alter basic functions, do not exceed the capacity of other system components, or modify intended land use are categorically excluded under Department of Homeland Security Instruction Manual 023–01–001–01, Revision 01, Implementation of the National Environmental Policy Act, Appendix A (N7). New construction upon or improvement of land where the proposed use is compatible with applicable planning and zoning standards and coastal management programs, the site is in a developed or previously-disturbed site, the proposed use will not substantially increase the number of motor vehicles in the area, the site and scale of construction are consistent with nearby buildings, and the construction or improvement will not result in uses that exceed the existing support infrastructure capacities are categorically excluded under Department of Homeland

Security Instruction Manual 023–01–001–01, Revision 01, Implementation of the National Environmental Policy Act, Appendix A (E2). No extraordinary circumstances exist that will trigger the need to develop an EA or EIS. See Department of Homeland Security Instruction Manual 023–01–001–01, Revision 01, Implementation of the National Environmental Policy Act, section (V)(B)(2). An EA will not be prepared because a categorical exclusion applies to this rulemaking action and no extraordinary circumstances exist.

E. Paperwork Reduction Act (PRA) of 1995

As required by the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, 109 Stat. 163, (May 22, 1995) (44 U.S.C. 3501 *et seq.*), FEMA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

In this proposed rule, FEMA is seeking a revision to the already existing collection of information, OMB Control Number 1660–0072, because FEMA is proposing to replace question E.1. on screenshot #10 in order to comply with the proposed FFRMS requirements. Currently, 1660–0072's screenshot #10, E.1. reads: ''Does a Flood Insurance Rate Map (FIRM), Flood Hazard Boundary Map (FHBM), hydrologic study, or some other source indicate that the project is located in or will affect a 100-year floodplain, a 500-year floodplain if a critical facility, an identified regulatory floodway, or an area prone to flooding?'' We are proposing to change it to: ''Does a Flood Insurance Rate Map (FIRM), Flood Hazard Boundary Map (FHBM), hydrologic study, or some other source indicate that the project is located in or will affect a floodplain (including a base floodplain, 500-year floodplain, or FFRMS floodplain), an identified regulatory floodway, or an area prone to flooding?'' This proposed rule serves as the 60-day comment period for this proposed change pursuant to 5 CFR 1320.11. FEMA invites the general public to comment on the proposed collection of information.

Collection of Information

Title: Mitigation Grant Program/e-Grants.

Type of Information Collection: Revision of a currently approved collection.

OMB Number: 1660–0072.

FEMA Forms: FEMA Form 101–0–0–1, Benefit Cost Determination; FEMA Form 093–0–0–1, Environmental Review; FEMA Form 080–0–0–12, Project Narrative-Sub-grant Application.

Abstract: The FEMA pre-disaster mitigation grant programs—FMA and PDM—both utilize an automated grant application and management system known as e-Grants to apply for these grants. These programs provide funding to allow for the reduction or elimination of the risks to lives and property from hazards. The e-Grants system also provides the mechanism to provide quarterly reports of the financial status of the project and the final closeout report.

Affected Public: State, local and Tribal Governments.

Estimated Number of Respondents: 56.

Estimated Number of Responses: 5,264.

Estimated Total Annual Burden Hours: 43,848.

Estimated Cost: There are no operation and maintenance, or capital and start-up costs associated with this collection of information.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

F. Privacy Act

Under the Privacy Act of 1974, 5 U.S.C. 552a, an agency must determine whether implementation of a proposed regulation would result in a system of records. A ''record'' is any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his/her education, financial transactions, medical history, and criminal or employment history and that contains his/her name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph. See 5 U.S.C. 552a(a)(4). A ''system of records'' is a group of records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. An agency cannot disclose any record, which is contained in a system of records, except by following specific procedures.

In accordance with DHS policy, FEMA has completed a Privacy Threshold Analysis for this proposed rule. This proposed rule does not affect the 1660–0072 OMB Control Number's current compliance with the Privacy Act of 1974, as amended, or the E-Government Act of 2002. OMB Control Number 1660–0072 is covered by the DHS/FEMA/PIA–006—FEMA National Emergency Management Information System Mitigation Electronic Grants Management System Privacy Impact Assessment (PIA). As a result, no update to DHS/FEMA/PIA–006 is necessary. OMB Control Number 1660–0072 is covered under the System of Records Notice (SORN) for DHS/FEMA–009 Hazard Mitigation, Disaster Public Assistance, and Disaster Loan Programs, 79 FR 16015, Mar. 24, 2014. This proposed rule does not create a new system of records and no update to this SORN is necessary.

G. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, ''Consultation and Coordination With Indian Tribal Governments,'' 65 FR 67249, Nov. 9, 2000, applies to agency regulations that have Tribal implications, that is, regulations that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Under this Executive Order, to the extent practicable and permitted by law, no agency shall promulgate any regulation that has Tribal implications, that imposes substantial direct compliance costs on Indian Tribal governments, and that is not required by statute, unless funds necessary to pay the direct costs incurred by the Indian Tribal government or the Tribe in complying with the regulations are provided by the Federal Government, or the agency consults with Tribal officials.

FEMA has reviewed this proposed rule under Executive Order 13175 and

has determined that this rule does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

Part 9 applies to FEMA disaster and non-disaster assistance programs, including PA, Individual Assistance, HMA, and grants processed by GPD. Pursuant to section 8 of Executive Order 11988, Part 9 does not apply to assistance provided for emergency work essential to save lives and protect property and public health and safety, performed pursuant to sections 403 and 502 of the Stafford Act, as amended (42 U.S.C. 5170b and 5192).

Indian Tribes have the same opportunity to participate in FEMA's grant programs as other eligible participants, and participation is voluntary. The requirements of this rule do not affect Tribes differently than other grant recipients. Therefore, FEMA does not expect this proposed rule to have a substantial direct effect on one or more Indian Tribes or impose substantial direct compliance costs on Indian Tribal governments, but will consider any information provided in comments to inform its analysis of this issue as part of a final rule.

Notwithstanding FEMA's conclusion that this proposed rule does not have tribal implications, FEMA recognizes the importance of engaging with Tribes with respect to the FFRMS. FEMA therefore summarizes below the extensive engagement process that precedes this rule, including significant engagement with Tribal leaders. As noted above, in the aftermath of Hurricane Sandy, the President issued Executive Order 13632,[75] which created the Federal Interagency Hurricane Sandy Rebuilding Task Force (Sandy Task Force). This Task Force was chaired by the Secretary of HUD, who led the effort in coordination with multiple Federal partners, as well as an advisory group composed of State, local, and Tribal elected leaders.

In June 2013, the President issued a Climate Action Plan which directs agencies to take the appropriate actions to reduce risk to Federal investments, specifically directing agencies to build on the work done by the Sandy Task Force and update their flood risk reduction standards for ''federally-funded projects'' to ensure that ''projects funded with taxpayer dollars last as long as intended.'' In November 2013, the Climate Task Force convened, with 26 Governors, mayors, and local and Tribal leaders serving as members. After a year-long process of receiving input from across State, local, Tribal and territorial governments; private businesses; trade associations; academic organizations; civil society; and other stakeholders, the Task Force provided a recommendation to the President in November 2014 that, in order to ensure resiliency, Federal agencies, when taking actions in and around floodplains, should include considerations of the effects of climate change, including sea level rise, more frequent and severe storms, and increasing river flood risks.

Executive Order 13690 amended Executive Order 11988 and established the FFRMS. It also set forth a process by which additional input from stakeholders could be solicited and considered before agencies took any action to implement the FFRMS. It required FEMA to publish, on behalf of the MitFLG, an updated draft version of the 1978 Guidelines[76] revised to incorporate the changes required by Executive Order 13690 and the FFRMS in the **Federal Register** for notice and comment. After the MitFLG received and adjudicated the comments, Executive Order 13690 required the MitFLG to submit to the WRC recommendations for finalizing the draft Guidelines.

FEMA, on behalf of MitFLG, published a **Federal Register** notice for a 60-day notice and comment period seeking comments on a draft of the Revised Guidelines, 80 FR 6530, Feb. 5, 2015. Additionally, on February 27, 2015, FEMA wrote to Tribal Leaders specifically asking for their comments regarding the Executive Order establishing the FFRMS.

In response to multiple requests, the MitFLG extended the comment period for an additional 30 days to end on May 6, 2015. The Administration also attended or hosted over 25 meetings across the country with State, local, and Tribal officials (including 26 mayors) and interested stakeholders to discuss Executive Order 13690 and the Guidelines. The MitFLG held 9 public listening sessions across the country that were attended by over 700 participants from State, local, and Tribal governments and other stakeholder organizations to discuss the Guidelines. There were Tribal representatives at both the Ames, Iowa and Sacramento, California listening sessions; however, the specific Tribes that they were representing were not identified. The MitFLG published notice of these public listening sessions in the **Federal Register**.

The public comment period closed on May 6, 2015. Two Tribes submitted formal comments on the Guidelines during the **Federal Register** comment period. The MitFLG adjudicated all comments and presented its adjudication and recommendations to the WRC as required. The WRC issued the Revised Guidelines on October 8, 2015 and the corresponding Notice published in the October 22, 2015 **Federal Register** at 80 FR 64008.

FEMA welcomes Tribal comments on all aspects of this proposed rule.

H. Executive Order 13132, Federalism

Executive Order 13132, ''Federalism,'' 64 FR 43255, Aug. 10, 1999, sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, that is, regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Federal agencies must closely examine the statutory authority supporting any action that would limit the policymaking discretion of the States, and to the extent practicable, must consult with State and local officials before implementing any such action.

FEMA has reviewed this proposed rule under Executive Order 13132 and has determined that this rule does not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore does not have federalism implications as defined by the Executive Order.

Part 9 applies to FEMA disaster and non-disaster assistance programs, including Public Assistance, Individual Assistance, HMA, and grants processed from GPD. Pursuant to section 8 of Executive Order 11988, Part 9 does not apply to assistance provided for emergency work essential to save lives and protect property and public health and safety, performed pursuant to section 403 and 502 of the Stafford Act, as amended (42 U.S.C. 5170b and 5192). The proposed rule does not significantly affect the rights, roles, and responsibilities of States, and involves no preemption of State law nor does it limit State policymaking discretion.

[75] 77 FR 74341, Dec. 14, 2012.

[76] The 1978 Guidelines were the original interpretation of Executive Order 11988.

I. Executive Order 12898, Environmental Justice

Under Executive Order 12898, ''Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations,'' (59 FR 7629, Feb. 16, 1994), as amended by Executive Order 12948, (60 FR 6381, Feb. 1, 1995), FEMA incorporates environmental justice into its policies and programs. The Executive Order requires each Federal agency to conduct its programs, policies, and activities that substantially affect human health or the environment, in a manner that ensures that such programs, policies, and activities do not have the effect of excluding persons from participation in programs, denying persons the benefits of programs, or subjecting persons to discrimination because of race, color, national origin or income level.

FEMA does not expect this rule to have a disproportionately high and adverse human health or environmental effect on low income or minority populations, but will consider any information provided in comments to inform its analysis of this issue as part of a final rule.

J. Executive Order 12630, Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, ''Governmental Actions and Interference With Constitutionally Protected Property Rights'' (53 FR 8859, Mar. 18, 1988).

K. Executive Order 12988, Civil Justice Reform

This NPRM meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, ''Civil Justice Reform'' (61 FR 4729, Feb. 7, 1996), to minimize litigation, eliminate ambiguity, and reduce burden.

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

This NPRM will not create environmental health risks or safety risks for children under Executive Order 13045, ''Protection of Children From Environmental Health Risks and Safety Risks'' (62 FR 19885, Apr. 23, 1997).

M. Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, OMB Circular A–119

''Voluntary consensus standards'' are standards developed or adopted by voluntary consensus standards bodies, both domestic and international. These standards include provisions requiring that owners of relevant intellectual property have agreed to make that intellectual property available on a non-discriminatory, royalty-free or reasonable royalty basis to all interested parties. OMB Circular A–119 directs agencies to use voluntary consensus standards in their regulatory actions in lieu of government-unique standards except where inconsistent with law or otherwise impractical. The policies in the Circular are intended to reduce to a minimum the reliance by agencies on government-unique standards.

Consistent with President Obama's Climate Action Plan,[77] the National Security Council staff coordinated an interagency effort to create a new flood risk reduction standard for Federally Funded Projects. The views of Governors, mayors, and other stakeholders were solicited and considered as efforts were made to establish a new flood risk reduction standard for Federally Funded Projects. The FFRMS is the result of these efforts.

List of Subjects in 44 CFR Part 9

Flood plains and Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, FEMA proposes to amend 44 CFR part 9, as follows:

PART 9—FLOODPLAIN MANAGEMENT AND PROTECTION OF WETLANDS

■ 1. The authority citation for part 9 is revised to read as follows:

Authority: E.O. 11988 of May 24, 1977. 3 CFR, 1977 Comp., p. 117; E.O. 11990 of May 24, 1977, 3 CFR, 1977 Comp. p. 121; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127 of March 31, 1979, 44 FR 19367, 3 CFR, 1979 Comp., p. 376; E.O. 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412, as amended; 42 U.S.C. 5201; E.O. 13690, 80 FR 6425.

■ 2. Revise § 9.1 to read as follows:

§ 9.1 Purpose of part.

This regulation sets forth the policy, procedure, and responsibilities to implement and enforce Executive Order 11988, Floodplain Management, as amended, and Executive Order 11990, Protection of Wetlands.

■ 3. Amend § 9.2 by revising paragraph (b)(3) to read as follows:

§ 9.2 Policy.

* * * * *

(b) * * *

(3) Reduce the risk of flood loss to life and property and improve the resilience of communities and Federal assets against the impacts of flooding based on the best-available and actionable science;

* * * * *

■ 4. In § 9.3:

■ a. Amend paragraph (a) by adding ''and was amended by Executive Order 13690, January 30, 2015,'' to the end of the phrase; and

■ b. Revise the third sentence of paragraph (d).

The revision reads as follows:

§ 9.3 Authority.

* * * * *

(d) * * * Section 2(d) of Executive Order 11988 and Section 3(c) of Executive Order 13690 require issuance of new or amended regulations and procedures to satisfy their substantive and procedural provisions. * * *

■ 5. In § 9.4:

■ a. Add in alphanumeric order definitions for ''0.2 Percent Annual Chance Flood,'' ''0.2 Percent Annual Chance Floodplain,'' ''1 Percent Annual Chance Flood or Base Flood,'' ''1 Percent Annual Chance Flood Elevation or Base Flood Elevation,'' ''1 Percent Annual Chance Floodplain or Base Floodplain,'' and ''Associate Administrator;''

■ b. Remove the definitions of ''Base Flood'' and ''Base Floodplain;''

■ c. Revise the definition of ''Critical Action;''

■ d. Remove the definition of ''Emergency Actions;''

■ e. Add in alphabetical order definitions for ''Emergency Work,'' ''Federal Flood Risk Management Standard (FFRMS),'' ''Federal Flood Risk Management Standard Floodplain,'' ''FEMA Federally Funded Project,'' and ''FIMA;''

■ f. Remove the definitions of ''Five Hundred Year Floodplain'' and ''FIA,''

■ g. Revise the definition of ''Floodplain;''

■ h. Remove the definition of ''Mitigation Directorate;''

■ i. Add in alphabetical order a definition for ''Nature-Based Approaches;'' and

■ j. Revise the definitions of ''New Construction,'' ''Orders,'' and ''Substantial Improvement.''

The additions and revisions read as follows:

§ 9.4 Definitions.

0.2 Percent Annual Chance Flood means the flood which has a 0.2 percent

[77] The White House, ''President Obama's Climate Action Plan, 2nd Anniversary Progress Report—Continuing to cut carbon, pollution, protect American communities, and lead internationally.'' June 2015. *https://www.whitehouse.gov/sites/default/files/docs/cap_progress_report_final_w_cover.pdf.*

chance of being equaled or exceeded in any given year.

0.2 Percent Annual Chance Floodplain means the area subject to flooding by the 0.2 percent annual chance flood.

1 Percent Annual Chance Flood or Base Flood means the flood that has a 1 percent chance of being equaled or exceeded in any given year.

1 Percent Annual Chance Flood Elevation or Base Flood Elevation means the computed elevation to which floodwater is anticipated to rise during the 1 percent annual chance or base flood. The specific term ''base flood elevation'' or BFE is used in the National Flood Insurance Program (NFIP) and shown on FEMA Flood Insurance Rate Maps (FIRMs) and on the flood profiles in the FEMA Flood Insurance Study (FIS) Reports to indicate the minimum level of flooding to be used by a community in its floodplain management regulations.

1 Percent Annual Chance Floodplain or Base Floodplain means the area subject to flooding by the 1 percent annual chance or base flood.

* * * * *

Associate Administrator means the Associate Administrator of the Federal Insurance and Mitigation Administration.

* * * * *

Critical Action means an action for which even a slight chance of flooding is too great. Critical actions include, but are not limited to, those which create or extend the useful life of structures or facilities:

(1) Such as those which produce, use or store highly volatile, flammable, explosive, toxic or water-reactive materials;

(2) Such as hospitals and nursing homes, and housing for the elderly, which are likely to contain occupants who may not be sufficiently mobile to avoid the loss of life or injury during flood and storm events;

(3) Such as emergency operation centers, or data storage centers which contain records or services that may become lost or inoperative during flood and storm events; and

(4) Such as generating plants, and other principal points of utility lines.

* * * * *

Emergency Work means work essential to save lives and protect property and public health and safety performed under sections 403 and 502 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988 (42 U.S.C. 5170b and 5192). See 44 CFR part 206, subpart C.

* * * * *

Federal Flood Risk Management Standard (FFRMS) means the Federal flood risk management standard established by Executive Order 13690 to be incorporated into existing processes used to implement Executive Order 11988.

Federal Flood Risk Management Standard (FFRMS) Floodplain means the floodplain established using one of the following approaches:

(1) Climate-Informed Science Approach (CISA)—the elevation and flood hazard area that result from using a climate-informed science approach that uses the best-available, actionable hydrologic and hydraulic data and methods that integrate current and future changes in flooding based on climate science. This approach will also include an emphasis on whether the action is a critical action as one of the factors to be considered when conducting the analysis;

(2) Freeboard Value Approach (FVA)—the elevation and flood hazard area that result from using the freeboard value, reached by adding an additional 2 feet to the base flood elevation for non-critical actions and by adding an additional 3 feet to the base flood elevation for critical actions;

(3) 0.2 Percent Annual Chance Flood Approach (0.2PFA)—the area subject to flooding by the 0.2 percent annual chance flood; or

(4) The elevation and flood hazard area that result from using any other method identified in an update to the FFRMS.

FEMA Federally Funded Project means actions where FEMA funds are used for new construction, substantial improvement, or to address substantial damage to a structure or facility.

* * * * *

FIMA means the Federal Insurance and Mitigation Administration.

* * * * *

Floodplain means the lowland and relatively flat areas adjoining inland and coastal waters. The floodplain may be more specifically identified as the 1 percent annual chance (base) floodplain, the 0.2 percent annual chance floodplain, or the FFRMS floodplain. ''Floodplain'' does not include areas subject only to mudflow until FIMA adopts maps identifying ''M'' Zones.

* * * * *

Nature-Based Approaches means the features (sometimes referred to as ''green infrastructure'') designed to mimic natural processes and provide specific services such as reducing flood risk and/or improving water quality. Nature-based approaches are created by human design (in concert with and to accommodate natural processes) and generally, but not always, must be maintained in order to reliably provide the intended level of service.

New Construction means the construction of a new structure or facility or the replacement of a structure or facility which has been totally destroyed.

* * * * *

Orders means Executive Order 11988, Floodplain Management, as amended by Executive Order 13690, and Executive Order 11990, Protection of Wetlands.

* * * * *

Substantial Improvement means any repair, reconstruction or other improvement of a structure or facility, which has been damaged in excess of, or the cost of which equals or exceeds, 50% of the market value of the structure or replacement cost of the facility (including all ''public facilities'' as defined in the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988) before the repair or improvement is started, or if the structure or facility has been damaged and is proposed to be restored, before the damage occurred. If a facility is an essential link in a larger system, the percentage of damage will be based on the relative cost of repairing the damaged facility to the replacement cost of the portion of the system which is operationally dependent on the facility. The term ''substantial improvement'' does not include any alteration of a structure or facility listed on the National Register of Historic Places or a State Inventory of Historic Places.

* * * * *

■ 6. In § 9.5:

■ a. Revise paragraph (a)(3) and the last sentence in paragraph (c) introductory text, and paragraphs (c)(1) through (12);

■ b. Remove paragraphs (c)(13) and (14);

■ c. Revise the last sentence of paragraph (d) introductory text, paragraphs (d)(1) through (3), paragraph (d)(4) introductory text, the second sentence of paragraph (e), paragraph (f)(1), paragraph (f)(2) introductory text, and the fourth and fifth sentences of paragraph (g) introductory text.

The revisions read as follows:

§ 9.5 Scope.

(a) * * *

(3) The amendments to this part incorporating the changes required by Executive Order 13690 and the FFRMS apply to new actions commenced on or after.

* * * * *

(c) * * * The provisions of these regulations do not apply to the following (all references are to the

Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988, Public Law 93–288, as amended, except as noted):

(1) Assistance provided for emergency work essential to save lives and protect property and public health and safety performed pursuant to sections 403 and 502;

(2) Emergency Support Teams (section 303);

(3) Unemployment Assistance (section 410);

(4) Emergency Communications (section 418);

(5) Emergency Public Transportation (section 419);

(6) Fire Management Assistance (Section 420);

(7) Community Disaster Loans (section 417), except to the extent that the proceeds of the loan will be used for repair of facilities or structures or for construction of additional facilities or structures;

(8) The following Federal Assistance to Individuals and Households Program (section 408) categories of financial assistance:

(i) Housing needs or expenses, except for restoring, repairing or building private bridges, purchase of mobile homes and provision of structures as minimum protective measures;

(ii) Personal property needs or expenses;

(iii) Transportation expenses;

(iv) Medical/dental expenses;

(v) Funeral expenses;

(vi) Flood insurance premium;

(vii) Temporary Housing.

(9) Use of existing resources in the temporary housing assistance program [section 408], except that Step 1 (§ 9.7) shall be carried out;

(10) Debris removal (section 407), except those grants involving non-emergency disposal of debris within a floodplain or wetland;

(11) Repairs or replacements under section 406, of less than $5,000 to damaged structures or facilities;

(12) Placement of families in existing resources and Temporary Relocation Assistance provided to those families so placed under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, Public Law 96–510.

(d) * * * The references are to the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988, Public Law 93–288, as amended.

(1) Actions performed under the Federal Assistance to Individuals and Households Program (section 408) for restoring or repairing a private bridge, except where two or more individuals or families are authorized to pool their grants for this purpose.

(2) Small project grants (section 422), except to the extent that Federal funding involved is used for construction of new facilities or structures.

(3) Replacement of building contents, materials and equipment. (sections 406 and 422).

(4) Repairs under section 406 to damaged facilities or structures, except any such action for which one or more of the following is applicable:

* * * * *

(e) * * * This finding will be made in consultation with the Federal Insurance and Mitigation Administration and the Council on Environmental Quality as provided in section 2(d) of Executive Order 11988.

* * *

(f) *The National Flood Insurance Program (NFIP).* (1) Most of what is done by FIMA in administering the National Flood Insurance Program is performed on a program-wide basis. For all regulations, procedures or other issuances making or amending program policy, FIMA shall apply the 8-step decision-making process to that program-wide action. The action to which the 8-step process must be applied is the establishment of programmatic standards or criteria, not the application of programmatic standards or criteria to specific situations. Thus, for example, FIMA would apply the 8-step process to a programmatic determination of categories of structures to be insured, but not to whether to insure each individual structure. The two prime examples of where FIMA does take site specific actions which would require individual application of the 8-step process are property acquisition under section 1362 of the National Flood Insurance Act of 1968, as amended, and the issuance of an exception to a community under § 60.6(b) of this chapter.

(2) The provisions set forth in this regulation are not applicable to the actions enumerated below except that the FIMA Associate Administrator shall comply with the spirit of the Orders to the extent practicable:

* * * * *

(g) * * * The references are to the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988, Public Law 93–288. The above requirements apply to repairs, under section 406, between $5,000 and $25,000 to damaged structures of facilities except for:

* * * * *

■ 7. In § 9.6, in paragraph (b), revise *Step 1* to read as follows:

§ 9.6 Decision-making process.

* * * * *

(b) * * *

Step 1. Determine whether the proposed action is located in a wetland and/or a floodplain; and whether it has the potential to affect or be affected by a floodplain or wetland (see § 9.7);

* * * * *

■ 8. In § 9.7, revise paragraphs (a), (b), and (c) to read as follows:

§ 9.7 Determination of proposed action's location.

(a) The purpose of this section is to establish Agency procedures for determining whether any action as proposed is located in or affects a floodplain or a wetland.

(b) *Information needed.* (1) The Agency shall obtain enough information so that it can fulfill the requirements of the Orders to:

(i) Avoid floodplain and wetland locations unless they are the only practicable alternatives; and

(ii) Minimize harm to and within floodplains and wetlands. In all cases, FEMA shall determine whether the proposed action is located in a floodplain or wetland. In the absence of a finding to the contrary, FEMA may assume that a proposed action involving a facility or structure that has been flooded is in the floodplain. Information about the 1 percent annual chance (base) floodplain, 0.2 percent annual chance floodplain, and FFRMS floodplain and location of floodways and coastal high hazard areas may also be needed to comply with these regulations, especially § 9.11.

(2) The following additional flooding characteristics shall be identified by the Regional Administrator as appropriate:

(i) Velocity of floodwater;

(ii) Rate of rise of floodwater;

(iii) Duration of flooding;

(iv) Available warning and evacuation time and routes;

(v) Special problems:

(A) Levees;

(B) Erosion;

(C) Subsidence;

(D) Sink holes;

(E) Ice jams;

(F) Debris load;

(G) Pollutants;

(H) Wave heights;

(I) Groundwater flooding;

(J) Mudflow.

(c) *Floodplain determination.* (1) In making the floodplain determination, FEMA shall follow this sequence:

(i) Determine whether the project is a FEMA Federally Funded Project as defined in § 9.4. If the project is a FEMA Federally Funded Project, FEMA shall establish the FFRMS floodplain and

associated flood elevation by using one of the following approaches:

(A) Climate-Informed Science Approach (CISA): The elevation and flood hazard area that result from using a climate-informed science approach that uses the best-available, actionable hydrologic and hydraulic data and methods that integrate current and future changes in flooding based on climate science. This approach will also include an emphasis on whether the action is a critical action as one of the factors to be considered when conducting the analysis;

(B) Freeboard Value Approach (FVA): The elevation and flood hazard area that result from using the freeboard value, reached by adding an additional 2 feet to the base flood elevation as determined using the process defined in paragraph (c)(1)(iii) of this section for non-critical actions and by adding an additional 3 feet to the base flood elevation as determined in paragraph (c)(1)(iii) of this section for critical actions;

(C) 0.2 Percent Annual Chance Flood Approach (0.2PFA): The area subject to flooding by the 0.2 percent annual chance flood; or

(D) The elevation and flood hazard area that result from using any other method identified in an update to the FFRMS.

(ii) Notwithstanding any other provision of FEMA regulations, FEMA may select among and prioritize the approaches in paragraph (c)(1)(i) of this section by separate policy. In addition, FEMA may provide an exception to using the FFRMS floodplain for FEMA Federally Funded Projects and instead use the 1 percent annual chance (base) floodplain for non-critical actions or the 0.2 percent annual chance floodplain for critical actions where the action is in the interest of national security, where the action is an emergency action, where application to a Federal facility or structure is demonstrably inappropriate, or where the action is a mission-critical requirement related to a national security interest or an emergency action.

(iii) If the project is not a FEMA Federally Funded Project as defined in § 9.4, FEMA shall use, at a minimum, the 1 percent annual chance floodplain for non-critical actions and the 0.2 percent annual chance floodplain for critical actions. FEMA shall establish the floodplain and associated elevation by following this sequence:

(A) The Regional Administrator shall consult the FEMA Flood Insurance Rate Map (FIRM), the Flood Boundary Floodway Map (FBFM), and the Flood Insurance Study (FIS).

(B) If a detailed map (FIRM or FBFM) is not available, the Regional Administrator shall consult a FEMA Flood Hazard Boundary Map (FHBM). If data on flood elevations, floodways, or coastal high hazard areas are needed, or if the map does not delineate the flood hazard boundaries in the vicinity of the proposed site, the Regional Administrator shall seek the necessary detailed information and assistance from other sources, such as the following Sources of Maps and Technical Information:

(*1*) U.S. Department of Agriculture: Natural Resources Conservation Service;

(*2*) Department of Defense: U.S. Army Corps of Engineers;

(*3*) Department of Commerce: National Oceanic and Atmospheric Administration;

(*4*) Department of Homeland Security: FEMA;

(*5*) Department of the Interior: Bureau of Reclamation; U.S. Fish and Wildlife Service; United States Geological Survey;

(*6*) Tennessee Valley Authority;

(*7*) Department of Transportation;

(*8*) Environmental Protection Agency;

(*9*) General Services Administration; or

(*10*) States and Regional Agencies.

(C) If the sources listed do not have or know of the information necessary to comply with the Orders' requirements, the Regional Administrator shall seek the services of a Federal or other engineer experienced in this type of work.

(2) If the determination of the floodplain involves an area or location within extensive Federal or State holdings or a headwater area, and an FIS, FIRM, FBFM, or FHBM is not available, the Regional Administrator shall seek information from the land administering agency before information and/or assistance is sought as described in paragraph (c)(1)(iii)(B) of this section. If none of these sources has information or can provide assistance, the services of an experienced Federal or other engineer shall be sought as described in paragraph (c)(1)(iii)(C) of this section.

* * * * *

■ 9. In § 9.8, revise paragraph (c)(5)(ii) to read as follows:

§ 9.8 Public notice requirements.

* * * * *

(c) * * *

(5) * * *

(ii) Based on the factors in paragraph (c)(3) of this section, a map of the area or other identification of the floodplain and/or wetland areas which is of adequate scale and detail so that the location is discernible; instead of publication of such map, FEMA may state that such map is available for public inspection, including the location at which such map may be inspected and a telephone number to call for information;

* * * * *

■ 10. In § 9.9:

■ a. In paragraph (b)(2), remove ''; and'' and add a period in its place and add a sentence to the end of paragraph (b)(2);

■ b. Revise paragraph (d)(1);

■ c. Remove paragraph (d)(2);

■ d. Redesignate paragraph (d)(3) as paragraph (d)(2); and

■ e. Lift the suspension of paragraph (e)(6) and remove the paragraph.

The addition and revision read as follows:

§ 9.9 Analysis and reevaluation of practicable alternatives.

* * * * *

(b) * * *

(2) * * * In developing the alternative actions, the Agency shall use, where possible, natural systems, ecosystem processes, and nature-based approaches; and

* * * * *

(d) * * *

(1) The Agency shall not locate the proposed action in the floodplain as established by § 9.7(c) or in a wetland if a practicable alternative exists outside the floodplain or wetland.

■ 11. In § 9.11:

■ a. Revise paragraph (c)(1);

■ b. Revise the first sentence of paragraph (d) introductory text, the second sentence of paragraph (d)(2), and paragraphs (d)(3) and (d)(9);

■ c. Revise paragraphs (e)(1), (e)(2) introductory text, and (e)(2)(ii) introductory text;

■ d. Revise the last sentence in the undesignated paragraph following the National Flood Insurance Program address in paragraph (e)(3)(i)(E);

■ e. Revise paragraph (e)(3)(ii); and

■ f. Lift the suspension of paragraph (e)(4) and remove the paragraph.

The revisions read as follows:

§ 9.11 Mitigation.

* * * * *

(c) * * *

(1) Potential harm to lives and the investment at risk in the floodplain as established in § 9.7(c);

* * * * *

(d) * * * The Agency shall apply at a minimum, the following standards to its actions to comply with the requirements of paragraphs (b) and (c), of this section (except as provided in § 9.5(c), (d), and (g) regarding categories of partial or total exclusion). * * *

* * * * *

(2) * * * There shall be no construction of a new or substantially improved structure in a coastal high hazard area unless it is elevated on adequately anchored pilings or columns, and securely anchored to such piles or columns so that the lowest portion of the structural members of the lowest floor (excluding the pilings or columns) is elevated to or above the FFRMS floodplain.* * *

(3) *Elevation of structures.* (i) There shall be no new construction or substantial improvement of structures unless the lowest floor of the structures (including basement) is at or above the level of the FFRMS floodplain.

(ii) There shall be no new construction or substantial improvement of structures involving a critical action unless the lowest floor of the structure (including the basement) is at or above the level of the FFRMS floodplain.

(iii) If the subject structure is nonresidential, FEMA may, instead of elevating the structure, approve the design of the structure and its attendant utility and sanitary facilities so that below the flood level the structure is water tight with walls substantially impermeable to the passage of water and with structural components having the capability of resisting hydrostatic and hydrodynamic loads and effects of buoyancy.

(iv) The provisions of paragraphs (d)(3)(i), (ii), and (iii) of this section do not apply to the extent that the Federal Insurance and Mitigation Administration has granted an exception under § 60.6(b) of this chapter (formerly 24 CFR 1910.6(b)), or the community has granted a variance which the Regional Administrator determines is consistent with § 60.6(a) of this chapter (formerly 24 CFR 1910.6(a)). In a community which does not have a FIRM in effect, FEMA may approve a variance from the standards of paragraphs (d)(3)(i), (ii), and (iii) of this section, after compliance with the standards of § 60.6(a) of this chapter.

* * * * *

(9) In the replacement of building contents, materials and equipment, the Regional Administrator shall require as appropriate, disaster proofing of the building and/or elimination of such future losses by relocation of those building contents, materials and equipment outside or above the floodplain as established in § 9.7(c).

(e) * * *

(1) The Federal Insurance and Mitigation Administration shall make identification of all coastal high hazard areas a priority;

(2) Beginning October 1, 1981, the Federal Insurance and Mitigation Administration of FEMA may only provide flood insurance for new construction or substantial improvements in a coastal high hazard area if:

* * * * *

(ii) The structure is rated by FEMA–FIMA based on a system which reflects the capacity to withstand the effects of the 100-year frequency flood including, but not limited to, the following factors:

* * * * *

(3)(i) * * *

(E) * * * *Unless a property owner is seeking an adjustment of the rate prescribed by FEMA–FIMA, this information need not be submitted.*

(ii) FIMA shall notify communities with coastal high hazard areas and federally related lenders in such communities, of the provisions of this paragraph. Notice to the lenders may be accomplished by the Federal instrumentalities to which the lenders are related.

* * * * *

■ 12. In § 9.13,

■ a. Revise paragraph (d)(1) and the first sentence of paragraph (d)(3) introductory text;

■ b. Add a sentence to the end of paragraph (d)(4)(i); and

■ c. Revise the first sentence of paragraph (d)(4)(ii), and revise paragraph (e).

The revisions and addition read as follows:

§ 9.13 Particular types of temporary housing.

* * * * *

(d) * * *

(1) The temporary housing action shall be evaluated in accordance with the provisions of § 9.7 to determine if it is in or affects the 1 percent annual chance (base) floodplain or wetland.

* * * * *

(3) An individual or family shall not be housed in the 1 percent annual chance (base) floodplain or wetland unless the Regional Administrator has complied with the provisions of § 9.9 to determine that such site is the only practicable alternative. * * *

* * * * *

(4) * * *

(i) * * * Actual elevation levels will be based on manufacturer specifications and applicable Agency guidance.

(ii) No mobile home or readily fabricated dwelling may be placed if such placement is inconsistent with the criteria of the National Flood Insurance Program (44 CFR parts 59–60) or any more restrictive Federal, State, or local floodplain management standard. * * *

* * * * *

(e)(1) FEMA shall not sell or otherwise dispose of mobile homes or other readily fabricated dwellings which would be located in floodways or coastal high hazard areas. FEMA shall not sell or otherwise dispose of mobile homes or other readily fabricated dwellings which would be located in floodplains or wetlands unless there is full compliance with the 8-step process. Given the vulnerability of mobile homes to flooding, a rejection of a non-floodplain location alternative and of the no-action alternative shall be based on—

(i) A compelling need of the family or individual to buy a mobile home for permanent housing; and

(ii) A compelling requirement to locate the unit in a floodplain.

(2) FEMA shall not sell or otherwise dispose of mobile homes or other readily fabricated dwellings in the FFRMS floodplain unless they are elevated at least to the level of the FFRMS floodplain.

(3) The Regional Administrator shall notify the Assistant Administrator for Mitigation of each instance where a floodplain location has been found to be the only practicable alternative for a mobile home sale.

■ 13. In § 9.17, revise the first sentence of paragraph (a) and paragraph (b) introductory text to read as follows:

§ 9.17 Instructions to applicants.

(a) * * * In accordance with Executive Orders 11988, as amended, and 11990, the Federal executive agencies must respond to a number of floodplain management and wetland protection responsibilities before carrying out any of their activities, including the provision of Federal financial and technical assistance.

* * *

(b) *Responsibilities of Applicants.* Based upon the guidance provided by the Agency under § 9.16, that guidance included in the U.S. Water Resources Council's ''Guidelines for Implementing Executive Order 11988, Floodplain Management, and Executive Oder 13690, Establishing a Federal Flood Risk Management Standard and a Process for Further Soliciting and Considering Stakeholder Input,'' and based upon the provisions of the Orders and this regulation, applicants for Agency assistance shall recognize and reflect in their application:

* * * * *

■ 14. In § 9.18, revise the second sentence of paragraph (b)(1) and the first

sentence of paragraph (b)(2) to read as follows:

§ 9.18 Responsibilities.

* * * * *

(b) * * *

(1) * * * When a decision of a Regional Administrator relating to disaster assistance is appealed, the Associate Administrator for FIMA may make determinations under these regulations on behalf of the Agency.

(2) Prepare and submit to the Office of Chief Counsel reports to the Office of Management and Budget in accordance with section 2(b) of Executive Order 11988, as amended, and section 3 of Executive Order 11990. * * *

Appendix A to Part 9 [Removed]

■ 15. Remove appendix A to part 9.

Dated: August 15, 2016.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

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